> UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF FLORIDA WEST PALM BEACH DIVISION

CASE NO. 20-md-02924-ROSENBERG

IN RE: ZANTAC (RANITIDINE) PRODUCTS LIABILITY . West Palm Beach, FL LITIGATION.
. October 6, 2021
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DISCOVERY CONFERENCE (through Zoom)
BEFORE THE HONORABLE BRUCE REINHART UNITED STATES MAGISTRATE JUDGE

FOR THE PLAINTIFFS:
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Pauline A. Stipes, Official Federal Reporter

THE COURT: This is Case Number $20-\mathrm{md}-02924$, In re:
Zantac (Ranitidine) Multi District Litigation.
We are here today on a discovery matter. Let me recognize counsel for the Plaintiffs.

MS. JUNG: Good morning, your Honor, Je Yon Jung on behalf of the Plaintiffs.

THE COURT: Good morning. On behalf of Boehringer Ingelheim.

MR. SHORTNACY: Good morning, your Honor, it's Michael Shortnacy speaking, from King \& Spalding, on behalf of Boehringer Ingelheim Pharmaceuticals, Inc.

THE COURT: Good morning. On behalf of Sanofi.
MS. SHARPE: Good morning, your Honor, Paige Sharp from Arnold \& Porter on behalf of the Sanofi Defendants.

THE COURT: Good morning. This matter was on today for a PTO 32 hearing relating to -- let me go back.

We had a hearing, I think it was a week ago, maybe a little over a week ago, and the issue on the table was that BI, on behalf of Sanofi, had retained certain product based upon its interpretation of the FDA's regulations that required it to keep a residual amount of product for some period of time, and the Plaintiffs were asking for samples from this -- I will call it regulatory retained product.

And BI told the Court that BI didn't have an objection to producing it, but because of its contractual obligations to

Sanofi, they needed to confer with Sanofi and Sanofi's regulatory counsel. I told the parties to confer and if we needed to get back together, we would get back together.

My understanding from at least the submission that I received this morning from Sanofi and BI is that Sanofi's regulatory counsel does not object to production of some of this material to the Plaintiffs, but they need an order from the Court to facilitate importing that material from the Promeco facility in Mexico.

Am I correct, Mr. Shortnacy?
MR. SHORTNACY: Your Honor, I won't speak for Sanofi, I will let Ms. Sharpe do that.

I do think that your recitation of the history is correct. I will also say the order, from BI's perspective, is to allow for the export of -- import of the product into the country designating BI as the importer of record and allowing it to work with its U.S. affiliate, BI Freemont, in order to do that. So, that paperwork is required to be submitted.

So, from our perspective, it is a requirement for import.

THE COURT: Okay. I don't know if I should direct this question to Mr. Shortnacy or Ms. Sharpe, but is it fair to say that neither Defendant, at this point, is objecting to producing what the Plaintiffs have asked for, it is just that your view is you need an order of the Court to facilitate
complying with their request, but there is no continuing objection at this time? Mr. Shortnacy?

MR. SHORTNACY: That is correct, your Honor.
THE COURT: Ms. Sharpe?
MS. SHARPE: Yes, your Honor, that is correct.
Just so the record is clear, if I may, we received the request for our consent during the hearing before your Honor on September 23rd, the last time that we were before you, so that was the first time that we actually received that request, was during the hearing.

So, from our perspective, we worked as quickly as possible with our regulatory counsel and internal regulatory colleagues to make sure that we could agree, and did provide that consent last week.

THE COURT: I appreciate that. I am going to turn to Ms. Jung in a second.

I said this at the last hearing, I will make the record clear in this regard. As I sit here today and as I sat here then, I am only trying to address a forward-looking question, which is how do we get -- is there an objection to producing this product, do I need to rule on that, and if I don't need to rule on anything, how do we facilitate and how quickly can we get this material to the Plaintiffs for the Plaintiffs to use.

The Plaintiffs may believe, looking backwards, that
they are entitled to some other remedy based on whatever may have happened in the past. I take no position on that other than to say, I am not precluding the Plaintiffs, if they believe they are entitled to a remedy based upon how this process played out, how long it took for this process to play out, or anything else, if they believe they are entitled to a remedy under the rules, they are free to file a motion seeking that remedy.

I just want the record to be very clear, all I am dealing with today is the forward-looking question, and I'm not foreclosing any sort of a backward-looking remedy.

With that, let me turn to Ms. Jung and see if you believe -- other than me entering this order that Sanofi and BI need, is there anything else you believe we need to do this morning?

