

1 UNITED STATES DISTRICT COURT
2 SOUTHERN DISTRICT OF FLORIDA
3 WEST PALM BEACH DIVISION

4 CASE NO. 20-md-02924-ROSENBERG

5 **IN RE: ZANTAC (RANITIDINE)** .
6 **PRODUCTS LIABILITY** . West Palm Beach, FL
7 **LITIGATION.** . September 23, 2021
8 .
9 .

10 DISCOVERY CONFERENCE (through Zoom)
11 BEFORE THE HONORABLE BRUCE REINHART
12 UNITED STATES MAGISTRATE JUDGE

13 FOR THE PLAINTIFFS:

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Official Court Reporter: Pauline A. Stipes
HON. ROBIN L. ROSENBERG
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1 *THE COURT:* Good morning, everybody. This is case
2 number 29 -- I'm sorry, 20-md-02924, In re: Zantac
3 (Ranitidine) Product Liability Litigation.

4 We are just here today for a brief status conference
5 as a followup to the hearing that we had last week. I had
6 ordered some productions. I am going to be unavailable
7 tomorrow, and I didn't want the weekend to hit us and have
8 loose ends that I needed to get involved with.

9 So, this just for purposes of getting everyone
10 together really quickly and hopefully find out that everything
11 is on target for where it should be, and if things are off
12 target, to help you get things moving.

13 With that, who is representing the Plaintiffs here
14 this morning for purposes of the hearing?

15 *MS. JUNG:* Good morning, your Honor, this is Je Yon
16 Jung and I am representing the Plaintiffs.

17 *THE COURT:* Good morning, Ms. Jung. And on behalf of
18 Boehringer Ingelheim?

19 *MR. SHORTNACY:* Good morning, your Honor, Michael
20 Shortnacy of King & Spalding for Boehringer.

21 *THE COURT:* Good morning. And on behalf of Sanofi?

22 *MR. BEROUKHIM:* Good morning, your Honor, Alex
23 Beroukhim of Arnold & Porter for Sanofi. The video is now up
24 and I really appreciate your cooperation and patience.

25 *THE COURT:* No problem. I appreciate your tenacity.

1 I understand you are in Brussels right now, so thank you for
2 Zooming in with us.

3 *MR. BEROUKHIM:* I am, your Honor, thank you.

4 *THE COURT:* And who do I have for GSK?

5 *MR. SACHSE:* Good morning, your Honor, Will Sachse for
6 GSK.

7 *THE COURT:* You do not appear to be in Brussels.

8 *MR. SACHSE:* I am in Philly, dreary Philly.

9 *THE COURT:* Okay. Ms. Jung, is there any issue with
10 Pfizer that we need to have them appear?

11 *MS. JUNG:* No, your Honor, my understanding is they
12 have no product.

13 *THE COURT:* Okay. Lucky them. So we just have the
14 three.

15 All right. So, as I said, this is hopefully a brief
16 status report. Ms. Jung, let me turn to you and if you can let
17 me know from the Plaintiffs' perspective where we are and if
18 there is anything that you feel the Court needs to get involved
19 with.

20 *MS. JUNG:* Thank you very much, your Honor. Sure. I
21 appreciate the opportunity to give an update and to make sure
22 that things don't slip as they sometimes do. We appreciate the
23 order that you issued on September 13th, as well as the
24 supplemental order for BI on September 15th.

25 Since then, we have been receiving product from the

1 Defendants. We have had a few issues regarding inventory
2 errors that the Defendants had regarding their initial
3 productions and representations to us, so we have had to pivot
4 and deal with those, but we have been dealing with those as
5 best we can, and there were some labeling issues where they
6 were going to incorrect individuals that were never named by
7 the Plaintiffs, but they, fortunately, did eventually get to
8 us.

9 So, despite those types of things, we have been
10 receiving product. We are still receiving some product from
11 GSK by the end of this week, as your Honor ordered, and we are
12 still going through all of the inventory to confirm the
13 receipt.

14 We do have an issue with the fact that all the
15 production of the product from all of the three Defendants did
16 not come with any chain of custody as previously agreed and
17 discussed, so none of the product has chain of custody. I have
18 made several requests for that chain of custody information, so
19 that when we receive it we can properly continue that chain of
20 custody on the product, but we have not been able to get any of
21 that.

22 We got some dates of potential delivery after this was
23 placed on the calendar before your Honor, so that is right now,
24 I think, the primary issue for us, is making sure that we get
25 the rest of the product, as well as the necessary documentation

1 relate thereto. So, that's where we are at this point.

2 One other issue, your Honor. For BI in particular, we
3 received new inventory disclosures from BI on September 11th,
4 the Saturday before your Honor's last PTO 32 hearing on Monday,
5 the 13th. We were surprised at how much inventory was
6 disclosed of retained product and we made our selections on
7 September 15th, made a request to promptly include that in the
8 productions that Your Honor had ordered, and we could not get a
9 date or a confirmation as to when and if we could receive the
10 product.

11 When this was placed on your Honor's calendar, we
12 received some emails saying that they anticipate being able to
13 produce them to us, but we did not get a confirmation on that
14 yet.

15 That is important as well because that is product that
16 we would assume would be part of the orders that your Honor had
17 made regarding their production. So, we would like to ensure
18 that those get to us as promptly as possible along with the
19 chain of custody. I think that is it.

20 *THE COURT:* All right. There is some what I would
21 have expected in a production of this magnitude and under this
22 timeframe, there are some inventory errors, there are some
23 labeling errors, but I assume the parties are going to work
24 through those and clean that up relatively quickly.

25 Chain of custody documents are an issue, and these

1 additional retained products, you want a deadline for the
2 production of those from BI. Is that correct, Ms. Jung?

3 *MS. JUNG:* Yes, your Honor.

4 *THE COURT:* Two other questions then. Understanding
5 everything you just told me, have your experts at least been
6 able to get started in doing whatever they are going to do?

7 *MS. JUNG:* Yes, your Honor. Thank you.

8 *THE COURT:* Understanding they are not going to be
9 able to do everything, but there is at least progress being
10 made?

11 *MS. JUNG:* Yes, your Honor.

12 *THE COURT:* Great. Explain to me in more detail the
13 significance of the chain of custody documents. Is the issue
14 that you are going to have your experts do something, the
15 expert is going to generate a report, and then at the end, you
16 don't want to be sitting in a situation where the brands come
17 back and say, well, actually the product you used was somehow
18 adulterated and it is your fault, and therefore your testing is
19 invalid, and that is why you want to make sure that you have at
20 least -- why does the chain of custody matter?

21 If it was adulterated in their hands and they still
22 gave it to you, who are they to complain, I guess is my
23 question.

24 *MS. JUNG:* I think that is a really good point, your
25 Honor. I think that future admissibility issues and

1 evidentiary issues are important because, of course, we want
2 that information and evidence ultimately to not have these
3 chain of custody issues.

4 I think also importantly that if -- there is a chain
5 of custody that was supposed to come with all the products that
6 they are producing. If there are major issues or errors or
7 problems with the product that they did produce regarding no
8 chain of custody, then we would actually seek alternative
9 production or -- immediately, as soon as we learn of the chain
10 of custody history of the particular product.

11 So, I think that is of the more immediate issues and
12 concerns regarding the chain of custody, is that if there are
13 some issues and problems we would like to quickly ask for
14 alternative product. Yes, evidentiary, and ultimately we do
15 want to make sure that any potential arguments that they
16 undoubtedly will make regarding chain of custody and
17 admissibility, that we have it from the time that it leaves
18 their hands into ours as well.

19 *THE COURT:* I understand. This is the first I am
20 hearing of chain of custody. Maybe you all have been talking
21 about it. This was never presented to me in the prior hearing,
22 so this is the first time I am hearing of it. All right. I
23 appreciate that is the Plaintiffs' perspective on what they
24 want, what they need.

25 Mr. Shortnacy, just because alphabetically BI comes

1 first, let me hear from you first.

