UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of:	
CERTAIN POTASSIUM CHLORIDE POWDER PRODUCTS	**Inv. No. 337-TA-1013**

ORDER NO. 4: **DENYING RESPONDENTS' MOTION SEEKING MODIFICATION OF ORDER NO. 2 TO CHANGE THE CURRENT TARGET DATE FROM A THIRTEEN MONTH TARGET DATE TO A FIFTEEN MONTH TARGET DATE**

(August 29, 2016)

I. INTRODUCTION

By publication of the Notice of Investigation ("NOI") in the Federal Register, this Investigation was instituted on July 27, 2016, pursuant to section 337 of the Tariff Act of 1930, as amended, to determine whether there is a violation of section 337 based on the importation into the United States, or sale of certain potassium chloride powder products by reason of false advertising. *See* 81 Fed. Reg. 49263 (July 27, 2016).

On August 5, 2016, pursuant to Commission Rule 210.51(a), Order No. 2 was issued, setting the target date for August 27, 2017, thirteen (13) months from the date of institution. (Order No. 2 at 2 (Aug. 5, 2016).).

On August 17, 2016, pursuant to 19 C.F.R. §§ 210.34, 210.51(a), and Ground Rule 2.1, Respondents Virtus Pharmaceuticals, LLC, Virtus Pharmaceuticals OPCO II, LLC, and Viva Pharmaceutical Inc. (collectively, "Respondents") filed a motion seeking to modify Order No. 2

and request a fifteen (15) month target date in this Investigation ("Motion"). (Motion Docket No. 1013-002; Mot. at 1; Mem. at 1.). Respondents certify that, pursuant to Ground Rule 2.2, Respondents contacted Complainants Lehigh Valley Technologies, Inc., Endo Global Ventures, Endo Ventures Limited, and Generics Bidco I, LLC (d/b/a Qualitest Pharmaceuticals and Par Pharmaceutical) (collectively, "Complainants") and Commission Investigative Staff ("Staff") regarding their Motion. (Mot. at 2.). Respondents also certify that they made reasonable, good-faith efforts to resolve this issue with Complainants and Staff. (*Id.*).

On August 22, 2016, Staff filed a response opposing Respondents' Motion ("Staff's Response"). (Doc. ID No. 588724.). On August 24, 2016, Complainants filed their opposition to Respondents Motion ("Opposition"). (Doc. ID No. 588954.).

II. DISCUSSION

Respondents submit that the current target date, and "the resulting highly compressed procedural schedule[,] . . . will not give Respondents a fair opportunity to present their defenses." (Mem. at 3.). Specifically, Respondents argue that Complainants' false advertising claims under Section 43(a) of the Lanham Act, 15 U.S.C. § 1125 (a) and the federal common law of unfair competition (together "Lanham Act"), with the violation of Section 337 of the Tariff Act of 1930, 19 U.S.C. § 1337, as amended, ("Section 337") include, *inter alia*, issues with regard to: consumer confusion, marketing practices in the pharmaceutical industry and FDA drug labeling requirements. (*Id.* at 3-4.). Respondents contend that their development of their defenses to the referenced issues "will require more time for development—fact and expert—in discovery than is afforded by the present schedule." (*Id.*). Moreover, Respondents assert that consumer surveys necessary to capture consumer impressions "cannot be prepared, executed, and analyzed in the time frame contemplated by the current order." (*Id.* at 5-6.). Respondents also argue that the

affirmative defenses they plan to assert will require additional "intensive fact discovery . . . that would be difficult to complete within the allotted time." (*Id.* at 6.). Respondents protest that it will be "extremely challenging to locate experts" under the current deadline, and that experts and fact witnesses would be required to be available over the holidays. (*Id.* at 7.).

Accordingly, Respondents assert that good cause exists to extend the target date by two (2) months. (Mot. at 2; Mem. at 3-7.). Specifically, Respondents contend that: (1) this Investigation entails complex factual and legal issues that will likely require extensive document productions, analysis by expert economists, consumer surveys, and third party discovery; (2) Respondents' proposed extension is appropriate because it is early in the Investigation; and (3) no final Procedural Schedule has been issued. (Mot. at 1; Mem. at 1.).

Complainants oppose Respondents' Motion, arguing that Respondents have failed to show that an extension is necessary in this Investigation. (Opp'n at 1.). Specifically, Complainants maintain that Respondents have not explained: (1) why this Investigation is "more complicated or discovery-intensive than originally anticipated"; and (2) why surveys cannot be prepared, fact discovery cannot be completed, and expert witnesses cannot be effectively used, on the current schedule. (*Id.* at 1-2.).

Staff also opposes Respondents' Motion, contending that, at this time, Respondents' arguments appear speculative. (Staff Resp. at 2.). In particular, Staff points out that the present investigation is "just getting under way" and that no discovery or other disputes have been raised. (*Id.*). Thus, Staff maintains that Respondents have not shown good cause for the extension. (*Id.*).

