PHILLIPS, GOLDMAN & SPENCE, P.A.
ATTORNEYS AT LAW
PENNSYLVANIA AVE. AND BROOM ST.
1200 N. BROOM STREET
WILMINGTON, DE 19806

JOHN C. PHILLIPS, JR.
STEPHEN W. SPENCE
ROBERT S. GOLDMAN
LISA C. MCLAUGHLIN
JAMES P. HALL
DAVID A. BILSON III
STEPHEN A. SPENCE
MEGAN C. HANEY

(302) 655-4200 (P)
(302) 655-4210 (F)

April 4, 2014

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 North King Street
Wilmington, Delaware 19801

Re: *Reckitt Benckiser Pharma. Inc. v. Par Pharma. Inc.*, C.A. No. 13-1461; *Reckitt Benckiser Pharma. Inc. v. Watson Labs., Inc.*, C.A. No. 13-1674; *Reckitt Benckiser Pharma. Inc. v. Alvogen Pine Brook*, C.A. No. 13-2003

Dear Judge Andrews:

Defendants request entry of a Protective Order that (1) permits in-house counsel to access confidential information produced by an opposing party and (2) bars access to confidential information by any counsel involved in communications with FDA that involves competitive decision making.

In-House Counsel Access to Confidential Information

Plaintiffs' argument that Defendants' counsel have no need for access to Plaintiffs' confidential research and development information ignores the importance of in-house counsel in managing this litigation and outside counsel. Indeed, Par and Alvogen do not seek unfettered access for their in-house counsel to all of Plaintiffs' proprietary information. Rather, Par and Alvogen seek access for specific in-house counsel only to information that is at the core of the present litigation, and thus necessary for in-house counsel to properly manage the activities of outside counsel. Denying in-house counsel access to this critical information would severely prejudice Par and Alvogen, reducing each parties' abilities to accurately evaluate the strengths and weaknesses of their cases for both managing of litigation activities and assessing potential settlement.

On the other hand, because of the limited roles of the two specified in-house counsel Par and Alvogen seek to qualify for access to this information under the Protective Order, there is little risk to Plaintiffs of improper use of this information. First, Defendants have agreed to prohibit in-house counsel from access to information pertaining to financial and economic information, which is the sort of information that typically could be relevant to competitive decision making. With that in mind, Plaintiffs rely solely on the claim that involvement in

settling patent litigations and patent licensing somehow implicates competitive decision making. Yet although outside counsel routinely engage in such activities, Plaintiffs do not seek a bar on such activities for outside counsel. *See U.S. Steel Corp. v. United States*, 730 F.2d 1465, 1468 (Fed. Cir. 1984) ("Thus the factual circumstances surrounding each individual counsel's activities, association, and relationship with a party, **whether counsel be in-house or retained,** must govern any concern for inadvertent or accidental disclosure."). If Plaintiffs contend such activities constitute such a serious risk, the same logic would apply to outside counsel. Thus, this argument is a red herring. Moreover, Par's and Alvogen's in-house counsel have certified that they will not engage in activities implicating competitive decision making for the products at issue in the litigation. (*See* Defendants' Opening Letter Brief, Exhibits 3-4). Accordingly, there is no persuasive reason to deny these two particular counsel access to this critical information, and their status as in-house counsel may not be the sole ground for denial of access. *U.S. Steel*, 730 F.2d at 1468.

Second, Plaintiffs' argument that all parties must be subject to the same rules of confidential access similarly lacks merit. There are three different actions at issue, each with uniquely situated parties. Contrary to Plaintiffs' assertion, Defendants' proposed Protective Order does not require Plaintiffs to produce its documents with different confidentiality markings to each Defendant. Instead, the level of confidentiality for the different categories of documents remains the same for all parties. What changes is the differing access each counsel has to the confidential information produced by an opposing party.[1]

Accordingly, for the reasons stated here and in Defendants' opening letter brief, Par and Alvogen respectfully request the Court enter Defendants' proposed Protective Order permitting access by in-house counsel to confidential information produced by an opposing party.