2 MR. SHORTNACY: Thank you, your Honor, Michael
3 Shortnacy speaking.

4 Just to report, when BI -- the Promeco affiliate was
5 able to effect the delivery of the prior product on September
6 17th, ahead of the Court's scheduled order date, and Ms. Jung
7 is right, we did disclose the existence of these regulatory
8 retains that are being held at Promeco. Those retains are, of
9 course, being subject to FDA regulations. The companies keep
10 them in the event there is an issue in the future and there are
11 specified time periods for retention.

12 We have been exploring with regulatory counsel those
13 issues, and what we wanted to do is to provide the information
14 to Plaintiffs so that they could make selections. They did do
15 that for us, we have that. We are in the process -- BI is in
16 the process of working with its affiliates to navigate some of
17 those regulatory issues to be able to ensure that we are able
18 to provide the products that Plaintiffs requested.

19 Your Honor, we took to heart the last go-rounds, and
20 have been working with the affiliate to sort of prepare for the
21 eventuality of shipment in the event that we can work through
22 these regulatory issues, and then everything will be cleared
23 from that perspective.

24 So, in parallel, we are working with the Customs
25 broker and sort of lining up all of the planes and trains, or I

1 guess in this case airplanes, to get the product where it needs
2 to go, assuming, again, we can navigate those issues. So, we
3 are working very hard to work on those two parallel tracks to
4 get the items available to Plaintiffs.

5 *THE COURT:* Just so I understand, when you say the
6 regulatory retain, flesh that out for me a little more. Does
7 that mean that, as a manufacturer of an FDA approved product,
8 you have to keep certain samples so that if the FDA ever comes
9 in and wants to see what came out of batch 712 on July 3rd, you
10 have to have a sample somewhere of that?

11 You have retained those, and you are required by law
12 to retain those for some period of time, but now the Plaintiffs
13 are asking for a sample of the sample, and that is what you
14 have to work through with regulatory counsel, how much do you
15 have to keep and can you keep enough and still give the
16 Plaintiffs what they want.

17 Am I interpolating that correctly?

18 *MR. SHORTNACY:* You are, your Honor, and you have
19 probably done it better than I could, as I would caveat that I
20 am not a regulatory lawyer and that I am reporting to the Court
21 my understanding, but that is correct. I think you
22 encapsulated it effectively. Those are the traps that we are
23 running at this point.

24 *THE COURT:* To bring it back to the world that you, by
25 choice or otherwise, have to live in right now, you are not

1 objecting to giving them those samples, assuming that your
2 regulatory counsel says, if we give it to them, we are still in
3 compliance with what the FDA requires us to do, and we are not
4 violating FDA regulations if we now take 4 grams out of our
5 vial and give those 4 grams to the Plaintiffs, we are still
6 above whatever threshold we are required.

7 *MR. SHORTNACY:* That's correct.

8 *THE COURT:* It is just figuring out the answer to that
9 question and then the logistics of production.

10 *MR. SHORTNACY:* Correct. I would also add, there are
11 complications with respect to those issues, with respect to the
12 regulations. Also, we have to navigate, you know, arrangements
13 and agreements between affiliates and third parties. So, we
14 have a couple of additional hurdles to clear through the
15 regulatory counsel, but that is right.

16 *THE COURT:* Okay. I understand the second half is a
17 logistics question. The first half seems to me to be a legal
18 question.

19 If your position becomes in order for us to give the
20 Plaintiffs what they want we have to then violate an FDA
21 regulation or an FDA requirement, I can see where that would
22 present a problem for you. Am I correct, I am bifurcating into
23 two questions, one is legal and one is logistical?

24 *MR. SHORTNACY:* That is correct, and there are also
25 contractual arrangements that would need to be navigated as

1 well that are not regulatory in nature, but just the product
2 itself. We would need to ensure we are in compliance with
3 various agreements.

4 *THE COURT:* Okay. I understand where you are coming
5 from in that regard. If I could ask, Mr. Shortnacy, the other
6 thing is, Ms. Jung referred to them as retained product, so I
7 will use that term to refer to what you just told me, what I'll
8 call the FDA holdbacks or the retained products.

9 This is all Ranitidine, so you have already provided
10 them samples of other batches of the same product, or is this a
11 different product completely? It's a different product because
12 it is produced on a different day in a different batch, but is
13 it a totally different product or is it simply a parallel batch
14 of Ranitidine produced on a different day?

15 *MR. SHORTNACY:* My understanding is that it's parallel
16 and in addition to. So, we had previously provided Plaintiffs
17 with both API and finished tablets. These retains would also
18 be more API and would be finished tablets in packaging, and I
19 suppose in that respect it is slightly different from the prior
20 shipment, which was loose tablets, but they are all the same
21 product of Zantac and Ranitidine.

22 *THE COURT:* Okay, I understand. Okay.

23 Ms. Jung, if it is okay with you, let me hear from all
24 three brands and then I will allow you to respond to everybody
25 at once rather than doing this piecemeal, just in the event

1 there is overlapping issues, you can respond to everything at
2 once.

3 Mr. Sachse, alphabetically GSK is next up, let me hear
4 from you. I understand you have until tomorrow to produce some
5 other things, so you may still be in process.

6 MR. SACHSE: We do. I guess this is the third leg of
7 what I hope to be a trilogy of hearings about retained product,
8 but we will see. Maybe there will be a part four as well.

9 So, we are on track. The API, which is coming from
10 Singapore, was put on a KLM flight routed through Amsterdam on
11 Monday, and I believe it actually might get there today in San
12 Francisco, and that was the biggest lift for us, to get the 245
13 samples packed up and sent over.

14 Otherwise, as Ms. Jung alluded to or said, we have had
15 a few hiccups in terms of we thought we had certain types of
16 product, inventory, it turned out we didn't have it, but we
17 have worked through that, I think, with counsel. I don't think
18 there are any remaining issues there.

19 The only other issue we had in terms of providing
20 product is that we had some injection ampules coming from
21 Parma, Italy, and given the time constraints, we were having
22 trouble finding a carrier who could ship these under the
23 controlled conditions that the Plaintiffs put into their
24 instructions.

25 So, I communicated that issue to the Plaintiffs and

1 said we can either wait and see if we can get a solution, or we
2 can ship ambient, and given the deadline -- and actually this
3 was happening earlier this week, right on the day of the
4 earlier deadline for finished product -- we made the decision
5 to ship under ambient conditions. So, I think hopefully they
6 already have that product, I am not sure. I haven't heard
7 anything to the contrary. But that will complete our product
8 sample provision to the Plaintiffs.

9 And just on that point about the Parma samples, I want
10 to segue into the chain of custody issue.

11 So, our perspective on chain of custody is, first of
12 all, we never had an agreement on chain of custody because that
13 was tied up with discussions we were having about the testing
14 protocol and the sample protocol generally. Plaintiffs did not
15 agree to that protocol, as you know, and we were litigating
16 these issues.

17 What they are terming chain of custody is like going
18 back to the beginning of time with the first molecule of Zantac
19 and then kind of following it all the way through the
20 manufacturing process to today. That is something that --
21 frankly, if that is what they want, that, to me, seems like a
22 discovery request. That is not something that we should be
23 doing informally.

24 The information that they have, and the information we
25 have given them and we have agreed to give them is sort of

1 two-fold. One is, they know all of the locations from which
2 the product was shipped. They know whether it was kept in
3 controlled conditions or whether it was returns or kept in what
4 we call ambient conditions, and as I referenced with Parma,
5 when we had an issue, for example with Parma, we told them we
6 are deviating from the shipping instructions, this is the way
7 we are deviating from the shipping instructions.

8 So, in terms of the chain of custody that I hear
9 matters here, which is we want to make sure that you are not
10 going to later on say there was something that happened during
11 the transit of this product from point A or from GSK to Emory,
12 they have all of that information. So, there is really nothing
13 more to be done on that front.

14 So that is kind of, I think, where we are on this. I
15 think it is, frankly, a bit of a nonissue.

16 *THE COURT:* Okay. As to chain of custody, what I hear
17 you saying is, you are breaking it temporally into two phases.
18 One is what happened up until the day that we shipped it to
19 you -- what happened when we had it, or maybe we sent it, and
20 it was returned by a customer, but -- there is that period of
21 time, and then there is, okay, the judge ordered us to give it
22 to you, here is how we got it to you, and these are the
23 conditions under which it went to you, and now you've got it,
24 and from here forward it is your thing.

