

MAZIE SLATER KATZ & FREEMAN, LLC

103 Eisenhower Parkway, Suite 207, Roseland, NJ 07068

Phone: (973) 228-9898 - Fax: (973) 228-0303

www.mazieslater.com

David A. Mazie*
Adam M. Slater*^o
Eric D. Katz*^o
David M. Freeman
Beth G. Baldinger
Matthew R. Mendelsohn*^o
David M. Estes
Adam M. Epstein^o

*Certified by the Supreme Court of
New Jersey as a Civil Trial Attorney

Karen G. Kelsen^o
Cory J. Rothbort*^o
Michael R. Griffith^o
Christopher J. Geddis
Samuel G. Wildman
Julia S. Slater^o
Trevor D. Dickson

^oMember of N.J. & N.Y. Bars

December 3, 2024

Via ECF

Honorable Thomas I. Vanaskie, Special Master
Stevens & Lee, P.C.
1500 Market Street, East Tower, 18th Floor
Philadelphia, Pennsylvania 19103

Re: *In re Valsartan, Losartan, and Irbesartan Products Liability
Litigation*, No. 1:19-md-02875 (D.N.J.)

Dear Judge Vanaskie:

Please accept this agenda letter on behalf of the Plaintiffs in advance of the
December 4, 2024 case management conference.

1. The Parties' *Lexecon* Waivers.

As discussed at the previous conference, out of the five randomly selected
cases, all five involved Mylan and/or Aurobindo API. Mylan refused to waive
Lexecon and Aurobindo has stated they would only waive *Lexecon* if the Plaintiffs
agreed to dismiss the foreign Aurobindo entity—which effectively equates to
Aurobindo refusing to waive *Lexecon*. Plaintiffs' understanding is that the Court

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wants a second pool of cases that can be worked up with the ability to be *tried by the Honorable Renée Marie Bumb*. Unfortunately, since Mylan and Aurobindo have refused to waive *Lexecon*, it does not appear that there is an easy solution for these five cases to have the capability to be tried by the Honorable Renée Marie Bumb. As a result, Plaintiffs suggest that five additional cases be randomly selected from the bellwether pool that include only the ZHP API manufacturing defendants (ZHP, Teva and Torrent) and do not include Mylan or Aurobindo.

2. Jurisdictional Issues of Track One Bellwether Cases.

First, the Plaintiffs are not aware of any jurisdictional issues related to the *Gaston Roberts* case (the first case to be worked up for trial). Plaintiff agrees not to pursue the local pharmacy defendant, so there is not a subject matter jurisdictional issue. In addition, Plaintiff waives *Lexecon*, so this case can be tried in New Jersey.

Defendants have also raised subject matter diversity issues related to the *Pate* case. Due to Mylan's refusal to waive *Lexecon*, *Pate* may not be a case that can be tried in New Jersey even if there were no subject matter diversity issues. Nonetheless, Plaintiffs' leadership counsel has asked defense counsel to meet and confer with individual counsel for *Pate* to work out an agreement for potentially being able to refile that case in the state court of New Jersey as long as the defendants to do try to then assert a statute of limitations defense.

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The Retailer Defendants have previously raised issues as to whether the *Guillory* and *Pizzolato* plaintiffs have viable claims against the retailer defendants in Louisiana. *Guillory* was not one of the five cases randomly selected. For *Pizzolato*, Mylan refused to waive *Lexecon*. The issue of whether these plaintiffs have viable claims against the retailer defendants does not impact whether or not either of these cases could be tried in New Jersey, because Mylan refused to waive *Lexecon*. Nonetheless, Plaintiffs believe that these cases do have viable claims against the retailer defendants. Plaintiffs' Leadership Counsel suggested that these parties continue to meet and confer, but also suggested that the second trial only proceed forward against the manufacturer defendants (to avoid any complications related to pharmacy *Lexecon* issues or pharmacy state-specific claims).

3. Plaintiffs' Request Regarding the Documents Needed for Jinsheng Lin's Deposition.

On October 24, 2024, Plaintiffs wrote to ZHP's counsel regarding documents that should have been produced previously but apparently were not, and which will be needed for the recently ordered deposition of Jinsheng Lin. Specifically, Plaintiffs wrote:

In preparation for that deposition, Plaintiffs have reviewed ZHP's document production for policies or procedures that would allow for the destruction of his custodial file from November 2017 and earlier; however, Plaintiffs have

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been unable to find such documents. Please identify those documents or produce them immediately.

Plaintiffs have also reviewed ZHP's document production for the certificates of analysis and material safety data sheets from its dimethylformamide, triethylamine, and triethylamine hydrochloride suppliers. Plaintiffs have not been able to find these documents in the production. Please identify the suppliers' certificates of analysis and material safety data sheets for the entire relevant time period in the production, or produce them immediately.

(Ex. 1 hereto). Four days later, ZHP responded: "We are looking into the issues raised in your letter and will get back to you soon regarding the requested discovery."

(Ex. 2 hereto).

