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April 3, 2014

VIA CM/ECF & HAND DELIVERY
The Honorable Richard G. Andrews
United States District Court for the District of Delaware
844 North King Street
Wilmington, Delaware 19801

Re: *Reckitt Benckiser Pharms., Inc. et al. v. Par Pharmaceutical, Inc., IntelGenx Technologies, Corp., Watson Laboratories, Inc., & Alvogen Pine Brook*, C.A. Nos. 13-1461-RGA, 13-1674-RGA, 13-2003-RGA

Dear Judge Andrews:

I write on behalf of Defendants Watson Laboratories, Inc., Alvogen Pine Brook, Par Pharmaceutical, Inc. and IntelGenx Technologies, Corp. in connection with two disputes relating to the proposed Protective Order in the above-captioned cases. The first is whether in-house counsel for the parties should be permitted access to certain categories of confidential information produced by opposing parties. The second is whether individuals with access to confidential information should be prohibited from participating in related FDA proceedings.

I. In-House Counsel Access to Confidential Information.

Defendants Par and Alvogen[1] propose that in-house counsel for the parties be permitted access to all confidential information produced by opposing parties, with the exception of non-public information related to highly sensitive financial and economic information.[2] (Exhibit 1.) The Federal Circuit has held that in-house counsel may not be denied access from the most confidential materials produced during litigation on the sole ground of their status as in-house counsel. *U.S. Steel Corp. v. United States*, 730 F.2d 1465, 1468 (Fed. Cir. 1984); *see also Matsushita Elec. Indus. Co. v. United States*, 929 F.2d 1577, 1580 (Fed. Cir. 1991). Rather, access must be decided based on in-house counsel's "actual activity and relationship with the party represented," where the key inquiry is the attorney's role in "competitive decisionmaking." *U.S. Steel*, 730 F.2d at 1468, 1469. The Federal Circuit defined competitive decision making as "a counsel's activities, association, and relationship with a client that are such as to involve 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." *Id.* at 1468 n.3.

[1] While Watson agrees with the proposal advocated by Par and Alvogen and is willing to operate under a Protective Order designating four levels of confidentiality, it is also amenable to Plaintiffs' proposal.

[2] Par and Alvogen's proposed confidentiality designations can be found in Sections 2.4-2.6 and 6.1 of Defendants' proposed Protective Order, attached hereto as Exhibit 1.

This Court has taken the same approach. *See, e.g.*, *Eurand, Inc. v. Mylan Pharm., Inc.*, C.A. No. 08-889-SLR, at *2 (D. Del. June 23, 2009) ("I am of the opinion that every client has the right to have at least one representative with access to as much information as the lawyers.") (Exhibit 2); *Avery Dennison Corp. v. 3M*, No. 01-125-JJF, 2001 WL 1339402, at *2 (D. Del. Oct. 26, 2001) ([T]he Court will allow the parties to craft a protective order that places adequate safeguards on the use and mode of reviewing all sensitive information, but that does not deny designated in-house counsel access to that information."); *Boehringer Ingelheim Pharma., Inc. v. Hercon Labs. Corp.*, 18 U.S.P.Q.2d 1166 (D. Del. 1990).

In-house counsel for Alvogen and Par each certify that they will not be involved in activities implicating competitive decision making for the products at issue in the present litigation; instead, they are responsible for coordinating and managing their respective clients' outside counsel for this (and other) litigation. *See* Declarations of David H. Silverstein and Andrea Sweet (Exhibits 3-4). These attorneys have agreed to be bound by, and to comply with, the Protective Order issued by the Court in this case. "Like retained counsel, . . . in-house counsel are officers of the court, are bound by the same Code of Professional Responsibility, and are subject to the same sanctions." *U.S. Steel*, 730 F.2d at 1468. Putative confidential information is likely to be disclosed in numerous documents key to litigation strategy and evaluation of the strengths and weaknesses of the parties' positions, including discovery responses, expert reports and briefs. Exclusion of the designated in-house counsel from access to this information would prevent them from reviewing the entirety of drafts, as well as served or filed documents, thereby seriously inhibiting their ability to effectively manage the litigation and make strategic decisions. *See Avery*, 2001 WL 1339402, at *1.