25 Your position is they got the second half, and the

1 first half doesn't matter. They should just take -- if they
2 want more than that they should do it a different way?

3 MR. SACHSE: Yes, I think that is basically right, and
4 really what I am saying is -- I think the example given earlier
5 is, well, if there is something, quote, wrong with the product
6 before it even left GSK's hands, they don't want to be
7 blindsided by that.

8 I am putting them on notice right now, and I did at
9 the earlier hearing, we are absolutely going to say that all of
10 the product that left GSK's control and then came back, all
11 those returns, we are absolutely going to say we have no idea
12 about chain of custody and that is a fatal flaw in the testing
13 of that product. It renders it unreliable.

14 So, I don't think there are any surprises there, but
15 there is also nothing more we can do to true up or sort of
16 trace out chain of custody.

17 For the products that they have that were in our
18 stock, that were in our inventory, they have batch numbers, and
19 they also have from previous discovery -- they could do the
20 work, they could go through and they could look at date of
21 manufacture, date of expiry.

22 In fact, I think they have that information already,
23 and they could go back to our records from the Jurong facility
24 and they could actually look at, you know, did it pass, here
25 are all the tests that were done, here are all the pictures.

1 They have all of that.

2 So, I don't think there is anything more that would be
3 really relevant or proportional that we could do, but if they
4 want to get more information, they can make that request and
5 then we can kind of look at it and take it in due course.

6 *THE COURT:* I understand your position on that.

7 Mr. Shortnacy, I raised that issue after you were done
8 and I forgot to ask you about chain of custody. Do you want to
9 adopt or add anything to what Mr. Sachse said?

10 *MR. SHORTNACY:* I would adopt that, I think that's
11 right. One slight addition to that is that BI is prepared to
12 provide what I think is perhaps the possession piece of the
13 puzzle in terms of where the API is sourced, in this case the
14 supplier in Spain coming into Vera Cruz, to the port.

15 We sort of worked out information provided to them and
16 the products are manufactured in Promeco and so it goes from us
17 to the shipper, and that chain of custody is very clear from
18 the shipping records.

19 So, I think that from the possession perspective, I
20 think that we are in agreement to provide that information. As
21 Mr. Sachse said, the remainder is sort of a discovery question,
22 which is these sort of variances and conditions and things.
23 Again, some of this information I think they do have from
24 responses to interrogatories and other sources, including the
25 batch records that we have produced to them.

1 But that having been said, I think that we have
2 prepared to provide the possession piece of it by tomorrow to
3 the Plaintiffs.

4 *THE COURT:* Thank you.

5 *MR. SHORTNACY:* What we believe is the chain of
6 custody.

7 *THE COURT:* I understand.

8 Let me turn to Mr. Beroukhim on behalf of Sanofi.

9 *MR. BEROUKHIM:* Thank you, your Honor. I will adopt
10 what Mr. Sachse said about the chain of custody as well. We
11 are prepared to give Plaintiffs a form that they wanted us to
12 use that -- we are basically going to be referencing documents
13 that we have already provided to them that will give them much
14 of the information they are seeking in those chains of custody.

15 I agree with what Mr. Sachse said with respect to
16 there is over 150 samples of recalled return product they have
17 asked for. We have no idea what happened to them after they
18 left our control and went into the distribution channels, and
19 they were returned to us and being held at a recall vendor.

20 There are four categories of samples they have asked
21 for from us, and during meet and confers we have told them
22 already they have all of the information they are seeking
23 already. We have told them how those products have been
24 maintained immediately before shipping.

25 There are no surprises here and I am willing to create

1 a form that just regurgitates information that I think
2 Plaintiffs already have, so there should be no surprises to
3 them about that at all.

4 With respect to the samples the Plaintiffs selected
5 and your Honor ordered us to produce, we met the Court's
6 deadline and we produced all the samples by the deadline your
7 Honor asked us to do so, and we have been working diligently to
8 get this documentation to them. I just didn't understand the
9 urgency given the Plaintiffs already have all of the
10 information they are asking for.

11 *THE COURT:* Thank you very much. Ms. Jung, you have
12 been very patient, let me allow you to respond.

13 *MS. JUNG:* Thank you, your Honor. First I will start
14 off with BI's position and your questions to Mr. Shortnacy
15 regarding the type of retained FDA products that are at issue.

16 To put it a little bit into perspective, again, we
17 went over months trying to get the inventory that they had, and
18 what they gave to us that we selected from before your hearing
19 on August 26th, quite frankly, was 29 lines of product, four of
20 which were finished goods, the rest were API. We selected from
21 that, and that is what we have been receiving from BI.

22 On September 11th, they disclosed hundreds of product,
23 API and finished dose, that -- our understanding is that it is
24 actually well above the FDA regulatory retained requirements
25 for those batches. They are not the same as what they

1 disclosed previously. There are substantial amounts of
2 unexpired retained product that are listed, there are
3 substantial numbers of finished dose tablets that are disclosed
4 in various milligrams.

5 So, again, it is very different, and much to our
6 surprise, significantly more information and more product. So
7 I will say that regarding the FDA retains and why it is so
8 important for us to continue to receive those in an expedited
9 fashion. Had they been disclosed months ago when we asked for
10 those disclosures, they would have been included in your
11 Honor's orders.

12 Secondly, on the chain of custody issue, I want to
13 first start with Mr. Shortnacy and Beroukhim for BI and Sanofi
14 first because they are in a bit of a different position
15 because, if you will recall, your Honor, before the first PTO
16 of our triumvirate of PTOs hearings here, before August 26th,
17 they at the very last minutes before agreed to a protocol that
18 included an extensive chain of custody form that they insisted
19 upon and what they issued as a condition precedent to even
20 giving us the product, causing us months of delays at that
21 time.

22 As a result, they attached a chain of custody form
23 that they wanted, there are very detailed provisions, which the
24 special master is very well aware of as well, that includes
25 their obligation to produce the storage conditions, the

1 manufacture dates of the API, the manufacture dates of the
2 finished dose. All of that was done within this agreement that
3 we agreed to in order to take them off the PTO hearing on
4 August 26th with your Honor.

5 That is why it is important that Sanofi and BI, while
6 they vigorously agree with what Mr. Sachse says, they are in a
7 bit of a different position because we would have addressed all
8 this back then.

9 *THE COURT:* Let me ask you, Ms. Jung, as to --
10 obviously if it was resolved before it ever came to me, I
11 wasn't part of the negotiations, I don't know the arrangements
12 or anything that was said.

13 Let me ask you, your understanding of what they agreed
14 to produce -- I am going to use Mr. Sachse's framework for
15 discussion purposes. Maybe it is a two by two matrix, maybe.
16 There are things -- what happened before you shipped it to me,
17 what happened after you shipped it to me and before we shipped
18 it to you, did it ever leave our possession or not. It seems
19 to me those are the four boxes that the brands are creating
20 here.

21 What they are saying is, as to stuff that we shipped
22 out to, I don't know, Cardinal Health, Walgreens, all the
23 former Defendants in this case, we don't know what they did
24 with it. We just know they sent it back to us, and there is no
25 way for us to reconstruct what they did with it. The

1 Plaintiffs know that and they will deal with it as they want.

2 Anyway, that is sort of the framework that I am seeing
3 develop here.

4 So, what was the agreement you understood you had as
5 to which of those four boxes they were going to provide
6 information about? Obviously how they sent it to you now, what
7 conditions it was in right before they sent it to you, I think
8 nobody is disputing you are going to get that.

9 I guess the question is: What is your understanding
10 of how far back they agreed to go in terms of the chain of
11 custody for the retained product?

12 *MS. JUNG:* I am happy to provide that information.
13 They actually agreed to the manufacturing date of the API that
14 was used, all the information that they have in their custody,
15 possession and control. So, of course anything that they know
16 was sent to the customer and sent back to them, we understand
17 that there is a chain of custody break there that they won't
18 know, but before they sent it out, they know what that chain of
19 custody is, and that was specifically included, the storage
20 conditions, the manufacturing date.

