

From: Stringham, Jared [<mailto:Jstringham@fchs.com>]

Sent: Tuesday, August 15, 2017 4:16 PM

To: Trials@uspto.gov

Cc: #ZortressAfinitorIPR <ZortressAfinitorIPR@fchs.com>; Brown, Daniel (NY) <Daniel.Brown@lw.com>; Strang, Jonathan (DC) <Jonathan.Strang@lw.com>; Danek, Brenda (CH) <brenda.danek@lw.com>

Subject: Par v. Novartis, IPR2016-01479

Dear Judges Green, Crumbley, and Pollock,

On August 3rd, Petitioner served its reply in IPR2016-01479 (Paper 21) along with 39 new exhibits and an expert declaration. The reply includes untimely and improper new arguments based on new evidence and theories that could and should have been raised in the petition. It would be highly prejudicial to permit Petitioner to introduce these new arguments and evidence, examples of which are provided below, at this late stage in the proceeding. Accordingly, Patent Owner respectfully requests a meaningful opportunity to explain to the Board why Petitioner's arguments and evidence are new in a brief motion to strike or alternatively to respond substantively in a limited surreply. *In re NuVasive, Inc.*, 841 F.3d 966, 972-73 (Fed. Cir. 2016).

Petitioner's improper new arguments and evidence include, *inter alia*:

- Newly relying on the disclosures of the '224 Patent (the patent at issue in the IPR), along with new exhibits, to assert that rapamycin and rapamycin analogs would allegedly have the same activity (reply pp. 8-10);
- Asserting a new legal theory for why a POSA would allegedly have a reasonable expectation of success (reply pp. 12-13, 19);
- Asserting a new basis for why Duran would allegedly provide a reasonable expectation of success (reply p. 16);
- Relying on a new cell line not referenced in the petition (reply p. 17); and
- Newly asserting based on new evidence that CA20948 was widely used as a model for targeted therapies in NETs (reply p. 17).

Patent Owner has conferred with Petitioner about Petitioner's improper new arguments and evidence, including Patent Owner's intent to request a motion to strike or surreply. Petitioner indicated that it would oppose Patent Owner's request.

Patent Owner is available for a conference call on Wednesday August 16 or Thursday August 17, or on an alternate day that is convenient for the Board and Petitioner. Patent Owner appreciates the Board's consideration of this request and looks forward to its response.

Very truly yours,

Jared

Jared Stringham

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From: brenda.danek@lw.com [<mailto:brenda.danek@lw.com>]
Sent: Tuesday, August 15, 2017 5:35 PM
To: Jstringham@fchs.com; Trials <Trials@USPTO.GOV>
Cc: ZortressAfinitiorIPR@fchs.com; Daniel.Brown@lw.com; Jonathan.Strang@lw.com; paripractions.lwteam@lw.com
Subject: RE: Par v. Novartis, IPR2016-01479

Dear Judges Green, Crumbley, and Pollock,

Petitioner disagrees with and oppose Patent Owner's request. Also, Petitioner objects to Patent Owner's repeated strategy of requesting relief from the Board without seeking a meet and confer and, if the parties cannot come to an agreement on the issue, a time when all counsel are available for a call with the Board.

Petitioner further objects to Patent Owner ignoring PTAB guidance and using the Trials email address for substantive communications with the Board. By doing so, Patent Owner has already granted itself more relief than is warranted. The Board regularly allows patent owners in this situation to file a "sequentially numbered, itemized list, containing no more information than citations to the paper/exhibit number...of the material the Patent Owner alleges exceeds the proper scope of the Reply," and gives petitioners an opportunity to respond similarly. E.g., *Google v. Intellectual Ventures II*, IPR2014-00787 (Paper 29, June 4, 2015). Petitioners would have agreed to this, as it is fair to the parties.

Patent Owner, however, has already impermissibly and without leave submitted citations, commentary on why it believes the material exceeded the scope of the Reply, and most egregiously, additional substantive argument on the merits.

The Board cannot unring this bell. Accordingly, Petitioner requests permission to file a five-bullet response addressing Patent Owner's five bullet points. Patent Owner's allegations are demonstrably false and can be disposed of at oral argument without going beyond the already filed briefs.