Based upon a careful review of the parties' arguments, my finding is that Respondents have failed to show good cause for the proposed extension at this time. As stated in Order No. 2,

the target date was set after reviewing the Complaint and NOI, as well as considering commitments to other investigations and the fact that ***no*** patents are involved in this Investigation. (Order No. 2 at 2 (Aug. 5, 2016).). Additionally, Respondents' contentions are speculative. As described above, Respondents' Memorandum in Support of their Motion is rife with arguments with regard to hypothetical discovery issues that have yet to occur, and may never occur. Fact and expert discovery cutoff is December 2, 2016. (Order No. 2 at Appendix A (Aug. 5, 2016).) Respondents have more than three (3) months to develop support for their defenses. If, later in the discovery process, Respondents are confronted with the types of challenges they have described in their Motion, which, for the time being, are hypothetical, the target date can be re-evaluated at that time.

Additionally, as Staff correctly observes, Section 337 investigations are fast-paced proceedings. (*Id.* at 1 (citing Order No. 2 at 5).). Commission Rule 210.2 provides:

> It is the policy of the Commission that, to the extent practicable and consistent with the requirements of law, all investigations and related proceedings under this part shall be conducted expeditiously. The parties, their attorneys or other representatives, and the presiding administrative law judge shall make every effort at each stage of the investigation or related proceeding to avoid delay.

19 C.F.R. § 210.2.

In support of their proposed extension, Respondents argue that: (1) target dates for Section 337 investigations are most commonly set sixteen (16) months after institution, with target dates of eighteen (18) months or more, depending on the complexity of the issues; and (2) "[w]here investigations are determined to be more complicated or discovery-intensive than originally anticipated, ALJs [Administrative Law Judges] [sic] have granted motions for extension of the target date." (Mem. at 2.). However, as explained below, seven of the eight investigations upon which Respondents rely are factually inapposite and do not support Respondents' propositions.

In *Certain Footwear Products*, where the target date was set for sixteen months after institution, the complainant alleged trademark infringement against ***thirty-one (31) respondents*** from ***six (6) different countries***. *Certain Footwear Prods.*, Inv. No. 337-TA-936, Order No. 21 at 1 (Dec. 4, 2014); *see also*79 Fed. Reg. 62670 (Oct. 20, 2014). Similarly, in *Certain Consumer Electronics and Display Devices and Products Containing the Same*, the presiding ALJ set a seventeen (17) month target date "in light of the ***number of respondents*** [sixteen in total] and the ***varied nature of the accused products***." *Certain Consumer Elecs. and Display Devices and Prods. Containing the Same*, Inv. No. 337-TA-836, Order No. 5 at 1 (May 21, 2012) (emphases added); *see also* 77 Fed. Reg. 14422 (Mar. 9, 2012). Here, there are four (4) complainants, three (3) respondents and only one (1) accused product.

In *Certain Electronic Devices, Including Mobile Phones and Tablet Computers, and Components Thereof*, the presiding ALJ set an eighteen (18) month target date because: (1) the investigation involved ***eighty-seven asserted claims*** spread over nine asserted patents; (2) the patents-in-suit covered "***eight completely unrelated (i.e., dissimilar) technologies***"; and (3) the Office of Unfair Import Investigations was not participating in the investigation. *Certain Elec. Devices, Including Mobile Phones and Tablet Computs., and Components Thereof*, Inv. No. 337-TA-847, Order No. 2 at 2 (July 24, 2012) (emphasis added). Likewise, in *Certain Sleep-Disordered Breathing Treatment Systems and Components Thereof*, the target date of eighteen (18) months was set from institution due to the fact that the complainant asserted almost ***two-hundred (200) patent claims*** against the named respondents and there were other scheduling constraints. *Certain Sleep-Disordered Breathing Treatment Sys. and Components Thereof*, Inv. No. 337-TA-997, Order No. 2 at 2 (June 2, 2016).

Here, there no patents involved and only one central issue is in dispute—whether Respondents' acts are in violation of the Lanham Act, and of course of Section 337.

In *Certain Stainless Steel Products, Certain Processes for Manufacturing or Relating to Same and Certain Products Containing Same*, the private parties ***jointly*** sought to extend the target date by three (3) months in order to accommodate the ***extensive foreign discovery*** in that investigation. *Certain Stainless Steel Prods., Certain Processes for Mfg. or Relating to Same and Certain Prods. Containing Same*, Inv. No. 337-TA-933, Order No. 7 at 1 (Feb. 18, 2015). In *Certain Stainless Steel Products*, *supra*, discovery issues involved, *inter alia*, document translations, and the logistics of scheduling and holding a number of depositions in India, Germany, Taiwan, and Italy. *Id.* In *Certain Plastics Molding Machines with Control Systems Having Programmable Operator Interfaces Incorporating General Purpose Computers and Components Thereof II*, the ALJ extended the target date by approximately 3.5 months due to "[d]evelopments in other investigations and the heavy burden on the ***undersigned's trial schedule***." *Certain Plastics Molding Machines with Control Sys. Having Programmable Operator Interfaces Incorporating Gen. Purpose Computs. and Components Thereof II*, Inv. No. 337-TA-462, Order No. 10 at 1-2 (Nov. 1, 2001) (emphasis added).