21 We listed them all and I am happy to share that
22 paragraph or even the entire agreement with you.

23 *THE COURT:* I don't know that I need to do that. Let
24 me make sure I am understanding the terminology and we are all
25 talking about the same thing here.

1 When I think of a chain of custody I think of a single
2 item that hasn't been changed and where has it been. The gun
3 was recovered at the crime scene, it went here, it went there,
4 it went into the evidence locker, deputy X signed it out, he
5 gave it to deputy Y, and now it is here in the courtroom.
6 That, to me, is kind of a classic traditional chain of custody.

7 Here you have API that was manufactured in, I don't
8 know, Bangalore, it was then shipped to Mexico, where it was
9 then put through some manufacturing process. At the end, some
10 product spit out, that was then sent somewhere else to be
11 compressed into pills or put into packaging. It was sent
12 somewhere else to be wrapped up in a nice box and then it was
13 shipped to Wal-Mart.

14 How much of that -- do you want all of that, like
15 every step of the process all the way through? Help me out
16 understanding what it is you want, and I will ask the other
17 side what is it they are objecting to giving you, given what
18 you want.

19 *MS. JUNG:* Sure, your Honor. You are right on that
20 typical chain of custody in the criminal evidentiary process.
21 For this in particular, all that you just went through up until
22 the point that they ship it to Wal-Mart is all within their
23 custody, control, and possession.

24 They are the ones that order the API, they are the
25 ones that receive it, they are the ones that send it off, if

1 they do send it off to someone else for a finished dose. At
2 all times they are the principal involved with that product.

3 So, what all we seek is everything that they are the
4 ones that are responsible, and the ones that ordered the API,
5 the ones that receive the API, the ones that actually made the
6 finished dose product, those are all things within their
7 possession, custody, and control.

8 That is the piece where we are asking for -- again,
9 this was specifically agreed to and those details are in the
10 agreements we had with them with respect to that product.

11 *THE COURT:* I haven't seen the agreement, I don't know
12 the agreement, so it is not appropriate for me to opine on that
13 right now.

14 I also have some recollection of ruling on an issue
15 like this. Someone was manufacturing something in Germany or
16 Austria, somewhere in eastern Europe, and we had a hearing
17 about how far back they had to go, and I ordered they had to
18 produce as to only product that was actually shipped into the
19 United States, and whether they had to -- is this Greek to
20 everybody? I have some recollection of having a hearing about
21 that.

22 *MR. SHORTNACY:* I don't recall that.

23 *THE COURT:* I will go back and look through my notes
24 as well, but we had a hearing and there was an issue as to
25 whether one Defendant had to produce records of API and other

1 manufacturing processes for product that never came into the
2 United States.

3 I don't remember, maybe I am wrong.

4 *MR. SACHSE:* Your Honor, that was an issue that I
5 raised as part of the August 26th, part one of the trilogy or
6 triumvirate. I don't think there was actually a ruling per se.
7 It might have been a generic manufacturer.

8 *THE COURT:* All right. It was long ago, so maybe it
9 was one of the generics, so never mind that issue.

10 I understand, Ms. Jung, what your ask is in that
11 regard, but I cut you off from other points you were going to
12 make and I apologize for that. Please continue.

13 *MS. JUNG:* No problem, your Honor. That is
14 essentially it, and again, we understand the bucket of product
15 that was sent out, but there is plenty of product that BI and
16 Sanofi had retained the whole time and had not been customer
17 returned, that they had custody and control over the entire
18 time.

19 Then, with respect to GSK, we understand that the
20 issues regarding kind of go back and look for this information
21 in your discovery, for us, the fact that we have an order where
22 you have ordered for them to produce particular product and for
23 us, to tell us to go and look for it, we have actually tried
24 and the information that they have given to us is very limited.
25 We cannot go and find the sequence of batch numbers in the

1 documents that they have given to us.

2 So, given that, again, in GSK's own PTO submission in
3 August where they indicate, and he has conceded here, that the
4 chain of custody is important, they indicated in their PTO
5 submission that "GSK cannot detail chain of custody or storage
6 conditions of product once it left GSK's control." We
7 understand that, but before it left GSK's control, that is the
8 piece that I think is important that even GSK acknowledged.

9 For all those reasons, we think that Plaintiffs are
10 seeking this information that they have on the product they are
11 giving to us, telling us to go look at a million pages of
12 documents to try to find what matches with the particular
13 product they gave to us I think is not reasonable or fair in
14 the scheme of things, but that's the response I have regarding
15 GSK, your Honor.

16 *THE COURT:* That's fine. If I could slice this one
17 other way, Ms. Jung, and try to clarify.

18 It seems to me there are two components to what you
19 are asking for, and I am going to use the following terms: One
20 is product tracing, who had it and how long did they have it,
21 and perhaps where did they have it. So it was in a warehouse
22 held by some freight forwarder in Singapore from day A to day
23 Z, kind of who had it and where was it product tracing.

24 Conditions of confinement or conditions of retention
25 seems to me to be a different question. How did that freight

1 forwarder keep it, did they keep it in a hot room, a cold room,
2 was it refrigerated or not. Are you asking for both the
3 product tracing and the conditions under which it was retained,
4 or just one or the other?

5 *MS. JUNG:* We would like both, your Honor.

6 *THE COURT:* All right. Thank you. Having clarified
7 that with the Plaintiffs, let me go back to the Defendants, and
8 I will start again with Mr. Shortnacy.

9 So, do you object -- maybe you want to speak as to
10 your understanding of what the agreement was, but again, since
11 I wasn't there, I don't think this is the right setting for me
12 to rule on whether there has been an agreement and who agreed
13 to what. I think I have to give the parties a more expansive
14 opportunity to flesh that out if the Plaintiffs are essentially
15 asking me to enforce an agreement that was made. Put that
16 aside.

17 I did hear you say, Mr. Shortnacy, and I think Mr.
18 Beroukhim as well, you are willing to provide certain
19 information, perhaps even to point the Plaintiffs to the other
20 particular discovery that you believe will give them the
21 information that they are asking for.

22 Can you help me understand how that fits into the
23 framework that I have been discussing with Ms. Jung about
24 timeframes and product tracing and conditions and all that?

25 *MR. SHORTNACY:* Sure, I'm happy to do that, your

1 Honor. With respect to the product tracing elements for BI,
2 and specifically the Promeco facility which had possession of
3 the product -- and when I speak of product I mean both the API
4 that shipped from Spain to Mexico and then used in the
5 manufacturing process at Promeco to then ship tablets out for
6 packaging, obviously when the product is being sold.

7 We are prepared to provide that information, and as I
8 said before, we had indicated to Ms. Jung that we would try to
9 provide that by tomorrow.

10 I will take your Honor's offer to not get into the
11 specifics of all of the agreements. I will only say that what
12 we are trying to use is the form -- there was a form that was
13 back and forth between the parties during that time period of
14 negotiation that did list some of the things that Ms. Jung had
15 mentioned, the date of manufacture, the source of the API,
16 which for us is Spain. So, it identifies in a table each of
17 the specific batches shipped that were shipped as samples to
18 Emory Pharma, and the specific data points I think that
19 Ms. Jung identified, and that is in the chart.

20 When it gets into if it was in a warehouse or it was
21 shipped by sea in 2016 or something, and what were the specific
22 conditions and all of that, that is a more difficult question.
23 It is sort of outside of what I view is kind of the possession
24 piece of the matrix that your Honor was describing.

25 So, if it is the lineage of the product that we

1 shipped as samples for this litigation and providing dates of
2 manufacture and those specific sort of objective data points,
3 we are prepared to do that.

4 *THE COURT:* As I understand, BI has a short product
5 tracing trail, basically Spain manufactures the API, Spain
6 ships it to Mexico and Mexico manufactures the finished
7 product. So you have a short chain.

8 *MR. SHORTNACY:* That is correct, your Honor, and no
9 returns. So, unlike others, there is no issue, for these
10 samples, of retailers shipping things back or customers, or
11 anything else. There is no complicating factor in that regard.