The documents are obviously relevant to the case in general, and the deposition in particular. Plaintiffs' need the policies allegedly justifying the destruction of most of Jinsheng Lin's custodial file, including years of emails, in order to question him about that process. Moreover, this Court explicitly ordered ZHP to produce all of its document retention policies on November 12, 2021. ([ECF 1753](#), p.3).

The certificates of analysis are needed to establish the extent to which ZHP had documentation of the presence of nitrosamine precursors in the chemicals used to manufacture its valsartan, since Jinsheng Lin's current custodial file fails to explain how he came to his understanding that there was NDMA in valsartan and

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that it was caused by the combination of dimethylamine and sodium nitrite during quenching of the substance, as documented in his July 27, 2017 email. Specifically, Plaintiffs have independently obtained Certificates of Analysis from the same suppliers for the same solvents used in the manufacturing processes at issue, for example showing that the DMF used in the process was known to contain a list of impurities including dimethylamine—the substance that combined with nitrous acid to form NDMA. ZHP would have been provided the same or similar certificate of analysis with every delivery of the solvents. (Ex. 3 hereto). And the Court-approved requests for production required the production of the requested certificates of analysis. ([ECF 328](#), p. 7-8 of Ex. A).

On December 3, 2024 at 4:00 pm, ZHP wrote to Plaintiffs providing some bates numbers for document related policies, and inviting a meet and confer on the documents. (Ex. 2 hereto). Plaintiffs are willing to speak to ZHP, but need to move to closure on these discrete issues, and respectfully ask the Court to enter an order for ZHP to identify or produce the requested documents within fourteen days of tomorrow's status conference, to the extent not already done.

Respectfully,



Adam M. Slater
Plaintiffs' Liaison Counsel

Cc: Counsel of record (via ECF)

Exhibit 1

MAZIE SLATER KATZ & FREEMAN, LLC

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Phone: (973) 228-9898 - Fax: (973) 228-0303

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*Certified by the Supreme Court of
New Jersey as a Civil Trial Attorney

October 24, 2024

VIA EMAIL

Jessica Davidson, Esq.
Skadden, Arps, Slate, Meagher & Flom LLP
One Manhattan West
New York, New York 10001

RE: *In re Valsartan Products Liability Litigation*, No. 1:19-md-02875

Dear Jessica:

The Court ordered Plaintiffs to take Jinsheng Lin's deposition in anticipation for his trial testimony. In preparation for that deposition, Plaintiffs have reviewed ZHP's document production for policies or procedures that would allow for the destruction of his custodial file from November 2017 and earlier; however, Plaintiffs have been unable to find such documents. Please identify those documents or produce them immediately.

Plaintiffs have also reviewed ZHP's document production for the certificates of analysis and material safety data sheets from its dimethylformamide, triethylamine, and triethylamine hydrochloride suppliers. Plaintiffs have not been

Jessica Davidson, Esq.
Skadden, Arps, Slate, Meagher & Flom LLP
October 24, 2024
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able to find these documents in the production. Please identify the suppliers' certificates of analysis and material safety data sheets for the entire relevant time period in the production, or produce them immediately.

If you are unwilling to provide any of these documents/identify them in the production if already produced, please advise so we can submit the issue to Judge Vanaskie for resolution.

Thank you,

A handwritten signature in blue ink, appearing to read "Adam M. Slater", written over a horizontal line.

ADAM M. SLATER

Exhibit 2

From: [Hansen, Milli Kanani](#)
To: [Christopher Geddis](#); [Rose, Nina R](#)
Cc: [Adam Slater](#); [Davidson, Jessica](#); [Bernardo, Richard T](#)
Subject: RE: Documents Needed for Jinsheng Lin's Deposition
Date: Tuesday, December 3, 2024 4:04:25 PM

Hi Chris –

I hope you had a good Thanksgiving.

Thanks for your patience and apologies for the delay – we were just tracking down some information and it took a little longer than expected due to client travel.

First, with respect to ZHP's retention policies, as ZHP has previously explained, there is no company-wide retention policy. Rather, it is our understanding that, to the extent documents are required to be retained for regulatory or other compliance-related reasons, those retention policies are generally embodied in a particular department's standard operating procedures or standard maintenance procedures. We have identified the following procedures that relate to retention: ZHP01793158, PRINSTON00486190, ZHP00692282, ZHP02385368, ZHP02978802, ZHP00336173, ZHP00703012, ZHP01866627, ZHP00336173, ZHP01793693, ZHP01523050, ZHP00245573, ZHP01525574, ZHP00356238, ZHP00070216, PRINSTON00486236, ZHP00702047, ZHP02672612, ZHP01793877, ZHP02667068, ZHP01525948, ZHP02379205, ZHP00702183, ZHP00494126, ZHP00859527, ZHP01793953, ZHP01794354, ZHP00275565. We are not aware of one pertaining specifically to CEMAT materials, but have asked that that be double checked since we were not involved in the original collection.

In terms of emails, our understanding is that while there has not been a ZHP policy specifically relating to email retention, ZHP's third-party email vendor had a policy of rolling off emails on its servers after two years, which we understand has been previously discussed. Individual employees may have separately maintained, at their own discretion and based on business needs, emails in their own inbox older than two years. However, such retention was subject to mailbox size and space limits.