Here, neither party has yet to confront the type of discovery concerns at issue in *Certain Stainless Steel Products*. Moreover, the schedule in this Investigation was considered given the scope and schedules of other investigations on my docket.

Most notably, as Complainants point out, Respondents cite to *Certain Flash Memory Cards, & Media Players & Products Containing Same* as an example of when a "target date was extended from 15 months to 18 months by respondents' motion, despite opposition from the other parties." (Mem. at 2 (citing *Certain Flash Memory Cards, & Media Players & Prods.*

Containing Same, Inv. No. 337-TA-619, Order No. 6 (Jan. 23, 2008)).). Respondents conveniently omit that: (1) the investigation included ***almost fifty (50) respondents***; (2) the investigation was "far more complex than a typical investigation because it involves ***complicated technology, a staggering number of parties represented by nearly a dozen law firms, five separate patents, and dozens of accused products***"; (3) the complainant expected to produce ***more than one million pages*** of discovery; and (4) there was a pending *Markman* hearing. *Certain Flash Memory Cards, & Media Players & Prods. Containing Same*, Inv. No. 337-TA-619, Order No. 6 at 2 (Jan. 23, 2008) (emphasis added).

The circumstances of this Investigation could not be more dissimilar to those of the investigations to which Respondents cite. This Investigation involves: ***three*** respondents and ***four*** complainants, each of which is represented by common counsel; ***one*** accused product; and essentially ***one*** central set of claims with regard to Respondents' alleged false advertising under the Lanham Act and Section 337. Because no patents are involved in this Investigation, there is no necessity to allow time for, *inter alia*: notices of prior art, claim construction, claim contentions, a *Markman* briefing, a *Markman* hearing, or a *Markman* Order. Accordingly, the cases to which Respondents cite do not support their contention that the target date for this Investigation should be extended.

Lastly, Respondents cite to ***one*** order setting a sixteen (16) month target date in an investigation involving only false advertising claims under the Lanham Act, and no patents. *Certain Prods. Advertised as Containing Creatine Ethyl Ester*, Inv. No. 337-TA-679, Order No. 2 (June 23, 2009). However, there is nothing in that order indicating that all such cases should have a sixteen (16) month target date. In that investigation, the presiding ALJ could have decided on that target date for any number of reasons, *e.g.*, scheduling, activity and/or deadlines

in other investigations, which prohibited him from setting an earlier target date. Citing to one case, without more, is not sufficiently persuasive.

Thus, Respondents have not adequately provided pertinent legal support for their proposed extension. Respondents also have not effectively explained: (1) how this Investigation rises to the level of complexity at issue in the investigations to which Respondents cite; or (2) why Respondents cannot properly present their defenses under the current schedule. Additionally, Respondents' arguments are speculative and based on theoretical discovery issues that have yet to occur, and may never occur. If circumstances should change, the target date can be re-evaluated at the proper time. However, presently, Respondents have not shown good cause for extending the target date by two (2) months.

III. CONCLUSION AND ORDER

For the reasons stated above, Respondents' motion seeking modification of Order No. 2 and requesting a fifteen (15) month target date, Motion Docket No. 1013-002, is hereby *denied.*

SO ORDERED.

MaryJoan McNamara
Administrative Law Judge

CERTAIN POTASSIUM CHLORIDE POWDER PRODUCTS **Inv. No. 337-TA-1013**

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **ORDER** has been served upon the Commission Investigative Attorney, Toddy Taylor, Esq. and upon the following parties as indicated, on **August 29, 2016**.

Lisa R. Barton, Secretary
U.S. International Trade Commission
500 E Street, SW, Room 112
Washington, DC 20436

On Behalf of Complainants Lehigh Valley Technologies, Inc., Endo Global Ventures, Endo Ventures Limited, and Generics Bidco I, LLC (d/b/a Qualitest Pharmaceuticals and Par Pharmaceutical:

David A. Hickerson, Esq.
FOLEY & LARDNER LLP
3000 K Street, NW, Suite 600
Washington, DC 20007

- ☐ Via Hand Delivery
- ☐ Via Express Delivery
- ☒ Via First Class Mail
- ☐ Other:_____

Respondents: Viva Pharmaceuitcals Inc., Virtus Pharmaceuticals, LLC And Virtus Pharmaceuticals OPCO II, LLC:

Tom M. Schaumberg
ADDUCI, MASTRIANI & SCHAUBERG, L.L.P.
113 Connecticut Avenue, N.W., 12th Floor
Washington, DC 20036

- ☐ Via Hand Delivery
- ☐ Via Express Delivery
- ☒ Via First Class Mail
- ☐ Other:_____