12 *THE COURT:* Okay. So, I am going to order BI to
13 produce the information that sounds like you are agreeing to
14 produce in terms of the what I call product tracing. I am
15 reserving right now on conditions, but product tracing, you say
16 you think you can get that information by tomorrow. I will
17 order you to do that.

18 We will circle back. I understand there is an open
19 question with BI as to what I will call the newly disclosed. I
20 don't mean that derogatorily, but the newly disclosed or
21 regulatory related matters.

22 Remind me, Mr. Shortnacy and Ms. Jung, I have put that
23 one to the side. I understand that has to be resolved before
24 we are done today.

25 Let me go back to Ms. Jung. I put aside conditions

1 for a second, and I put aside the issue of what I will call the
2 regulatory retained product.

3 Is there anything else with BI that you think is still
4 out there, Ms. Jung?

5 *MS. JUNG:* No, your Honor.

6 *THE COURT:* Okay. These are the two issues left for
7 BI. I am just trying to narrow the scope as we go through the
8 hearing.

9 Let me go to Mr. Beroukhim, the same questions to you
10 that I put to Mr. Shortnacy. It sounded to me in your earlier
11 remarks that you weren't objecting to providing the product
12 tracing information that I have discussed, but that your
13 objection was, again, to providing information about the
14 conditions under which the product was retained by each of
15 these steps in the process?

16 You are on mute, Mr. Beroukhim.

17 *MR. BEROUKHIM:* Sorry, your Honor. Um-m-m, what we
18 are prepared to do, your Honor, is provide the information that
19 is requested in the form, however, we think the Plaintiffs have
20 much of that information, and we are willing to provide it in
21 a -- in a form that refers them to other documents they already
22 have that will give them the information they are seeking, and
23 it will be based on a category description of the types of
24 product they have asked for.

25 *THE COURT:* So, what you are talking about is

1 essentially doing akin to what the Federal Rules of Civil
2 Procedure allow you to do in an interrogatory response. I
3 think it is Rule 33(d) or 34(d). You are allowed to say the
4 answer to this interrogatory can be found on Bates numbers A,
5 B, C, D, and F, that we have already provided to you.

6 So, that is essentially, Mr. Beroukhim, what you want
7 to do? You will give them the information by pointing them to
8 stuff they already have?

9 *MR. BEROUKHIM:* Stuff they already have.

10 *THE COURT:* Okay. That seems reasonable to me. I
11 will hear from Ms. Jung in a second. That seems reasonable to
12 me, as long as it's not go look in 400 file drawers. It has to
13 be targeted, pointing them to, with reasonable specificity,
14 something that is relatively easy for them to find. I am not
15 suggesting Sanofi would play that game, but I just want to make
16 it clear that would be my expectation.

17 Is that also your understanding of how you could do
18 it, you could, with a reasonable specificity, target them into
19 what they are looking for?

20 *MR. BEROUKHIM:* I believe so, your Honor.

21 *THE COURT:* Okay. I will hear from Ms. Jung on that
22 issue in a second.

23 As far as the conditions of storage, how long was your
24 chain? Mr. Shortnacy had a nice short chain, it was just two
25 steps in the chain. Do you have a sense for Sanofi for the

1 product you produced what the chain looks like?

2 MR. BEROUKHIM: We never produced product, your Honor,
3 we had CMOs that would produce the products for us.

4 THE COURT: No, I mean product you have now produced
5 to the Plaintiffs pursuant to my order in this litigation.

6 MR. BEROUKHIM: Yes, your Honor. They came from --
7 there was one API supplier, there were two manufacturers. It
8 came to us, it got sent to a distribution center in Reno for
9 West Coast distribution, it stayed in Chattanooga for Midwest
10 and East Coast distribution, and I think Plaintiffs know all of
11 that already through meet and confers we have already had.
12 None of this is --

13 THE COURT: I don't know it, that is why I am asking
14 the question.

15 Again, it is an overseas API facility to a
16 manufacturing facility. As I recall, your manufacturing
17 facility is domestic; is that right?

18 MR. BEROUKHIM: One domestic and Promeco was the other
19 manufacturing facility.

20 THE COURT: Right. Then you would ship it into the
21 United States, you said you have two distribution centers.

22 MR. BEROUKHIM: It would all come into one
23 distribution center. Whatever was earmarked for distribution
24 on the West Coast would go to our Reno distribution center from
25 Chattanooga, and they would distribute to the Cardinals and

1 Walgreens of the world from there.

2 *THE COURT:* Okay. Again, just to make sure I
3 understand, it went API to either Promeco or the other
4 manufacturer, then everything went to Chattanooga, and then
5 some of the stuff in Chattanooga went to Reno, and then some of
6 the stuff in Chattanooga went straight out to other people.

7 *MR. BEROUKHIM:* That is my understanding, your Honor.

8 *THE COURT:* I should say once it left Chattanooga,
9 some of it stayed in your control until it got to Reno, then it
10 left your control, and some of it left your control out of
11 Chattanooga.

12 *MR. BEROUKHIM:* That is correct, your Honor.

13 *THE COURT:* Okay. I understand. All right.

14 You say the information you will provide is the
15 information requested on the form. Whose form? Which form?
16 Let's make sure the record is clear which form we are talking
17 about.

18 *MR. BEROUKHIM:* Your Honor, I don't know if -- it was
19 something that we were discussing back and forth with
20 Plaintiff, it is an exhibit to the PTO.

21 *THE COURT:* That, okay, I understand. But again, it's
22 -- okay.

23 I am going to put you aside for a second, Mr. Sachse,
24 because your issues are a little more complex than these. Let
25 me go back to Ms. Jung.

1 I am going to order BI to give you the information you
2 want by tomorrow, at least as far as product tracing. It
3 sounds to me like Sanofi is willing to give you the information
4 you want by pointing you to what you already have. It sounds
5 like maybe I'll need to work out which form they are going to
6 use. It doesn't seem to me that should be an insurmountable
7 obstacle.

8 Tell me, Ms. Jung, what is your feelings on that?

9 *MS. JUNG:* Thank you, your Honor. I think part of
10 this -- this is indicative of how we got here in the first
11 place, is that there are certain efforts of good faith and
12 trying to meet and confer and try to work things out with
13 Defendants and get things done without having to involve your
14 Honor.

15 And then we find ourselves weeks behind because we get
16 representations and agreements to take things off of PTOs
17 because they agree to provide detailed information, including
18 storage conditions and locations as a condition of removing
19 their appearance before your Honor in a PTO.

20 My frustration is that there are things that I know
21 that you want us to work out, and you rely on us to do so, and
22 we try, and then when we come here, there are things that are
23 raised as things that were never brought to your attention
24 because they were part of the things that we were working out.

25 I appreciate that you are going to give us the product

1 tracing. They agreed to more than that, and I just want to
2 reserve the right that we may want to seek enforcement of the
3 agreement that they made with us if we get less.

4 *THE COURT:* Thank you. Let me address your point.
5 Even as we sit here right now, if you think you are entitled to
6 some legal remedy based upon the fact that they told you
7 something in advance of the August 26th PTO, and then didn't do
8 whatever it is you think they were supposed to do, if you think
9 you are entitled to a legal remedy, you have every right to
10 come and ask me for it. I don't know what that might be. I am
11 not suggesting there is one.

12 The Plaintiffs are never precluded from -- whether it
13 is enforce the agreement or some other sanction, if you think
14 you are entitled to it, come and ask. Just tell me what you
15 want and why you deserve it, and if you are entitled to it, you
16 will get it.

17 Here is my sense on the conditions issue. What I am
18 hearing inferentially from the other side is, that is a
19 proportionality argument, that for us to go back and really
20 figure out what was the temperature in the Promeco facility on
21 this day, or when we shipped it by boat did the boat hit a
22 hurricane or a storm or something else, that is how they are
23 going to portray it. They are going to make it sound as
24 onerous as possible, I understand that, but they are making a
25 proportionality argument.