Should the Board desire a conference call, and because Patent Owner did not inquire as to our availability before sending its improper email, Petitioner is available the afternoon of Thursday, August 17 or the afternoon of Friday, August 18.

Very Respectfully,

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From: Vignone, Maria [<mailto:Maria.Vignone@USPTO.GOV>] **On Behalf Of** Trials
Sent: Friday, August 18, 2017 1:56 PM
To: brenda.danek@lw.com; Stringham, Jared; Trials
Cc: #ZortressAfinitorIPR; Daniel.Brown@lw.com; Jonathan.Strang@lw.com;
paripractices.lwteam@lw.com; uspto
Subject: RE: Par v. Novartis, IPR2016-01479

Counsel: The Patent Owner is authorized to file, on or before Due Date 3 (September 5, 2017), a sur-reply not to exceed five (5) pages. The sur-reply may substantively address the evidence and arguments submitted with the Reply, or explain why the evidence and arguments are untimely. No new evidence may be submitted with the sur-reply. No further briefing is authorized at this time.

Thank you,
Maria Vignone
Paralegal Operations Manager
Patent Trial and Appeal Board
United States Patent and Trademark Office
703-756-1288

From: Stringham, Jared [<mailto:Jstringham@fchs.com>]

Sent: Friday, August 25, 2017 8:43 AM

To: 'Trials' <Trials@USPTO.GOV>

Cc: #ZortressAfinitorIPR <ZortressAfinitorIPR@fchs.com>; Brown, Daniel (NY) <Daniel.Brown@lw.com>; Strang, Jonathan (DC) <Jonathan.Strang@lw.com>; #C-M PAR IPR ACTIONS - LW TEAM <paripractions.lwteam@lw.com>; uspto <uspto@fchs.com>; Danek, Brenda (CH) <brenda.danek@lw.com>

Subject: RE: Par v. Novartis, IPR2016-01479

Dear Judges Green, Crumbley, and Pollock,

In view of the Board's authorization for Patent Owner to file a limited sur-reply (1:56 PM Email of August 18, 2017), Patent Owner writes to request guidance regarding (1) the proper scope of the Motion for Observation on Cross-Examination, and (2) whether cross-examination testimony may be cited in the sur-reply.

By way of background, Patent Owner has noticed a deposition of Petitioner's reply witness for **August 28, 2017**. The Board has authorized Patent Owner to file a limited sur-reply on or before Due Date 3 (**September 5, 2017**). Pursuant to the Scheduling Order filed by the Board (Paper 9), any Motion for Observation of cross-examination testimony is due on Due Date 4 (**September 25, 2017**).

As Patent Owner's sur-reply will be due after the deposition of Petitioner's reply witness, is Patent Owner authorized to file a Motion for Observation directed to issues that are not addressed in Patent Owner's sur-reply, as no further substantive paper will be permitted on these issues? Authorizing Patent Owner to file a Motion for Observation directed to issues not addressed in Patent Owner's sur-reply is consistent with the Board's decision in another proceeding and the Trial Practice Guide. *See LG Elecs., Inc. v. ATI Techs. ULC*, IPR2015-00325, Paper 52 at 4 (Jan. 25, 2016) (stating that the Patent Owner "also could have filed a motion for observation on other issues" that were not addressed in the limited sur-reply); Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,767-68 (Aug. 14, 2012) (describing a motion for observation on cross-examination that "occurs after a party has filed its last substantive paper on *an issue*," not an entire proceeding (emphasis added)).

In addition, Patent Owner respectfully requests guidance regarding whether Patent Owner's sur-reply may cite the cross-examination testimony of Petitioner's reply witness, to be taken on August 28, 2017, related to the limited issues addressed in the sur-reply. As Patent Owner is not permitted to raise any issue in the Motion for Observation that is addressed in the sur-reply (*see LG Elecs.*, IPR2015-00325, Paper 52 at 2-4; Office Patent Trial Practice Guide, 77 Fed. Reg. at 48,768 (explaining that a Motion for Observation "is not an opportunity to ... re-argue issues")), the sur-reply would be Patent Owner's only opportunity to draw the Board's attention to testimony relevant to the issues in the sur-reply.

Patent Owner appreciates the Board's guidance on these issues.

Kind regards,

Jared

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