Second, you have requested certificates of analysis and material safety data sheets for certain raw materials. Although we are willing to work with plaintiffs to facilitate Dr. Jinsheng Lin's deposition, these documents are not the types of documents Dr. Lin would ordinarily review, rely on, or use in the course of his work at CEMAT. For example, Dr. Lin has no recollection at all – which you can of course confirm during your deposition – of ever reviewing a certificate of analysis or material safety data sheet for dimethylformamide, triethylamine, or triethylamine hydrochloride in the course of his investigations into an impurity for any product. This is not surprising, as these documents are generally handled by the QC/QA departments and are not the kinds of documents he generally comes across as part of his job responsibilities. To the extent that you continue to be interested in these documents despite the foregoing explanation, we would like to meet and confer with you to discuss ways to minimize the burdens associated with plaintiffs' request for these materials.

Milli

Milli Kanani Hansen

Skadden, Arps, Slate, Meagher & Flom LLP
1440 New York Avenue, N.W. | Washington | D.C. | 20005-2111
T: +1.202.371.7128 | M: +1.214.235.8938
milli.hansen@skadden.com

From: Christopher Geddis <CGeddis@mazieslater.com>
Sent: Wednesday, November 27, 2024 11:21 AM
To: Rose, Nina R (WAS) <Nina.Rose@skadden.com>
Cc: Adam Slater <ASlater@mazieslater.com>; Hansen, Milli Kanani (WAS) <Milli.Hansen@skadden.com>; Davidson, Jessica (NYC) <Jessica.Davidson@skadden.com>
Subject: [Ext] RE: Documents Needed for Jinsheng Lin's Deposition

Hi Nina,

Any update on this?

Thanks,
Chris

From: Rose, Nina R <Nina.Rose@skadden.com>
Sent: Monday, October 28, 2024 4:46 PM
To: Christopher Geddis <CGeddis@mazieslater.com>
Cc: Adam Slater <ASlater@mazieslater.com>; Hansen, Milli Kanani <Milli.Hansen@skadden.com>; Davidson, Jessica <Jessica.Davidson@skadden.com>
Subject: RE: Documents Needed for Jinsheng Lin's Deposition

Hi Chris,

We are looking into the issues raised in your letter and will get back to you soon regarding the requested discovery.

Thanks,
Nina

From: Christopher Geddis <CGeddis@mazieslater.com>
Sent: Thursday, October 24, 2024 3:49 PM
To: Davidson, Jessica (NYC) <Jessica.Davidson@skadden.com>; Rose, Nina R (WAS) <Nina.Rose@skadden.com>
Cc: Adam Slater <ASlater@mazieslater.com>
Subject: [Ext] Documents Needed for Jinsheng Lin's Deposition

Hi Jessica and Nina,

Please see attached for Plaintiffs' letter regarding the documents needed for Jinsheng Lin's deposition.

Best,
Chris

Christopher J. Geddis
Associate Attorney
Mazie Slater Katz & Freeman, LLC
103 Eisenhower Parkway
Roseland, New Jersey 07068
(973) 228-9898
cgeddis@mazieslater.com
www.mazieslater.com



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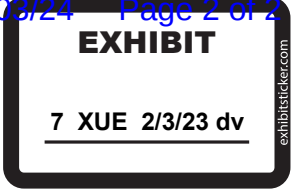
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Further information about the firm, a list of the Partners and their professional qualifications will be provided upon request.

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Exhibit 3



山东华鲁恒升化工股份有限公司

SHANDONG HUALU-HENGSHENG CHEMICAL CO., LTD.

CERTIFICATE OF ANALYSIS

COMMODITY:N,N-DIMETHYL FORMAMIDE

BATCH NO.:20101026

THE RESULTS OF INSPECTION ARE AS FOLLOWS:

| ITEM | SPECIFICATION | RESULTS |
|---|---------------|----------|
| Pt-Co chrominance | ≤10 | 5 |
| Distillation test 0° C 101325Pa 151-155° C distillate volume | ≥98.5 | 98.6 |
| dimethylamine ppm | ≤15 | 1 |
| Formic acid ppm | ≤25 | 2 |
| PH:25° C 20%Aqueous solution | 7.0-7.5 | 7.05 |
| Electric Conductivity: 25° C 20%Aqueous solution, us | ≤10 | 1.1 |
| Moisture ppm | ≤500 | 122 |
| Fe ppm | ≤0.05 | 0.002 |
| Refractivity: $n_d^{25^{\circ}c}$ | 1.4270-1.4290 | 1.4286 |
| Methanel ppm | ≤20 | 2 |
| Heavy compoment (dimethyl Acetamide) ppm | ≤500 | 43 |
| DMF % | ≥99.9 | 99.98 |

SHANDONG HUALU-HENGSHENG CHEMICAL CO., LTD.

NO.24 TIANQU XI RD, DEZHOU SHANDONG ,CHINA

SIGNATURE _____