

The *PTAB Strategies and Insights* newsletter provides timely updates and insights into how best to handle proceedings at the USPTO. It is designed to increase return on investment for all stakeholders looking at the entire patent life cycle in a global portfolio.

This month, we cover three topics:

- A look at the PTAB's first trial examining a patent involving a cannabis invention;
- A cautionary case study regarding the importance of reviewing notices received from the PTAB in detail;
- A high level review of 2018 trends and statistics for PTAB proceedings.

We welcome feedback and suggestions about this newsletter to ensure we are meeting the needs and expectations of our readers. So if you have topics you wish to see explored within an issue of the newsletter, please reach out to me.

To view our past issues, as well as other firm newsletters, please click here.

Thank you.

Best regards, Jason

Editor: Author: Author:

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## PTAB ONLY PARTIALLY SMOKES CANNABIS PATENT

By: Pauline M. Pelletier

Eleven of thirteen cannabis patent claims survive PTAB challenge.

Insys Development Company, Inc. filed a petition requesting *inter partes* review of claims 1-13 of GW Pharmaceutical Ltd.'s patent directed to the use of cannabinoids, including cannabidiol ("CBD"), in the treatment of certain types of epilepsy. After a trial on the prior art challenges raised by Insys, the PTAB concluded[i] that while claims 1 and 2 were obvious, the remaining claims, claims 3-13, were not. The prior art asserted was clinical literature involving administration of CBD or tetrahydrocannabinol ("THC"). The level of ordinary skill was defined as an M.D. or Ph.D. in pharmacology, chemistry, biochemistry, neurology, or a related field.



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#### UNREVIEWED FILING DATE NOTICE DOOMS PETITION

By: Lisa Schreihart

Petitioners beware. Your Notice of Filing date needs to be reviewed immediately – and not just the notice email, because the email does not alert petitioner to defects in filing.

On December 18, 2018, the USPTO's Patent Trial and Appeal Board (PTAB) denied Petitioner

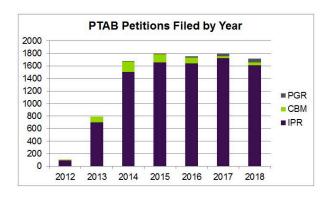
Nuna Baby Essentials, Inc.'s motion to excuse a two-day-late filing of its exhibits to its *inter* partes review (IPR) petition, for which Petitioner requested excusal due to a clerical error in the filing process.[i] Further, the PTAB ordered Petitioner's exhibits be expunged from the record.

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# 2018 TRENDS AND STATISTICS FOR PTAB PROCEEDINGS

By: Patrick Murray

Total PTAB petition filings dropped to their lowest level since 2014, but the 2018 figure was still in the same range as each of the previous four years. For the second straight year, more PGRs than CBMs were filed, a trend that is expected to persist.

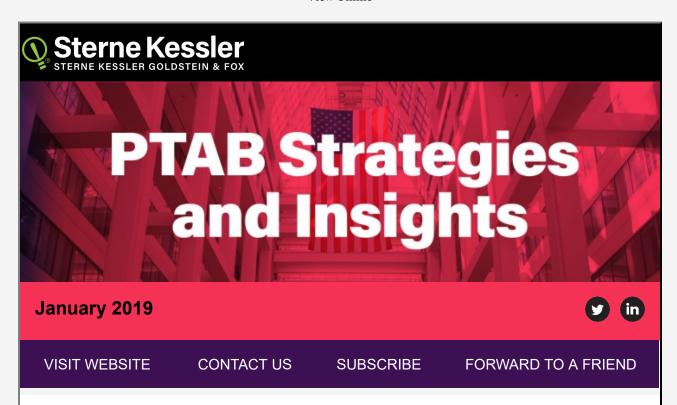


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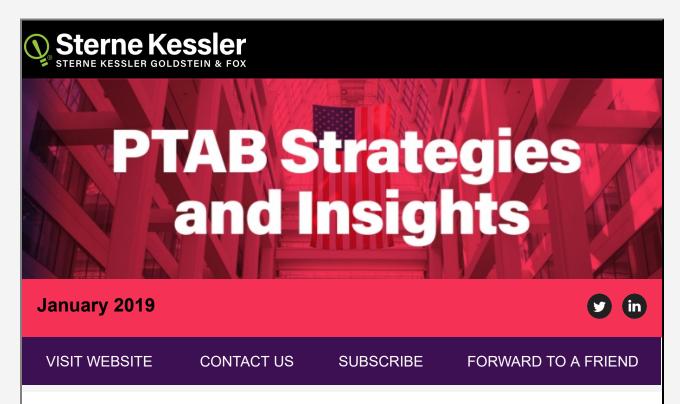
The patent at issue in this IPR is notable because it is associated with the first FDA-approved drug comprised of an active ingredient derived from cannabis: Epidiolex, which is indicated to treat rare, severe forms of epilepsy in patients two years of age and older. The PTAB's decision is notable because, notwithstanding the unique subject matter, it analyzed the issues in largely the same way that one would expect to see in a typical biopharmaceutical case involving the obviousness of dose ranges. As the first post-grant trial on medicinal cannabis, this decision thus removes a few unknowns for those who own or are seeking patents in this space.

