WOMBLE CARLYLE SANDRIDGE & RICE
A LIMITED LIABILITY PARTNERSHIP

222 Delaware Avenue
Suite 1501
Wilmington, DE 19801

Telephone: (302) 252-4320
Fax: (302) 252-4330
www.wcsr.com

Mary W. Bourke
Partner
Direct Dial: 302-252-4333
Direct Fax: 302-661-7733
E-mail: MBourke@wcsr.com

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VIA CM/ECF & HAND DELIVERY

The Honorable Richard G. Andrews
United States District Court for the District of Delaware **Redacted Version D.I. 75**
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

Dear Judge Andrews,

MonoSol writes in response to Par's letter brief of April 3, 2014, regarding Par's insistence that MonoSol identify its trade secrets before discovery proceeds in this case. This is the third time that Par is attempting to derail the discovery process and to hijack the patent infringement case. This Court already rejected Par's first two attempts to prevent Plaintiff MonoSol from obtaining discovery in this case, at the December 13, 2013 scheduling conference, and the discovery hearing of January 31, 2014. Par can cast its arguments however it choses, but the arguments are the same and should again be rejected.

THE DISCOVERY DISPUTE HAS ARISEN IN A CASE THAT LACKS SUBJECT MATTER JURISDICTION.

This Court lacks subject matter jurisdiction over the present action and any decision on the discovery dispute would be merely advisory. This is not the first time that Par's premature Paragraph IV letter caused a "false start" to patent litigation. *See Otsuka Pharm. Co. v. Par Pharm., Inc.*, Docket No. 13-1979 (D. Del. Mar. 10, 2014) (Andrews, J.) (attached as Exhibit 1).

[redacted] The AFF letter, referred to in 21 C.F.R. § 314.101(a)(1), 21 U.S.C. § 355(j)(2)(B)(ii)(I), and 21 C.F.R. § 314.95(b), is the communication in which FDA acknowledges to the filer of an Abbreviated New Drug Application ("ANDA") that the ANDA is sufficiently complete to permit a substantive review and which, in turn, triggers the running of the 20 days that the ANDA filer has to send a Paragraph IV notice under 21 U.S.C. § 355(j)(2)(B)(iv). The current litigation is based upon Par's Paragraph IV letters transmitted months before it received the AFF letter. The premature letters were ineffective to confer jurisdiction over the dispute.

On March 25, 2014, Par sent Plaintiffs another Paragraph IV letter. [redacted] Based upon this letter, Plaintiffs are concurrently filing a complaint in this judicial district to preserve their right to a 30-month injunction against Par. Plaintiffs intend to move to dismiss the current case (D. Del. 13-cv-1461). In short, the current discovery dispute arises in a case that should not have been filed, but for Par's premature service of its initial Paragraph IV letter.

MONOSOL DID NOT ASSERT TRADE SECRET MISAPPROPRIATION AND PAR SHOULD NOT BE ALLOWED TO SHIFT ITS BURDEN OF PROOF TO MONOSOL.

MonoSol has never alleged that Par has misappropriated its trade secrets. Rather, Par inserted the trade secrets issue into this case via its counterclaim. Based upon its false underlying premise, Par is now requesting the extraordinary remedy of compelling MonoSol to disclose any potential trade secrets before proceeding with discovery. Par cannot cite to a single case in which a trade secrets counterclaimant can impose on a plaintiff the burden of identifying potential trade secrets. MonoSol has not accused Par of stealing any trade secrets; the burden of proof here is on Par, not MonoSol.

The focus of this case is patent infringement based on Par's ANDA. Par's trade secret counterclaim is satellite litigation and is delaying the discovery process. Par did not produce its ANDA in a timely fashion and MonoSol was forced to compel Par's compliance with the Scheduling Order. Now, Par continues to hold up discovery by accusing MonoSol of attempting to build a trade secret misappropriation case through improper discovery. However, the scope of discovery is not dictated by a potential trade secrets claim but by the patent infringement claims. Par conceded during the January 31, 2014 hearing that the scope of discovery is not at issue. *See* Jan. 31, 2014 Tr. at 14:19-20, attached as Exhibit 2. Contrary to Par's assertions, a simple reading of Plaintiffs' document requests 70-72 and 76 indicate that they are not directed "solely" to trade secret claims but are relevant to the patent case, including issues of obviousness of the patented technology.

If MonoSol at any point learns that Par has misappropriated MonoSol's confidential information, MonoSol should be allowed to amend its complaint to assert such a claim. Parties are permitted to amend disclosures or pleadings to add trade secret misappropriation claims, so long as they bring such claims in a timely fashion. *See, e.g., Dura Global Technologies, Inc. v. Magna Donnelly Corp.*, Docket No. 2:07-cv-10945, 2011 WL 4527576, *1, *8 (E.D. Mich. Sep. 29, 2011) (allowing plaintiff to assert, at trial, additional trade secrets identified through discovery), attached as Exhibit 3; *Lobo Recording Corp. v. Waterland*, 197 F.R.D. 23 (E.D.N.Y. 2000) (allowing defendant to amend its answer to assert a trade secret counterclaim). Further, amending a patent infringement complaint to include trade secret claims is neither unusual nor impermissible. *See, e.g., Reckitt Benckiser, Inc. v. Tris Pharma, Inc.*, Docket No. 3:09-cv-03125-DEA, D.I. 51, Amended Complaint (D.N.J. June 11, 2010), attached as Exhibit 4. This case is no different. If the discovery reveals evidence of misappropriation, MonoSol should not be prevented from later amending its complaint.