MS. JUNG: Yes, your Honor. I think it is very important for us to be clear that, while I appreciate your forward looking, the reason why we are here on what is now the fourth PTO 32 on this is because of the continual and serial delays and misrepresentations, quite frankly, that the Defendants have made to your Honor as well as to the Plaintiffs repeatedly.

If it is true that Ms. Sharpe said that Sanofi, the first time that they learned of this request was on September 23rd, that is contrary to Mr. Shortnacy's position
and representation to the Court that they had already made a request to Sanofi.

The reason why that is important, your Honor, is because on September 11th, we received notice of 860 new lines of previously undisclosed product.

On September 13th, we were already appearing before your Honor regarding a previous batch of disclosed product to be produced, and so on September 23rd, we were before your Honor again trying to make sure that we were getting what was delayed, which is now going to be our forward-looking process, yet we had to have another PTO hearing on September 23rd regarding what they were producing.

Query, your Honor, why your order of September 23rd was not sufficient for what BI and Sanofi needed and further delayed us by weeks in order to get the product.

Moreover, their position, as you indicated on September 23rd, was that BI's position was that they needed regulatory counsel consultation regarding the retains. We have to date not received any basis for why they continue to delay producing this product.

And the new position was that on September 30th, when your Honor ordered the product to be delivered to Emery Pharma by 12:00 p.m. -- actually the order ended up saying 3:00 p.m. Pacific time, instead, they simply said actually Sanofi needs to consult with regulatory counsel.

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While, again, $I$ appreciate you only moving forward, there is a reason why our forward looking keeps moving weeks and weeks on top of each other further delaying this process.

Also, your Honor, their position, quite frankly, on September 30th, through the special master, was not that they needed an order, but yet they wanted to have correspondence and draft correspondence together to request FDA approval yet again, not providing any basis for the regulatory withholding at that time.

So, your Honor, it is important to note that until and unless your Honor places something on a PTO 32 hearing, or until and unless the Plaintiffs insist that we need an order from the Court in order to have Defendants give us a date certain, we don't make any progress, and the representations are a little different before your Honor than they are in these meet and confers and this protracted process with the special master.

Again, query whether the Judge's order on September 23rd was not sufficient and why are here now on October 6th asking for another order so that they can have the authorization.

Recall, your Honor, it is important that on September 13th your Honor was dealing with product previously disclosed by BI that also had potentially -- their excuse at that point was there were Customs broker issues. Again, query
whether that product and that inventory had the same reasons that they provided late on October 1st as to why they needed this new order from your Honor that was different from your Honor's order on September 23rd ordering them to produce this product.

So, your Honor, at this point, we have to spend a lot of time and energy dealing with these delays that, quite frankly, we feel are intentional and are misrepresentative of their positions. In fact, Special Master Dodge made it clear that your Honor ordered BI's regulatory counsel to appear today to provide further explanation if necessary regarding their delays to date.

I presume that also should apply to Sanofi's position that their regulatory counsel's recommendation was to continue to withhold this product from Plaintiffs.

Again, it is inconsistent with what we have been here several times before discussing with your Honor, and again, while I appreciate your Honor only looking forward, we continue to have to look forward several times, and that is also why the Plaintiffs had requested costs and sanctions for having to continuously appear before your Honor to only get another order indicating the same thing that your Honor previously ordered.

THE COURT: As I have said, if you want to submit a motion, supported by evidence in the form of affidavit, declaration, whatever other evidence to support, and you
believe you are entitled to a remedy, whether it is costs, fees, or something else, you will file a motion. The other side will have a fair opportunity to respond to it, and if $I$ need to have a hearing to adjudicate that, I will adjudicate that, but you need to identify the remedy that you want and provide evidence to support it, and the evidence will be on both sides and I will have a hearing.

In terms of regulatory counsel, I did ask that regulatory counsel be available for this hearing if we were going to have to have a resolution of whether Sanofi, as a matter of law -- let me go back a step. Sorry.

One of the issues I had discerned from our last discussion was, I think Mr. Shortnacy -- I forget who was representing Sanofi at the time, Mr. --

MR. SHORTNACY: Beroukhim.
THE COURT: Yes. Because they are not regulatory lawyers, they were candid with the Court that they weren't sure whether this was a question that, as a matter of law, they could not take samples out of the regulatory retained material or whether they could, and there was some other regulatory reason why they couldn't provide.

And what I asked the special master to notify the parties was, if we were going to have to resolve the regulatory questions of law, I wanted to have regulatory counsel here so that I could talk directly to the people who were the experts
in the area.