1 I don't feel that I am capable of ruling on that
2 today, but if you want to make an issue of it, if you want to
3 set a different PTO to address that specific objection, then we
4 can tee it up and the parties can educate me and brief me and I
5 will rule on it. If you are entitled to get information about
6 the conditions under which things were stored or things were
7 shipped that you don't already have, then I will be in a better
8 position to rule on that.

9 I am absolutely not foreclosing you from seeking that
10 remedy either. To the extent you want to reserve that, that is
11 a very long way of me saying you can absolutely reserve it. If
12 you want to tee it up -- I think formalistically that is how it
13 is being teed up.

14 Mr. Beroukhim, Mr. Shortnacy, and Mr. Sachse can
15 disagree with me, but what I am hearing is they are making a
16 proportionality argument, not that it's not relevant. I think
17 there is a decent argument that anything in terms of how this
18 product was handled at all stages is arguably relevant, given
19 that relevancy is a very low standard, but whether it's
20 proportional.

21 It sounds to me, at least as to Sanofi and BI, I am
22 going to order them to produce what I call the product tracing
23 information, and it can be done in the manner in which Mr.
24 Beroukhim has indicated, by pointing you to specific other
25 documents that have already been produced. Mr. Shortnacy

1 indicated he can do it by tomorrow.

2 Ms. Jung, is there a material difference between five
3 o'clock tomorrow and, say, 10:00 o'clock Monday morning for
4 them to produce that information to you?

5 MS. JUNG: No, your Honor, assuming that we get
6 actually substantive information.

7 THE COURT: Okay. I am going to ruin an associate's
8 life at both of your law firms. I am going to give you until
9 10:00 o'clock Monday morning East Coast time to provide the
10 Plaintiffs with what I have called the product tracing
11 information. Again, it can be in the form that Mr. Beroukhim
12 has indicated.

13 Okay. I have dealt with that issue. Mr. Beroukhim, I
14 think that was the only Sanofi issue that I had left.

15 Am I correct, Ms. Jung? Do you have any other issues
16 with Sanofi that we needed to take up today, given that I have
17 put conditions off to the side?

18 MS. JUNG: No, your Honor.

19 THE COURT: Mr. Beroukhim, I know it is late in the
20 day there in Brussels, so if you want to leave the call, you
21 are free to go. I think we are done with you for now unless
22 you have anything else you wanted to raise.

23 MR. BEROUKHIM: The only thing I would say, your
24 Honor, we will do whatever the Court would like us to do. I
25 told Ms. Jung earlier today we would be able to get it to her

1 by Wednesday, and given that I am traveling back over the
2 weekend, it would be helpful to me, but we will get it done if
3 you need us to, your Honor. I understand.

4 *THE COURT:* I need you to get it done by Monday at
5 10:00. Like I said, I will ruin some poor associate's weekend,
6 but I am sorry for that. I will excuse you, then, if you want
7 to be excused, Mr. Beroukhim. Thank you.

8 *MR. BEROUKHIM:* Thank you, your Honor.

9 *THE COURT:* Let me go back, then, to Mr. Shortnacy. I
10 think the remaining issue that I had put to the side was the
11 issue dealing with the unexpired retained regulatory related
12 product, which you are not objecting to producing it, you just
13 need time to get through the traps.

14 It seems to me your regulatory lawyer should be able
15 to answer these questions relatively quickly. How much more
16 time do you need to confer with regulatory counsel for them to
17 tell you whether you need to retain 50 grams or 40 grams or 20
18 grams?

19 *MR. SHORTNACY:* Your Honor, I think we are close on
20 that. The challenges have been not only navigating the
21 regulatory landscape, but also we have foreign affiliates
22 involved and the like. I do think we are close to resolving
23 that issue.

24 The other issue I raised was the sort of contractual
25 issue.

1 *THE COURT:* Give me some more depth on that. I am not
2 sure I am following when you say contractual issues.

3 *MR. SHORTNACY:* Sure. So, because Promeco was a
4 contract manufacturer, there are also requirements to retain
5 product pursuant to quality agreements, and there are
6 provisions of agreements that have to be navigated as well,
7 where we, BI, have to be satisfied that we are not going to be
8 in breach of an agreement in order to provide the requested
9 samples.

10 *THE COURT:* I understand. So, what is your ask in
11 terms of time to get all this done?

12 *MR. SHORTNACY:* I would say, your Honor, from our
13 perspective, and again, recognizing that this sort of the
14 regulatory landscape and risk assessment is something we can
15 take advice on and to somewhat control, navigating the waters
16 of contractual arrangements would require other parties to
17 weigh in.

18 So, that is a little bit uncertain in our view, but I
19 do believe that, with respect to the regulatory requirements, I
20 think that we will have clarity on this probably by no later
21 than Monday. But, again, we are going to need input from other
22 contractual parties to be able to be cleared to release it.

23 I would just only emphasize the point that I made
24 earlier to your Honor, we are already taking steps to be ready,
25 and so all of the Customs clearance and shipping, all of those

1 arrangements are being done in parallel so that time is not
2 lost once the final kind of approvals -- necessary approvals
3 are obtained.

4 *THE COURT:* The Plaintiffs are asking me to order you
5 to do it by a certain date. I am inclined to do that. I am
6 asking you, what is your position as to what that date ought to
7 be? Whatever you are going to produce after having run the
8 traps with your regulatory lawyers and your contract lawyers, I
9 need you to give me a deadline to get it done, so what is your
10 request as to what that deadline ought to be?

11 *MR. SHORTNACY:* Your Honor, I guess if I could try to
12 frame it a little differently. I fully appreciate -- I am
13 probably testing your patience at this point, but I appreciate
14 what your Honor is trying to do, which is provide firm
15 timelines, but what I would say is that we have made requests
16 to the relevant contractual parties, who then may or may not
17 agree that these product retains are allowed to be released.

18 That ask has been made, but I don't know what the
19 response is going to be.

20 *THE COURT:* Let me clarify for my own self. Within
21 this category of material that we are talking about, okay, is
22 it all both regulatory and contractual, or are we talking about
23 kind of intersecting Venn diagrams where some of it is -- the
24 holdup is regulatory only, some of it, the holdup is
25 contractual only, and some of it, the holdup is both, or is

1 everything requiring regulatory and contractual approval?

2 MR. SHORTNACY: Everything is both.

3 THE COURT: Okay. How many different contractual
4 parties are we talking about?

5 MR. SHORTNACY: One.

6 THE COURT: Okay.

7 MR. SHORTNACY: As I said, that request and notice has
8 been sent, and I would expect a response very quickly. And as
9 I said, we are prepared to ship as though, you know, it is
10 going to be given. I guess just to kind of cut to the chase
11 and provide some timing for your Honor, I would expect, all
12 things being equal, that we would be able to ship this out by
13 Friday of next week to allow time, again, for this to play out
14 and to be able to get it out the door.

15 THE COURT: All right.

16 MR. SHORTNACY: Assuming permissions are given which,
17 again, is outside of our control.

18 THE COURT: I am going to -- yes, Ms. Jung, go ahead.

19 MS. JUNG: Sorry, your Honor, one thing. I am curious
20 as to who the contractual party is, if it is Sanofi or another
21 Defendant in this case, because if it is a quality assurance
22 retained issue, this product has been recalled, it is not
23 commercially available. So, I am not sure what the quality
24 retained issue is under the contractual provisions that Mr.
25 Shortnacy is discussing.

1 I am sure that there are provisions with their well
2 drafted contracts that indicate that in times when there is a
3 court order or when a product has been recalled, this quality
4 assurance retained issue should not be taking precedent over
5 production in this type of litigation.

6 I just wanted to weigh in on that. I'm not sure who
7 this contractual party is, and I am curious as to whether it is
8 Sanofi.

9 *THE COURT:* Mr. Shortnacy, are you at liberty to
10 answer that question?

11 *MR. SHORTNACY:* Yes, that is correct.

12 *THE COURT:* Okay. That is fine.

13 *MR. SHORTNACY:* That ask has been made, and to respond
14 to that, your Honor, I assure the Court that those issues are
15 being looked at and have been looked at very closely in terms
16 of contractual arrangements. I appreciate Ms. Jung's comment
17 off the cuff, but it is not, obviously, so simple.