[i] Insys Development Company, Inc. v. GW Pharma Limited and Otsuka Pharmaceutical Co., Ltd., IPR2017-00503, Paper No. 36 (P.T.A.B. Jan. 3, 2019)

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Petitioners beware. Your Notice of Filing date needs to be reviewed immediately – and not just the notice email, because the email does not alert petitioner to defects in filing.

On December 18, 2018, the USPTO's Patent Trial and Appeal Board (PTAB) denied Petitioner Nuna Baby Essentials, Inc.'s motion to excuse a two-day-late filing of its exhibits to its *inter partes* review (IPR) petition, for which Petitioner requested excusal due to a clerical error in the filing process. [1] Further, the PTAB ordered Petitioner's exhibits be expunged from the record.

Petitioner filed its IPR petition on September 10, 2018, but failed to file the exhibits with the petition, although Petitioner timely served the petition with the exhibits on Patent Owner Britax Child Safety, Inc. Petitioner's counsel "believed that all documents were successfully uploaded" because Petitioner's counsel received a "Filing Date Accorded" email correspondence from the PTAB's E2E system on September 21, stating that "[t]he Petition has been verified and has been accorded a filing date."[2]

In a subsequent Notice of Filing Date, entered September 21, the PTAB notified Petitioner that "[n]o exhibits have been filed" and accorded the Petitioner five business days (until September 28) to correct the defect.[3] On October 2, when reviewing the docket, Petitioner's legal assistant first realized that the exhibits had not been filed.[4] Petitioner then filed the exhibits, after the five-day deadline had passed, and requested authorization from the Board to file a motion to excuse the late filing. The Board granted the Petitioner's request as well as authorization to the Patent Owner to file an opposition to Petitioner's motion.

Petitioner relied on Rule 42.5(c)(3),[5] arguing that its late filing should be excused because "(1) good cause exists to extend by two business days the Board's period for correcting Petitioner's clerical mistake, (2) Petitioner timely served the exhibits on Patent Owner, and (3) Petitioner promptly responded upon first learning of the clerical mistake and promptly filed [the

#### exhibits]."[6]

Petitioner offered several reasons for good cause.[7] Among them, Petitioner argued, citing several cases, that "[t]he Board has routinely allowed petitioners to correct mistakes in petition filings, including the failure to properly upload exhibits," for good cause. Petitioner argued that good cause exists because (a) Patent Owner, having been served with the petition and all exhibits on September 10, 2018, suffered no prejudice; (b) Rule 42.104(c) permits correction of a clerical error without change to the filing date of the petition; and (c) Petitioner believed in good faith that it had filed the petition and all exhibits on September 10, 2018, because the Filing Date Accorded email did not notify Petitioner's counsel that a separate document, that being the Notice of Filing Date, had been uploaded to the record. Petitioner further argued that the interests of justice support Petitioner's late filing because "[p]etitioner promptly served Patent Owner, and no delay had resulted," causing "no impact on the ability to secure a just resolution." [8]

The PTAB rejected Petitioner's arguments because diligence required the petitioner to correct its error within the allotted time found on the notice.[9] And the PTAB held that "the fact that other panels have allowed petitioners to correct clerical and typographical mistakes, also in accordance of the rule,... does not establish good cause in and of itself."[10] As to the Patent Owner suffering no prejudice, the PTAB held that "lack of prejudice does not demonstrate good cause for excusing a late filing, particularly when opportunity has been provided already to correct the error or mistake."[11] Further, the PTAB cited the lack of evidence that counsel reviewed the filing, filing note, and/or the file as irreconcilable with Petitioner's good faith argument, because Petitioner took no action even after the Board informed Petitioner of the error.[12]

The PTAB stated that "[i]gnorance of the PTAB's procedures and the breakdown or lack of sufficient internal procedures to substantively review notices from the Board does not establish good cause to excuse a late filing."[13] And because "this issue is of Petitioner's own making," additionally because Petitioner filed shortly before the time bar under 35 U.S.C. § 315(b), the PTAB held that it would not be in the interests of justice to excuse the late filing.[14] The PTAB reminded Petitioner that there is no automatic right to petition for an IPR, and Congress sets the limits, such as the time bar under Rule 315(b).[15]

**Takeaway:** All parties need to review both the electronic filing notice **and** the uploaded Board document associated with the notice. Finally, parties need to implement a backstop procedure to review all filings and uploads for errors just after making the filing to meet diligence requirements.