Given that it appears that the Defendants have withdrawn their objection to producing this, I didn't formally excuse regulatory counsel because I didn't know that until this morning, but $I$ find no reason to criticize them for not having regulatory counsel here today. That was the reason I wanted them here, and if they have withdrawn their objection, then there is no reason for them to be here.

There is one other question, and I should turn to Mr. Shortnacy. I do think I should give you some deadline to provide -- the materials that were submitted to the Court indicated that as soon as -- I will sign the order today. Once you get that order, that you thought you could begin your production by Friday. How soon after that should we expect that the Plaintiffs will have the materials?

MR. SHORTNACY: That is a good question, your Honor. If past is prologue -- so, we can't guarantee what will happen at Mexico Customs and we can't guarantee what happens at U.S. Customs and Border Protection and we can't guarantee what FDA does.

If past is prologue, however, your Honor's order may have some sway with those Federal agencies, I don't know, but the prior shipment took, I think, two days from start to finish, meaning leaving the loading dock to being received by Emery Pharma, and there was a Mexican Independence Day in
between.
Again, our goal is to get the product as quickly as we can. By Friday into the stream of shipment -- we have done all we can, as we did last time, to facilitate the smooth entry of the product into the country. Of course, we can't control any of the things I just said, so our hope would be that it would track same as last time.

THE COURT: What I am going to do is this. I appreciate that at some point it is beyond your control.

But I am going to order that it be produced by noon California time on Tuesday, so that if it is, in fact, shipped out on Friday that gives you -- well, noon California time -I'm sorry, five o'clock p.m. on Tuesday. Five o'clock California time on Tuesday, October 13th, which I think is a week from today. I am off by a day. October 12th. Five o'clock on Tuesday, October 12th.

That way, if it goes into the stream of commerce on Friday, understanding there is a weekend involved, it ought to arrive either Monday or Tuesday. So, send it overnight or second day overnight, is my point. It should be shipped in a manner designed for it to arrive by that date.

If things beyond your control intervene, we will deal with that on the back side, but I am going to put a deadine on it. Perhaps that will help with Customs as well. If Customs is aware that a judge has ordered that this product has to get
to California by close of business on Tuesday, maybe that helps you.

MS. JUNG: Your Honor, may I --
THE COURT: In a second. Mr. Shortnacy.
MR. SHORTNACY: Your Honor, may I be heard? I would say -- I appreciate that and I appreciate your Honor's thinking on it. If it is possible, if we could get until Wednesday. I want to avoid -- as I said, these things are out of our control. I understand why your Honor is setting the deadline and appreciate the sort of out for the liege of things that could happen that we cannot control.

But I do think getting something on a flight, it has to be reserved, and we assume that is going to happen on Friday, but there are variables at play that make me want to ask your Honor for at least until the end of day Wednesday so that we have a full week.

THE COURT: Let me hear from Ms. Jung.
MS. JUNG: Thank you, your Honor. Plaintiffs would request that we actually receive the products by Friday.

If your Honor recalls, at the last hearing several weeks ago Mr. Shortnacy made representations to your Honor that they had already started, that they already had collected the samples, and that they would be ready to go short of confirming with their regulatory counsel and getting confirmation from co-defendant Sanofi regarding release of that production of
that product.
So, again, not understanding why we have these continued delays when they make representations to this Court otherwise, so we would request that it be delivered by Friday because an intervening weekend actually jeopardizes delays and the product sitting, as we indicated in our previous hearings before your Honor, and again, there were no issues despite the parade of horribles and the potential problems and delays that were presented to your Honor in previous PTO 32 hearings.

So, we would request that the same format and the same manner in shipping with your Honor's order for Friday would be more reasonable given the representations that they have already started several weeks ago, and there really should be no reason for any further delays.

THE COURT: I am going to stick with my order. My order is going to be that they provide it as soon as possible, but no later than 5:00 p.m. California time on Tuesday, October 12th.

With that, then, Ms. Jung, without waiving any objection you may have to any orders I have entered or any decisions I have made today, is there anything else we need to take up today?

MS. JUNG: Your Honor, I just want to make sure that the order is very clear that it requires that BI as well as Sanofi -- or BI, on behalf of Sanofi, produce this product.

The proposed order that BI submitted to your Honor only indicates $B I$, whereas the reasons for the delay was because of Sanofi's position as the contractual owner of the product. So, to make sure that we are covered by everything, we would request that the order include BI and Sanofi as the entities that are ordered to produce the product.

THE COURT: Let me break that apart.
When you say "the order," I think I am actually doing two orders. One order I am doing is for the use of BI, who has possession, custody, and physical control over the product, to bring it into the country.