MONOSOL HAS COMPLIED WITH ITS DISCOVERY OBLIGATIONS.

Despite Par's allegations to the contrary, MonoSol has complied with its discovery obligations and answered Par's second interrogatory as thoroughly as possible at this stage of the litigation. *See* Exhibit 5. MonoSol will supplement its response as discovery progresses.

MonoSol has reviewed the ANDA and determined that it requires further discovery before it can ascertain whether it "evidences Par's misappropriation," as requested in Par's interrogatory. For instance, despite the January 21, 2014, deadline for Par to produce its Core Technical Documents, Par has yet to produce any development documents, including laboratory notebooks, memoranda, testing records, and work records. These documents are essential to review. MonoSol's review of the ANDA is further complicated by the fact that MonoSol's in-house employees who are knowledgeable about MonoSol's trade secrets do not have access to

Par's ANDA or any of Par's confidential information. Thus, MonoSol's litigation counsel will likely need expert review by a person with access to both MonoSol's confidential technology and Par's ANDA and related documents.

MonoSol explained that it would be burdensome to identify all potentially relevant trade secrets at this stage of the litigation. *See* Jan. 31, 2014 Tr. at 15:20-24 ("[I]f we were to do what Par is asking, we would need to comb through all the physical documents, interview our people, take depositions of their people who -- who have received, or could have received trade secret information."), Exhibit 2. Further, MonoSol never represented that, from the ANDA alone, it can positively identify any potentially relevant trade secret. *See* Jan. 31, 2014 Tr. at 12:23-13:1 ("And, as we said during the scheduling conference, MonoSol has never made an assertion that its trade secrets have been misappropriated. Never made an allegation that the trade secrets are in the ANDA of Par."), Exhibit 2.

While the ANDA discloses information about Par's generic product, it is an administrative document and does not tell the whole story. For instance, it does not disclose on its face what information was acquired from MonoSol and whether Par improperly used such information. MonoSol needs to conduct discovery, including depositions, to respond to Par's inquiry on whether Par misappropriated any of MonoSol's trade secrets. At this time, MonoSol does not have a good faith basis to assert trade secret misappropriation and has refrained from doing so. MonoSol is following the rules and its obligations under Rule 11 of the Federal Rules of Civil Procedure. Par, on the other hand, is attempting to manipulate the rules to obtain an extraordinary and unsupported relief.

Cherry-picking from the transcript of the last hearing on this issue, Par makes much of this Court's statement that trade secrets must be identified before Plaintiffs start "real discovery." Par is attempting to convert a statement, out of context, on a "hypothetical" question into a mandate from the Court. *See* Jan. 31, 2014 Tr. at 35:7-11, Exhibit 2. What is impermissible is discovery into trade secret claims before the claimant identifies the alleged trade secrets, not discovery into patent infringement claims because they may happen to expose trade secret misappropriation. As discussed above, the scope of its discovery is properly within the confines of a typical ANDA patent litigation. MonoSol should be allowed to conduct fact and expert discovery to the full extent permitted in the Scheduling Order and to supplement or amend its interrogatory responses and pleadings, if and when required. Preventing MonoSol from doing so would render meaningless the December 15, 2014, deadline for amending pleadings, as well as the Federal Rules of Civil Procedure for amending pleadings and for supplementing discovery responses. MonoSol would be severely and unjustly prejudiced if it is required to provide a complete response at this stage of the litigation, and if it is not permitted to amend its pleadings or supplement its interrogatory response, if and as needed. On the other hand, Par has suffered no prejudice and even if it has, any prejudice to Par is the result of its own litigation tactics.

MONOSOL DOES NOT OPPOSE DISMISSAL OF PAR'S COUNTERCLAIMS

As discussed during the previous hearing, MonoSol did not move to dismiss the trade secret claim for several practical reasons. *See* Jan. 31, 2014 Tr. at 13:19-14:7, Exhibit 2. Further, MonoSol is particularly concerned about Par's likely attempt to obtain a dismissal with prejudice, precluding MonoSol from ever bringing a trade secret misappropriation claim if the evidence supports one.

Respectfully Submitted,



Mary W. Bourke

cc: Daniel G. Brown (via electronic mail)
Jennifer R. Saionz (via electronic mail)
James K. Lynch (via electronic mail)
Emily C. Melvin (via electronic mail)
Steven J. Fineman (via electronic mail)
Katharine C. Lester (via electronic mail)

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