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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 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,

Plaintiffs submit this letter in response to Defendants' 4.3.14 letter (Defendants' 4.3 Letter) in regard to discovery disputes relating to the proposed Protective Order for these matters. Plaintiffs' positions on these points are detailed in their 4.3.14 letter to the Court on these issues (Plaintiffs' 4.3 Letter), and the Court is respectfully referred thereto. Here, Plaintiffs limit their response to replying to Defendants' 4.3 Letter.

1. Defendants' Rationale For The One-Sided FDA Bar Is Unavailing

Defendants assert that communications with FDA (by Plaintiffs, but *not* by Defendants) or involvement with the U.S. Pharmacopeia (USP) monographs (or foreign equivalents) necessarily involves competitive decision making that should somehow preclude both inside and outside counsel who see Defendants' confidential information from having any involvement with the FDA or the USP.

- To begin with, Defendants' attempt to analogize communications with FDA to patent prosecution is inapposite. Patent claims can be amended during prosecution; communications with the FDA involve administrative matters in relation to a patent record, including issued patents, that has already been made and is fixed.

- Second, Defendants' proposed bar, as pointed out in Plaintiffs' 4.3 Letter, is vastly overbroad because it would apply ***regardless*** of whether any of Defendants' confidential information is actually used in connection with communications to FDA or in regard to the USP.

- Third, Defendants simply ignore the fact, as also pointed out in Plaintiffs' 4.3 Letter, that the harm that they seek to avoid is already entirely prevented by provision 14.1 of the proposed Protective Order, which specifies that confidential

information cannot be used for purposes other than this litigation and further specifies that confidential information cannot be used 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."

- Fourth, Citizens Petitions to FDA are public and can readily be policed by Defendants.

- Fifth, Defendants' one-sided exemption that would allow their in-house and outside counsel (but not Plaintiffs' counsel) to communicate with FDA regarding Defendants' respective ANDA filings, even after seeing Plaintiffs' confidential information, logically contradicts, and hence undermines, Defendants' protestations about Plaintiffs' counsel having the same rights. Furthermore, in the case of RBP's General Counsel, who is in charge of managing this suit for his company and is necessarily is involved in regulatory communications, this FDA Bar could effectively eliminate, with no justification, his ability to see any confidential information in the case.

Thus, Defendants' FDA Bar proposal does nothing but unfairly and without justification restrict both in-house and outside counsel for Plaintiffs from either seeing confidential information or being involved in, among other things, FDA-related communications and is entirely unnecessary in any event given the restrictions on the use of confidential information spelled out in section 14.1 of the proposed Protective Order. Accord: *Alza Corp. v. Par Pharmaceutical, Inc.*, Docket No. 1:13-cv-01104-RGA, D.I. 78 (Dec. 17, 2013 Tr. at 26:11-15 (Andrews, J.).

2. The ANDA Filers' In-House Counsel Should Not Have Access To Plaintiffs' Confidential Research And Development Information

Defendants' positions as to what constitutes competitive decision-making are conflicting and entirely one-sided. In one breath, Defendants see fit to assert that somehow, if Plaintiffs' counsel have access to Defendants' confidential information, they should be barred from involvement in making any communication to FDA (or the USP) ***even if no confidential information was used*** for the purpose of making that communication. (Although as noted, Defendants don't think the same shoe fits their counsel who, according to Defendants, should have access to Plaintiffs' confidential information and still communicate with FDA nonetheless.) In the next breath, Defendants assert that their in-house counsel—counsel who according to their own declarations, are charged with managing Defendants' ANDA case litigation strategy, including settlement (which of course could entail licensing)—are not involved in competitive decision-making and should be able to see ***all*** of Plaintiffs' proprietary, confidential information, including information concerning the research and development of Plainiffs' products, including future products, with the sole exception being financial information. Plainly, Defendants' arguments on competitive decision-making are inconsistent and insupportable.

As noted in Plaintiffs' 4.3 Letter, Par and Alvogen are generic drug companies who are in the ANDA lawsuit, litigation business. Bringing, prosecuting, and settling these cases are at the

core of their business; indeed, the structure of the Hatch Waxman Act requires these companies to make ANDA litigation, its strategy and resolution no less fundamental to their business than submitting their ANDA to FDA (at least insofar as the proposed product is covered by unexpired patents). Accordingly, the in-house counsel at these ANDA filing companies are necessarily involved in competitive strategizing and decision-making that is at the core of their companies' business model. When Defendants say that their designated in-house will not engage in competitive decision-making, they simply ignore the nature, the mission, the business model of these generic pharmaceutical companies and the crucial, competitive role of ANDA litigation in those business. The concept of competitive decision-making is functional and is not limited to, for example, determining the price of the proposed generic product; these companies are, and are by necessity, in the ANDA litigation business.

Furthermore, there is no basis for Defendants' naked assertion that the exclusion of generic in-house counsel from Plaintiffs' highly confidential information will "seriously inhibit" their ability to manage the cases and make strategic decisions. First, it is a commonplace in patent litigation for the in-house counsel of one party to be barred from seeing highly confidential information of the opposing party. (Indeed, Defendant Watson has no objection to such a confidentiality structure.) Second, Defendants' assertion simply makes no sense in the context of the issues presented here and given the nature of the information they (improperly) seek to disclose to their in-house counsel. For example, the issue of infringement depends on comparing the claims of the patents to the accused products—Plaintiffs' confidential information is not implicated in that analysis. Third, as indicated by Defendants' Paragraph IV notice letters setting forth their positions on invalidity, those positions rely, as would be expected, on prior art and on assertions about what would constitute routine experimentation. Fourth, there is no legitimate rationale for Defendants' in-house counsel to have access to information concerning Plaintiffs' highly confidential *future* products; such information necessarily cannot speak to infringement or to validity and only can concern Defendants' litigation, settlement, ANDA amendment or other strategies—in other words, can only concern competitive decision-making. Fifth, section 5.4 of the proposed Protective Order provides that the Protective Order "shall not bar any Counsel from rendering legal advice to such attorney's client that is based in part on the attorney's analysis or evaluation of materials" designated as confidential as long as the substance of such designated materials is not disclosed.

Respectfully Submitted,

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