

From: [Samuel T Lockner](#)
To: [Yixin Tang](#); [Justin Oakland](#); [Brent Batzer](#); [Shashank Upadhye](#); [Melissa Smith](#); [Tom Gorham](#)
Cc: [Alexandra J Olson](#); [Seung Sub \(Elvis\) Kim](#); [Sun-Sezaby](#); [Eric Findlay](#)
Subject: RE: Nivagen v. Sun (E.D. Tex.) Meet and Confer Follow-up
Date: Friday, April 11, 2025 5:20:13 PM
Attachments: [REDACTED]

Yixin,

A point of clarity – we never discussed any portion of the protective order nor did we suggest we’d have to modify the protective order to designate our samples under the PO. Particularly in light of the additional information we gained today about Nivagen’s intentions, we do not think that is the case. Still, we are doing our best to efficiently determine whether there is a workable way to resolve this issue without court intervention and will continue to do so.

Have a good weekend.

Sam Lockner
(612) 436-9654 (office)
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From: Yixin Tang <yixin@ipfdalaw.com>
Sent: Friday, April 11, 2025 5:12 PM
To: Justin Oakland <joakland@carlsoncaspers.com>; Brent Batzer <brent@ipfdalaw.com>; Shashank Upadhye <shashank@ipfdalaw.com>; Melissa Smith <melissa@gillamsmithlaw.com>; Tom Gorham <Tom@gillamsmithlaw.com>
Cc: Samuel T Lockner <SLockner@carlsoncaspers.com>; Alexandra J Olson <AOlson@carlsoncaspers.com>; Seung Sub (Elvis) Kim <ekim@carlsoncaspers.com>; Sun-Sezaby <Sun-Sezaby@carlsoncaspers.com>; Eric Findlay <efindlay@findlaycraft.com>
Subject: RE: Nivagen v. Sun (E.D. Tex.) Meet and Confer Follow-up

Justin,

First, thanks for confirming that Sun will promptly provide 10 vials of its Sezaby product from the only batch it has in possession, free of charge. You also offered that Nivagen could purchase additional vials at \$133 per vial. Upon further discussion, we agreed that the per-vial cost can be adjusted pending any additional tariff that may be applied. We will let you know soon if Nivagen would like to obtain additional vials, but please let us know when the first 10 vials are available for shipping, and we will provide you with shipping instructions.

You (meaning you and your colleague on the call) indicated that Sun’s reluctance to produce samples stems from its view that it should not be providing materials and information that could be used against Sun. I asked you to provide from the Protective Order the basis for Sun’s insistence of attaching conditions to product samples that should be produced without a confidentiality designation. You did not provide any such basis, but indicated that you may ask the Court to modify the

Protective Order. Your asking for case law on why Sun *couldn't* attach conditions to non-confidential material is also baseless. We do have a party-negotiated and Court-ordered procedure in place. A document or thing can either be labeled "confidential" which will engender a dispute process delineated in the PO which we are already engaging in when the receiving party deemed the designation improper, or be produced without any designation – in which case none of the restrictions in the PO applies. Our dispute now is whether Sun can properly label product samples confidential under the PO.

I explained to you that, given the size of Nivagen, any restrictions as to who might test the samples (or be involved directly or indirectly in the testing), interpret the data generated, and participate in the litigation upon seeing the data, would cause severe burden on Nivagen's ability to conduct litigation, and any restrictions placed on individuals who had access to such testing, data, analysis, would be impractical.

You were put on notice that, if the sample production is delayed or denied due to this "confidentiality" dispute or any insistence that Amneal is entitled to more information or assurance before producing non-confidential product samples, Nivagen intends to seek adverse inference that (1) any samples Nivagen might obtain from the market should be deemed representative of all Sezaby commercial products; and (2) certain claim elements are met.

Regarding interrogatory responses and the new idea you floated today of some stipulation to bypass the issue, Nivagen will give it some further thought. We will let you know if we want to discuss your new further, or if Nivagen intends to supplement any responses.

Have a good weekend,

Yixin

From: Justin Oakland <joakland@carlsoncaspers.com>

Sent: Friday, April 11, 2025 4:40 PM

To: Yixin Tang <yixin@ipfdalaw.com>; Brent Batzer <brent@ipfdalaw.com>; Shashank Upadhye <shashank@ipfdalaw.com>; Melissa Smith <melissa@gillamsmithlaw.com>; Tom Gorham <Tom@gillamsmithlaw.com>

Cc: Samuel T Lockner <SLockner@carlsoncaspers.com>; Alexandra J Olson <AOlson@carlsoncaspers.com>; Seung Sub (Elvis) Kim <ekim@carlsoncaspers.com>; Sun-Sezaby <Sun-Sezaby@carlsoncaspers.com>; Eric Findlay <efindlay@findlaycraft.com>

Subject: Nivagen v. Sun (E.D. Tex.) Meet and Confer Follow-up

Yixin,

Thank you for your time today.

Nivagen is demanding that Sun produce samples without any designation under the protective order. We have been trying to gain insight into the overall scope and impact of Nivagen's request for

the past couple weeks. Today, we learned that Nivagen's demand stems from the fact that Sun's product has been commercially sold. Nivagen contends this means that Sun's samples must be produced without any designation under the PO and further allows Nivagen to do what it wants with the samples (e.g., conduct whatever tests it wishes) and disclose that information to anyone within Nivagen or the public at large. Upon further inquiry, it became apparent that Nivagen wants the ability to test Sun's product at Nivagen (i.e., without use of a 3rd party lab) and show results to Nivagen individuals who also have an active role in patent prosecution. Nivagen wants to ensure that the parties' negotiated FDA and PTO bars would not apply to any results or analyses of Sun's samples.

We explained that we have never had an opposing party make this demand in our 20+ years of pharma-related experience. Samples and resulting data are routinely protected by protective orders. We asked if Nivagen had any legal support for its position. Nivagen did not provide any. We further asked that Nivagen forward any legal support it later identifies so we can make Sun aware of it. Upon further questions, Nivagen agreed that the data contained in Sun's NDA, for example, is rightfully confidential even though Sezaby is now available on the market. Similarly, we strongly suspect (and please correct us if we are wrong) that Nivagen maintains its internal data relating to its commercially available products are rightfully treated as confidential too.

We told you that we would reach out to Sun immediately with the further understanding we gained from our discussion today and return with Sun's position. We said that given the atypical request, we anticipate that Sun's consideration may take some time and internal discussion. With that in mind, we offered to expedite production of Sun's samples so long as Nivagen treated them as CONFIDENTIAL under the protective order while the parties resolved this potential dispute. Nivagen declined our offer. Please let us know if Nivagen changes its mind.

Additionally, we raised issues identified in our March 11th letter, and specifically Sun's RFA Nos. 11 and 12 and Interrogatory No. 18 directed to whether Nivagen can identify any alleged novel compositions in the provisional or original applications containing an organic solvent. You said you were not prepared to discuss and that we could reconvene next week. In advance of any discussion, Sun said that this issue might be mooted if Nivagen would stipulate that it will not argue or offer any evidence that the provisional and original applications of the '076 patent disclose any novel compositions containing organic solvents. We further indicated that, if Nivagen refuses to stipulate, and further refuses to supplement its interrogatory, we will later move to exclude any attempt by Nivagen to argue or offer evidence that the provisional or original applications of the '076 patent disclose any novel compositions containing organic solvents. We look forward to your responses to those positions.

Please identify dates when you are available.

Have a great weekend.

Justin Oakland
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