18 *THE COURT:* I accept your -- you are not testing my
19 patience, first of all. Second of all, I take your point for
20 what it is.

21 I am going to order BI to -- if you are going to
22 produce from this, you are to produce by a week from today at
23 noon West Coast time, so three o'clock p.m. East Coast time on
24 September 30th. If you are withholding any of the requested
25 samples based upon either contractual or regulatory claims, you

1 need to provide essentially the equivalent of a privilege log
2 so that Ms. Jung knows what she is getting, what she is not
3 getting, and why she is not getting it.

4 That is my order as to that product.

5 I think I have now wrapped up all the issues with BI.
6 Mr. Shortnacy, again, not waiving any objections you might have
7 to what I have ordered, but have I addressed everything that
8 you think needs to be addressed?

9 *MR. SHORTNACY:* I think so, your Honor, thank you.

10 *THE COURT:* Ms. Jung, have I at least addressed
11 everything you wanted to address with BI or taken it under
12 advisement?

13 *MS. JUNG:* Yes, your Honor.

14 *THE COURT:* Good. All right, Mr. Sachse, you are back
15 in the barrel.

16 Ms. Jung, remind me what the issues are that you
17 wanted me -- well, let me go back to Mr. Sachse. Now I
18 remember.

19 Product tracing versus conditions, what is your
20 position as to whether you will provide or have already
21 provided the product tracing information?

22 *MR. SACHSE:* Sort of two answers. First of all, I
23 think you know me well enough by now to know I don't typically
24 stand on process, but this is a disturbing trend that we are
25 seeing with the Plaintiffs, raising these informal requests.

1 There is no formal discovery about any of this, and yet they
2 set up these hearings through the special master and then they
3 raise informal requests. We got another one today during this
4 hearing and we are forced to respond to that. I think we need
5 to get back to process because it is important.

6 But on the substance, which I think is what really
7 matters, so I am going to break it up. I am going to try to
8 put things in boxes like you have been doing, Judge.

9 This is easy. Jurong API is all retained samples, so
10 those regulatory samples you were talking about earlier, they
11 have always been in controlled conditions until we packed them
12 and shipped them to Emory earlier this week, so they have all
13 of that information.

14 I don't think there is any -- and they have also the
15 date of manufacture and the batch number, because that is how
16 they selected what they wanted. There is nothing more to give
17 them there.

18 On the secondary product -- and I went off camera
19 while you were dealing with the other Defendants because I was
20 actually going to look for a good demonstrative exhibit. It is
21 a chart that shows -- for the entire 40-year life cycle it
22 shows where the API came from that GSK used and where the
23 finished product was made, and the Plaintiffs have that
24 information.

25 The Plaintiffs have the specific information about

1 where -- the different formulations that they are getting,
2 where it was being held, and whether it was being held under
3 controlled conditions or whether it was being stored in ambient
4 conditions, and that is actually part of what they used to make
5 their selections.

6 They also have already the manufacturer of the API
7 because for all of the product that they are going to be
8 testing, the API was manufactured by Dr. Reddy's. I won't go
9 back into the history of why -- none of this product was, of
10 course, U.S. product, but we are going to try to use it as an
11 analog, or the Plaintiffs are going to try to use it as an
12 analog, and Dr. Reddy's was the only other API manufacturer who
13 GSK got authorized to use in the U.S.

14 So, they have all of that information, and if they
15 want more, and they say, well, we want to, I guess, trace chain
16 of custody, I am not exactly sure what more they want. They
17 know where it was made, they know how it was stored, and they
18 know, based on this week, when it was shipped, how it was
19 shipped. In the instances where we had to deviate, we told
20 them we deviated, the Parma injectables.

21 So, I don't understand what more is at issue here, and
22 if there is something more, they should serve a discovery
23 request.

24 *THE COURT:* Okay. I take your point on process, but
25 discovery runs in 97 days, so for them to serve a discovery

1 request -- the first thing I am going to do is shorten your
2 response time. I am not going to make them wait 30 days out of
3 the 97 that are left. Yes, we can stand on ceremony and follow
4 the normal process, but it is not going to be the normal
5 process anyway, but I hear you. I understand the point, we do
6 want to have an orderly process here, whatever that may be. I
7 am not suggesting this isn't, but I hear your point.

8 Let me turn to Ms. Jung for a second. Ms. Jung, what
9 I am hearing Mr. Sachse say, at least in terms of what I have
10 called product tracing information, he is saying you have it.

11 What is it that you think you don't have in terms of
12 where the product has been and who had it and that kind of
13 thing, other than possibly it was in a UPS box that went from A
14 to B, and so UPS had it? What else are you looking for on the
15 product tracing side of GSK?

16 *MS. JUNG:* Thank you, your Honor. Mr. Sachse, I
17 apologize, I don't know if this information was provided to us
18 during the negotiations we had regarding this particular
19 product, or whether you are saying we have it in the document
20 production that GSK has produced over the course of several
21 months and it is somewhere in there.

22 If it is the latter, then I don't know where it is,
23 and I don't know which one is associated with the product that
24 has been produced. I guess that is the first response or
25 question.

1 The second one is, it sounded to me like you were
2 talking about API. I am not sure if you are applying that to
3 the finished dose as well.

4 MR. SACHSE: Yes, let me answer those questions. You
5 should talk to Ms. Finken and Mr. Watts. There was a chart
6 that we did in connection with, I believe it was the supply
7 chain 30(b)(6) deposition that kind of traces from beginning to
8 end here is where the API -- the facilities where the API was
9 made, the years when those facilities were in operation, and
10 then for the finished product, here is the facilities that were
11 implicated there.

12 If you want to know where a syrup came from or where a
13 syrup was made, it was Mississauga, Ontario, et cetera, et
14 cetera.

15 MS. JUNG: Thank you, Mr. Sachse. That information,
16 is it tied directly to the batches?

17 MR. SACHSE: The information is a summary form and it
18 is tied to time periods.

19 THE COURT: So, if I am hearing you right, Mr. Sachse,
20 if there is a batch in July 1998, they can look at the chart
21 and it will show that in July 1998 syrup came from Ontario, and
22 then they can connect those dots. Is that what you are
23 suggesting?

24 MR. SACHSE: Yes. Just to make sure the record is
25 clear, I think in 1998, it was -- syrup was coming from Roxane

1 Labs, it was actually an outside manufacturer, but yes, that is
2 correct.

3 *THE COURT:* Here is how I am going to resolve this
4 issue. I do believe, just as I have with Sanofi and BI, the
5 Plaintiffs are entitled to the product tracing information at
6 the level that we are talking about, not the UPS truck or the
7 FedEx shipment number or anything like that, but which facility
8 made it, where did they send it to, how long did they have it,
9 et cetera.

10 If GSK's position is that the Plaintiffs already have
11 that information and it is readily available to them, again, I
12 would ask GSK to point them with reasonable specificity, maybe
13 it is just that one chart, but I would ask GSK to point them to
14 that information because I think they are entitled to have
15 that. I will leave it at that.

16 Ms. Jung, why don't you go back and talk to Mr.
17 Watts, talk to Ms. Finken, and if you believe it is going to be
18 more problematic than otherwise to find all that, and you need
19 me to put a deadline on GSK's help, we can circle up quickly or
20 you can communicate with me through the special master, both
21 sides.

22 But the Plaintiffs are entitled to have that
23 information and GSK shouldn't just -- I am not suggesting they
24 are, but GSK shouldn't just throw a bunch of boxes at them and
25 say, it is in there somewhere. So, find the middle ground

1 there and, Ms. Jung, if you need me to get involved and give
2 you some deadlines, I am happy to do that. That's how I think
3 I should leave that issue.

4 *MS. JUNG:* Understood, your Honor.

5 *THE COURT:* Ms. Jung, back to you. What else is left
6 on the GSK side of the ledger that I haven't either taken under
7 advisement or addressed yet?

8 *MS. JUNG:* I think that covers it, your Honor.

9 *THE COURT:* Okay. Okay. Here is what I am going to
10 do on the last issue.