Bar on Communications with FDA

Plaintiffs failed to address the bar on communications with FDA regarding standards or requirements for approval of therapeutically equivalent products of Suboxone®. This category of communication is fundamentally focused on thwarting generic competition and fits squarely within the bounds of competitive decision making that warrants limited access to confidential information. *See U.S. Steel Corp.*, 730 F.2d at 1468 n.3 (defining competitive decision making as involving "counsel's advice and participation in any or all of client's decisions (pricing, product design, etc.) made in light of similar or corresponding information about a competitor"). Plaintiffs also failed to address the bar on involvement with United States Pharmacopeia ("USP") monographs. USP monographs are another tool that brand companies may use to define their exclusionary rights over a drug product. Changes to a brand's USP monograph also can change the requirements for approval of a therapeutic equivalent product. *See* Letter from Gary Buehler, FDA to Ranbaxy Inc. 1 (Oct. 25, 2007) ("[T]he agency regards the change in the USP monograph for Valsartan . . . to be a change in the requirements for approval imposed after the date on which your ANDA was filed.") (Exhibit 1). There is little that could be considered

[1] Under Defendants' Proposal, in the Watson case, in-house counsel would have access to only the lowest tier, and not the middle and top tiers. In the Par and Alvogen cases, in-house counsel would have access to the lowest and middle tiers, but not the top tier. Furthermore, Watson has indicated that either proposal is acceptable.

more competitive than participating in the process for determining whether a competitor's product can obtain approval to come to market.

Plaintiffs complain that the proposed FDA bar carves out Defendants' counsel's right to communicate with FDA regarding their own ANDAs. Plaintiffs object because they do not have a similar carve-out, arguing that the bar would prevent communication with FDA about Plaintiffs' own product. But the bar is only intended to prevent counsel for Plaintiffs who have access to Par and Watson's confidential information from simultaneously participating in communications with FDA where the express purpose of the communications is to define Plaintiffs' exclusionary right and prevent marketing approval of Par's and Watson's respective products. Defendants do not object to a carve-out that would permit Plaintiffs' counsel to communicate with the FDA regarding their own products. But throughout the negotiations regarding the Protective Order, Plaintiffs never proposed such a carve-out. Indeed, Par and Watson do not oppose Plaintiffs' counsel's involvement in FDA communications that have no bearing on Defendants' products at issue in this case. Had Plaintiffs brought up that issue during the parties' extensive meet and confers on the Protective Order, Par and Watson would have been willing to agree to a more narrowly-crafted provision. Instead, Plaintiffs dismissed the proposed bar out of hand and refused to provide any compromise proposals.

Plaintiffs further suggest that because Citizen Petitions are public and thus may be policed for disclosure of confidential information, the risk of inadvertent disclosure is minimized. But the public nature of the proceedings does not prevent Plaintiffs from using Defendants' confidential information in its decision making process as to whether to engage in such proceedings, or the strategy to take—decisions that may never be reflected in public disclosures. Similarly, the patent prosecution process is public, yet the Federal Circuit has deemed prosecution bars appropriate where the attorney's "opportunity to control the content of patent applications and the direction and scope of protection sought in those applications may be significant." *In re Deutsche Bank Trust Co. Ams.*, 605 F.3d 1373, 1380 (Fed. Cir. 2010). Thus, the public nature of those proceedings has no bearing on whether a bar is appropriate. The FDA communications that Par and Watson seek to bar are precisely those communications where the opportunity to control the direction and scope of plaintiffs' protection from generic competition is the most significant.

Accordingly, for the reasons stated here and in Defendants' opening letter brief, Par and Watson respectfully request the Court enter Defendants' proposed Protective Order barring counsel with access to confidential information produced by an opposing party from certain FDA communications.

Respectfully submitted,

/s/ John C. Phillips, Jr.

John C. Phillips, Jr. (No. 110)

cc: All Counsel of Record (via CM/ECF and email)