Accordingly, Par and Alvogen respectfully request entry of the Protective Order proposed by Defendants permitting access by in-house counsel to confidential information produced by an opposing party.

II. Bar Against Communications With FDA Implicating Competitive Decision Making

Par and Watson[3] propose that any individual with access to an opposing party's highly sensitive or highly proprietary technical or business information be barred from involvement with communications with FDA(or foreign equivalent) where those communications are directed to citizen petitions, standards or requirements for approval of therapeutically equivalent products of Suboxone®, or involvement with United States Pharmacopeia ("USP") monographs (or foreign equivalents).[4] Communications with FDA directed to these activities directly and unequivocally implicate exactly the sort of competitive decision making which the Federal Circuit has said should preclude access to confidential information by both in-house and outside counsel. *See U.S. Steel*, 730 F.2d at 1468 & n.3 (stating that an attorney's involvement in

[3] Alvogen does not oppose the position advocated by Par and Watson, although it contends that an FDA bar is unnecessary between itself and Plaintiffs.

[4] The proposed bar is at Section 6.4 of Defendants' proposed protective order, attached hereto as Exhibit 1.

competitive decision making should be the basis of denial of access rather than classification as in-house or outside counsel).

The Federal Circuit addressed the issue of an activity-related bar in a Protective Order in *In re Deutsche Bank Trust Co. Americas*. 605 F.3d 1373 (Fed. Cir. 2010). There, the Federal Circuit explained that a central consideration in determining whether a bar is appropriate "should turn on the extent to which counsel is involved in 'competitive decisionmaking "with its client"—the same standard described above. *See id.* at 1378. Considering patent prosecution, the Court explained that attorneys responsible for "strategic decisions on the type and scope of patent protection that might be available or worth pursuing" or "strategically amending or surrendering claim scope during prosecution" engage in competitive decision making and thus may be properly barred from access to confidential information produced by an opposing party. *Id.* at 1380.

The same underlying principles in *Deutsche Bank* guide the inquiry here. Communications directed to citizen petitions, standards or requirements for approval of therapeutically-equivalent products and USP monographs are analogous to patent prosecution activities because they, too, are tools used to define the NDA holder's exclusionary rights over its product. Citizen petitions routinely request FDA to disapprove a competitor's product.[5] USP monographs define the specifications for a product, 21 U.S.C. § 351(b), and thus the standards that an ANDA product must meet to achieve therapeutic equivalence. The competitive decision making activity in these communications with FDA is the identification and selection of technical arguments that can place a competitor's product in the worst light before FDA or technical specifications for a product which, whether or not related to safety and efficacy, are beyond the scope of the competitor's product. These activities seek to obtain commercial advantage using information about a competitor's products. While specific information about a competitor's product may not be disclosed in these communications, the argument presented to FDA cannot help but be informed by confidential knowledge of the competitor's product.

Under *Deutsche Bank*, access to confidential information, such as knowledge about any differences in formulation or manufacturing between Suboxone® sublingual film and Par's and Watson's respective ANDA products may prevent an attorney from participating in strategic decisions concerning the scope of patent protection over these products. So too should such knowledge prevent an attorney from participating in strategic decisions that impact the bioequivalence standards for Suboxone® sublingual product.

Accordingly, Par and Watson respectfully request entry of the Protective Order proposed by Defendants prohibiting counsel involved in certain communications with FDA from access to confidential information produced by an opposing party.

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[5] *See* FDA Report to Congress, *Fifth Annual Report on Delays in Approvals of Applications Related to Citizen Petitions and Petitions for Stay of Agency Action for Fiscal Year 2012*, at 1 (Sept. 2013) (Exhibit 5).

Respectfully,

/s/ Steven J. Fineman

Steven J. Fineman (#4025)

cc: Counsel of Record (via CM/ECF)