11 If the Plaintiffs make a request to GSK for better
12 information about where this stuff is found, GSK will have
13 seven calendar days, not counting the day of the request, so on
14 the eighth calendar day to respond to that request. If GSK has
15 an objection to that as being unreasonable, unduly burdensome,
16 problematic, take it up with the special master. She will
17 communicate with me and we may convene a quick PTO 32 on that.

18 I am expecting the Plaintiffs are not going to ask
19 unless they really, really need it, and if they don't really,
20 really need it, then they better not ask. I think it is always
21 good to have deadlines out there.

22 *MR. SACHSE:* Judge, you don't want to have a face
23 forward here?

24 *THE COURT:* I am here, so if I don't see you all every
25 couple of weeks I get bored.

1 *MR. SACHSE:* We will try to keep you entertained,
2 Judge.

3 Ms. Jung, feel free to reach out to me. I can
4 probably point you to some stuff or get you whatever
5 information you need. I think you probably already have it,
6 but let me see what I can do on that front.

7 *THE COURT:* Given the way you all work together, I
8 believe -- I have said what I said, I will stand on what I
9 said.

10 Then going back to Ms. Jung, and understanding that
11 you have reserved any arguments you want to make as far as the
12 conditions under which the product was maintained, and you can
13 tee that up separately if you want to do that, are there any
14 other issues you wanted to raise today that I haven't taken up?

15 *MS. JUNG:* No, your Honor, I don't believe I have any
16 more at this time. Thank you so much.

17 *THE COURT:* Mr. Shortnacy, any other issues or any
18 clarifications you need of the rulings that I have made?

19 *MR. SHORTNACY:* No, your Honor, thank you very much.

20 *THE COURT:* Thank you. Mr. Beroukhim.

21 *MR. BEROUKHIM:* Thank you, your Honor, thank you for
22 your time.

23 *THE COURT:* Nothing else?

24 *MR. BEROUKHIM:* No, your Honor.

25 *THE COURT:* Mr. Sachse, anything else or any

1 clarifications you need?

2 MR. SACHSE: I have lots of other issues, but not with
3 today's hearing.

4 THE COURT: Very well. I will excuse all the parties.
5 I wish you all a nice weekend and we will be in recess. Thank
6 you very much.

7 MS. JUNG: Thank you.

8 MR. SHORTNACY: Thank you, your Honor.

9 *(Thereupon, the hearing was concluded.)*

10 * * *

11 I certify that the foregoing is a correct transcript
12 from the record of proceedings in the above matter.

13
14 Date: September 24, 2021

15 /s/ Pauline A. Stipes, Official Federal Reporter

16 Signature of Court Reporter
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Pauline A. Stipes, Official Federal Reporter

MR. BEROUKHIM: [17] 3/21 4/2 18/8 30/16 31/8 31/19 32/1 32/5 32/17 32/21 33/6 33/11 33/17 37/22 38/7 50/20 50/23 MR. SACHSE: [12] 4/4 4/7 13/5 16/2 25/3 43/21 47/3 47/16 47/23 49/21 49/25 51/1 MR. SHORTNACY: [25] 3/18 9/1 10/17 11/6 11/9 11/23 12/14 17/9 18/4 24/21 27/24 29/7 38/18 39/2 39/11 40/10 41/1 41/4 41/6 41/15 42/10 42/12 43/8 50/18 51/7 MS. JUNG: [24] 3/14 4/10 4/19 7/2 7/6 7/10 7/23 19/12 22/11 23/18 25/12 27/4 30/4 34/8 37/4 37/17 41/18 43/12 46/15 47/14 49/3 49/7 50/14 51/6 THE COURT: [74]	3200 [1] 1/13 33 [1] 31/3 34 [1] 31/3 3434 [1] 2/2 3rd [1] 10/9 4 4 grams [1] 11/4 40 [1] 38/17 40-year [1] 44/21 400 [1] 31/12 4000 [1] 1/18 404-572-4600 [1] 1/24 4059 [1] 1/21 4600 [1] 1/24 5 50 [1] 38/17 561-803-3434 [1] 2/2 7 712 [1] 10/9 777 [1] 1/20 9 90017 [1] 1/21 97 [2] 45/25 46/3 A able [12] 5/20 6/12 7/6 7/9 9/5 9/17 9/17 37/25 38/14 39/22 41/12 41/14 about [26] 8/21 13/7 14/9 14/13 16/12 17/8 18/10 19/3 22/6 22/25 24/17 24/20 27/23 30/13 30/25 33/17 36/5 40/21 40/22 41/4 44/1 44/10 44/25 47/2 48/6 49/12 above [3] 11/6 19/24 51/12 absolutely [4] 16/9 16/11 36/9 36/11 accept [1] 42/18 acknowledged [1] 26/8 actually [15] 7/17 8/8 13/11 14/2 16/24 19/24 22/13 24/5 24/18 25/6 25/23 37/6 44/20 45/4 48/1 add [2] 11/10 17/9 addition [2] 12/16 17/11 additional [2] 7/1 11/14 address [3] 35/4 36/3 43/11 addressed [5] 21/7 43/7 43/8 43/10 49/7 admissibility [2] 7/25 8/17 adopt [3] 17/9 17/10 18/9 adulterated [2] 7/18 7/21 advance [1] 35/7 advice [1] 39/15 advisement [2] 43/12 49/7 affiliate [2] 9/4 9/20 affiliates [3] 9/16 11/13 38/21 after [5] 5/22 17/7 18/17 21/17 40/7 again [20] 10/2 17/23 19/16 20/5 24/8 25/14 26/2 27/8 27/10 30/13 32/15 33/2 33/21 37/11 39/13 39/21 41/13	41/17 43/6 48/11 ago [2] 20/9 25/8 agree [5] 14/15 18/15 21/6 34/17 40/17 agreed [10] 5/16 14/25 20/17 21/3 21/13 22/10 22/13 24/9 27/12 35/1 agreeing [1] 29/13 agreement [13] 14/12 17/20 21/2 22/4 22/22 24/11 24/12 27/10 27/12 27/15 35/3 35/13 39/8 agreements [7] 11/13 12/3 24/10 28/11 34/16 39/5 39/6 ahead [2] 9/6 41/18 airplanes [1] 10/1 akin [1] 31/1 ALEX [2] 1/19 3/22 all [68] allow [4] 12/24 19/12 31/2 41/13 allowed [2] 31/3 40/17 alluded [1] 13/14 along [1] 6/18 alphabetically [2] 8/25 13/3 already [22] 12/9 14/6 16/22 18/13 18/22 18/23 19/2 19/9 30/21 31/5 31/8 31/9 32/11 32/11 34/4 36/7 36/25 39/24 43/20 45/6 48/10 50/5 also [13] 8/4 11/10 11/12 11/24 12/17 16/15 16/19 24/14 31/17 38/21 39/4 44/14 45/6 alternative [2] 8/8 8/14 always [2] 44/11 49/20 am [66] ambient [4] 14/2 14/5 15/4 45/3 amounts [1] 20/1 ampules [1] 13/20 Amsterdam [1] 13/10 analog [2] 45/11 45/12 Angeles [1] 1/21 another [2] 41/20 44/3 answer [5] 11/8 31/4 38/15 42/10 47/4 answers [1] 43/22 anticipate [1] 6/12 any [17] 4/9 5/16 5/20 8/15 13/18 16/14 37/15 42/24 43/6 44/1 44/14 50/11 50/13 50/15 50/17 50/17 50/25 anything [12] 4/18 14/7 17/2 17/9 21/12 22/15 29/11 30/3 36/17 37/22 48/7 50/25 anyway [2] 22/2 46/5 API [27] 12/17 12/18 13/9 17/13 19/20 19/23 21/1 22/13 23/7 23/24 24/4 24/5 24/25 28/3 28/15 29/5 32/7 32/15 33/3 44/9 44/22 45/6 45/8 45/12 47/2 47/8 47/8 apologize [2] 25/12 46/17 appear [2] 4/7 4/10 appearance [1] 34/19 applying [1] 47/2 appreciate [9] 3/24 3/25
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