I am going to do a separate order memorializing the oral rulings I have made here today. So, it would be Ms. Sharpe.

Any objection if the second order incorporates Sanofi as well as being responsible for the production of the materials by a certain time?

MS. SHARPE: Your Honor, I don't have any objection to the order referencing Sanofi, but Sanofi has no ability to control BI's production of the product outside of the consent that we have provided. It is BI's facility in Promeco that has the product and will be shipping it, so I don't think it would be appropriate to order Sanofi to produce product that is entirely outside of our control.

However, obviously we have provided our consent and
don't have any objection to the order acknowledging that Sanofi has consented to BI's production of the product.

THE COURT: Here is what I am going to do. I am going to order that BI has to produce it, but that Sanofi must cooperate as necessary and provide all assistance necessary to facilitate the production.

That is the appropriate way to define what Sanofi's role should be. They can't throw a roadblock in front of this, and if they need to execute documents, if they need to sign things for the Customs brokers or things like that, I will direct Sanofi to do that, but in terms of the actual physical production, that burden falls on BI. So, that is how the order will be structured.

MS. SHARPE: Thank you, your Honor.
THE COURT: Ms. Jung, any other issues you wanted to raise or any other clarifications?

MS. JUNG: No, your Honor.

THE COURT: Thank you. Mr. Shortnacy, without waiving any objections you may have to any rulings I have made, anything else you wanted to raise today?

MR. SHORTNACY: Yes, your Honor, thank you.
I did have one issue to raise that is separate from the regulatory routine productions that we have all been focused on, but it is sort of thematically related.

As you know, we have all been focusing on getting the
imports into the country. In connection with understanding that process and the samples available, we did come to learn that it appears that the Promeco company procedures governing those retains may not have been suspended.

Just for background to your Honor, those procedures typically require that regulatory retains be preserved for a period of time, after which there is a controlled mechanism for disposal of those products. So, we have come to learn that it looks like that policy may not have been suspended.

We provided notice to Plaintiffs of that on September 11th. We committed to keeping the special master and Plaintiffs informed as we investigate, and we will do so, but we did just want to raise that with the Court as an issue.

Again, I am just trying to get our arms around the issue, but wanted to make it aware for the Court.

THE COURT: I appreciate that. It seems to me this is somewhat akin to an issue $I$ think we had with some emails about a year or so ago. Look, if the product was not retained and -if it was not preserved and it should have been preserved as a matter of -- for trial purposes or as a matter of your evidentiary or discovery obligations, and it wasn't preserved, there are remedies for that which the Plaintiffs can avail themselves of as they see fit, if it fits.

The only thing I would expect, and it sounds like we are on that road, is there should be transparency, that the

Plaintiffs should just be aware if things have not been retained, it is what it is, let's just get the facts out there, and if the Plaintiffs are entitled to a remedy, Plaintiffs will file what they need to file and they will get the remedy they are entitled to, or if they have some proposal for how to remediate, we will address that.

I appreciate you presenting it to me. I don't think there is anything for me to do today. If -- Ms. Jung, again, if the Plaintiffs reach a point where they either feel they are not getting the transparency that they need or they have gotten the transparency they need and they think they are entitled to another remedy, please raise it and bring it before the Court.

Ms. Jung, I shouldn't have cut you off and not let you respond before $I$ said that. Please go ahead.

MS. JUNG: No problem, your Honor. I actually am just a little confused as to what Mr. Shortnacy just represented. Is he indicating that their previous productions were not retained in accordance with their requirements?

MR. SHORTNACY: No.
MS. JUNG: I am a little confused as to what your position is. I would appreciate any clarification on that because I didn't understand it.

THE COURT: What I think I heard was there is sort of a historical tale, so stuff that was ten years old, it is destroyed after ten years, and maybe because of this litigation
we should have stopped destroying it two years ago, and we didn't. So, now we only have ten years worth of stuff, not twelve years worth of stuff, and those first two years are now gone forever.

Did I understand you correctly, Mr. Shortnacy?
MR. SHORTNACY: That is correct. The time periods are slightly different, but that is directionally correct and I think conveys the concern, and that is what we are getting our arms around right now.

What we have tried to do is focus as best we can, sort of running parallel tracks, which is provide notice to the Plaintiffs to let them know, you know, continue to investigate this issue, but also press full steam ahead getting the Plaintiffs the products that they want because the things that are in existence today are the things they can test.

That is something that we have been, again in parallel, very focused on with your Honor and with Plaintiffs, but that is correct.