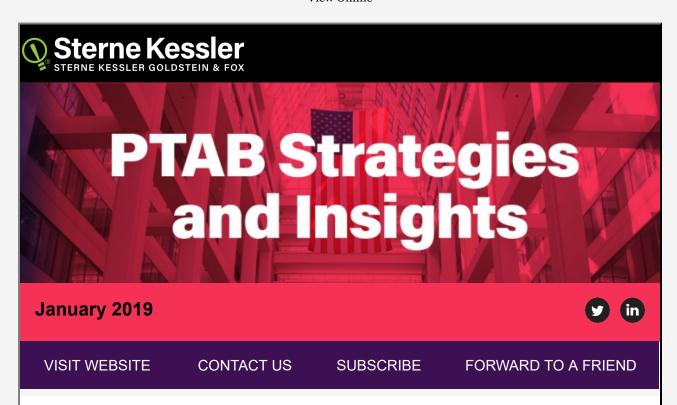
- [1] Nuna Baby Essentials, Inc. et al. v. Britax Child Safety, Inc., IPR2018-01683, Paper 11 (P.T.A.B. Dec. 18, 2018).
- [2] Nuna Baby Essentials, Inc. et al. v. Britax Child Safety, Inc., IPR2018-01683, Paper 8 at 1-2 (P.T.A.B. Nov. 13, 2018).
- [3] *Id*. at 2.
- [4] *Id*.
- [5] 37 C.F.R. § 42.5(c)(3) states that "[a] late action will be excused on a showing of good cause or upon a Board decision that consideration on the merits would be in the interests of justice."
- [6] IPR2018-01683, Paper 8 at 1.
- [7] See id. at 3-8.
- [8] *Id*. at 8.
- [9] IPR2018-01683, Paper 11 at 5.
- [10] *Id.* at 6.
- [11] *Id*.
- [12] See id. at 7.

[13] *Id*. [14] *See id*. at 8. [15] *Id*.

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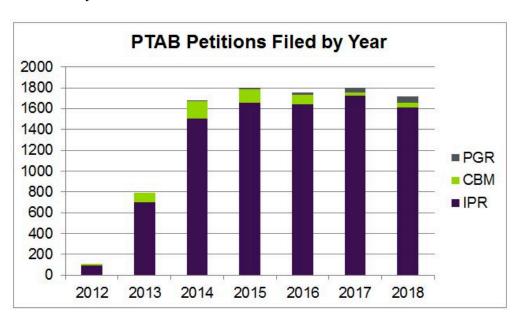
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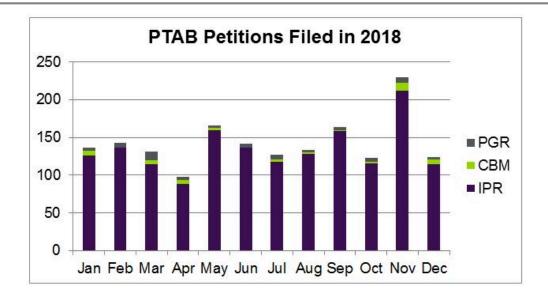


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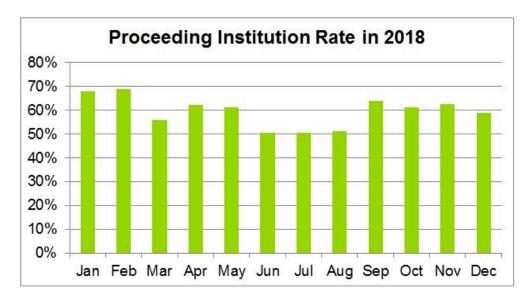
By: Patrick Murray



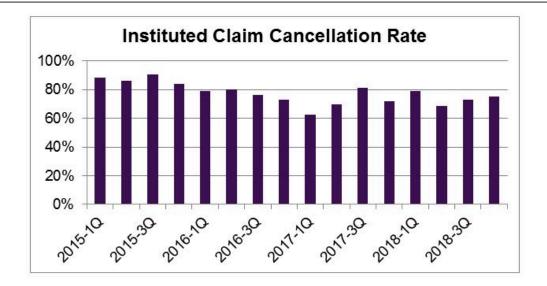
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Year-end totals were boosted by an active November, as petitioners rushed to get on file prior to the PTAB's shift from broadest reasonable interpretation to *Phillips* claim construction.



After the Supreme Court's *SAS* ruling in April requiring the Board to issue all-or-nothing institution decisions, proceeding institution rates dipped throughout the summer. The institution rate rebounded to pre-*SAS* levels in the fall, suggesting that *SAS* was more of a tremor than a landscape-altering earthquake.



The Board cancelled about 75% of instituted claims that it ruled on in 2018 – close to the long run average of 77%. Time will tell whether this rate declines as a consequence of *SAS*. With the Board prevented from instituting on a claim-by-claim basis, it's conceivable that fewer instituted claims will be cancelled at final written decision.

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