THE COURT: Okay. Ms. Jung.
MS. JUNG: Thank you for that clarification, Mr.
Shortnacy.

With respect to any spoliation, are you saying that you provided that information on September 11th to the Plaintiffs?

MR. SHORTNACY: Correct. I wouldn't call it

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spoliation, $I$ think that is a legal conclusion, of course, but that was in our notice that you attached as Exhibit A to the PTO submission.

THE COURT: What I am going to do is, I don't think this is something we ought to flesh out in an open hearing with everybody else here. We are spending a lot other people's time and money. This is an issue the parties should continue to discuss. If you need to get the special master involved to facilitate, feel free, but it sounds like it is what it is. What is not there isn't there.

BI should tell the Plaintiffs what is not there any more, and as we did in the other situation, there may be some limited exchange of information about how this happened and who is responsible. Again, there is a process there, I expect the parties to follow the process and we will let it play its way out. Thank you.

While $I$ have you -- before $I$ ask, anything else, Mr. Shortnacy?

MR. SHORTNACY: No, your Honor, thank you.

THE COURT: Ms. Sharpe, same question to you, any other issues you wanted to raise today?

MS. SHARPE: Nothing further, your Honor, thank you.

THE COURT: I have one, and candidly, neither of you may be able to answer this, and that's perfectly fine. If I can short circuit something, I will.

Judge Rosenberg forwarded to me a motion that Sanofi had filed relating to Letters Rogatory to, I believe it's a doctor or a scientist of some kind in Canada, and the conferral aspect of the motion indicated it had been provided to Plaintiffs' counsel, Plaintiffs' lead counsel hadn't yet had time to review it and to form an opinion as to whether they would oppose the request for Letters Rogatory.

Ms. Jung, or if you want to throw the ball to somebody else who is on this call, do you know if the Plaintiffs have arrived at a position as to whether they agree, don't agree? If they want more time to think about it, that is fine, but if there is a resolution that is easy, I would like to deal with it.

MS. JUNG: Your Honor, if there is someone else on the Zoom that would like to jump in on this, my lane has been squarely the product issue, so I am afraid I cannot answer that question.

THE COURT: Okay.
MR. McGLAMRY: Your Honor, this is Mike McGlamry. I am not on the screen because $I$ am not properly suited up.

THE COURT: That's all right.
MR. McGLAMRY: Can you ask that question again,
because I have had discussions about this issue.
THE COURT: It is very simple, Mr. McGlamry, and if the answer to the question is, we are not there yet, that is
perfectly fine.
I saw that Sanofi filed a request for the court to issue Letters Rogatory relating to a gentleman in Canada who I believe may have been the original source of the referral to Valisure, and it indicated in the motion that the Plaintiffs filed that they had notified Plaintiffs' lead counsel that they were going to make this request; that Plaintiffs lead counsel hadn't, as of the filing of the motion, had time to consult and review it and had not taken a position on it.

My only question is, if you have now had that process and your position is we don't oppose it, $I$ will grant it. If your position is we need more time to think about it, that's perfectly fine and $I$ will let you file whatever you want to file.

MR. MCGLAMRY: Thank you, your Honor, again, Mike McGlamry. I would ask for a little more time. Just to put it in context, this was originally brought to us, $I$ don't know, maybe a month ago, and we said, look, we think this is way too broad and it is overreaching and all of that, however, you all need to contact, under the local rule, the attorney for who you are asking this for, including Valisure, because otherwise it may appear as if we do not oppose the request, which we do because we think they are too broad.

However, I think then -- $I$ know then, at least I believe they had conversations with the attorneys for this

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individual and maybe Valisure as well, but we had not actually seen the motion before it got filed. So, yes, we would like a little more time.

THE COURT: No problem. Just for your information, it does indicate as well that they conferred with counsel, I think for the individual, and that they oppose it. Again, that is fine, you review it, you will file a response within the time required by the rules, and $I$ will address it as I need to.

That is fine. I just thought if there was no disagreement, I would deal with it now, but it sounds like I can't and that's perfectly fine.

MR. MCGLAMRY: Your Honor, maybe we have no
disagreement, but let us have a chance to look at it.
THE COURT: No problem. Thank you very much, Mr.
McGlamry, for stepping in.
MR. MCGLAMRY: Thank you, your Honor.
THE COURT: With that, then, I think we have addressed all of the issues the parties had and I thank the parties. I will excuse everyone and have a good day.

MR. SHORTNACY: Thank you, your Honor.
MS. JUNG: Thank you, your Honor.
MS. SHARPE: Thank you, your Honor.
(Thereupon, the hearing was concluded.)


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