1 2	UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF FLORIDA WEST PALM BEACH DIVISION
3	CASE NO. 20-md-02924-ROSENBERG
4	IN RE: ZANTAC (RANITIDINE) .
5	PRODUCTS LIABILITY . West Palm Beach, FL LITIGATION April 8, 2021
6	. April 0, 2021
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8	DISCOVERY HEARING (through Zoom) BEFORE THE HONORABLE BRUCE REINHART
9	UNITED STATES MAGISTRATE JUDGE
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THE MAGISTRATE JUDGE: All right. Good afternoon, everyone. We are here on Case Number 20-md-2924, In Re: Zantac Ranitidine Multi District Product Liability Litigation. We are here this afternoon for a PTO 30 discovery hearing relating to Apotex Corp, Apotex Inc.

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Let me start by having the relevant parties make their appearances. I'll start with counsel for the Plaintiffs.

MS. GOLDENBERG: Good afternoon, your Honor, this is Marlene Goldenberg on behalf of the Plaintiffs.

THE MAGISTRATE JUDGE: Good afternoon. On behalf of the Defense.

MR. HENRY: Your Honor, Terry Henry on behalf of Apotex Corp. with my partner, Stephanie Chomentowski.

THE MAGISTRATE JUDGE: Mr. McGlamry, did you want to make an appearance on behalf of the Plaintiffs as well?

MR. McGLAMRY: Your Honor, I will, Mike McGlamry on behalf of Plaintiffs, although I fully expect that

Ms. Goldenberg will be handling all of this. I am just here to match up with the second on their side.

THE MAGISTRATE JUDGE: I am pleased to have all of you. First of all, welcome, everyone. Before I turn to the merits of this afternoon's discussion, I did want to make a few comments.

First of all, the special master -- I am pleased to hear there is only one issue left to be resolved this

afternoon. The special master had been advising me that there were a number of other issues and that the parties, through meet and conferral and some direct discussions, were able to resolve all of those issues. So I want to commend the parties for their efforts in that regard. I think that has been the norm in this litigation and I am pleased to see it is continuing in this regard.

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I also did want to comment -- I know we are getting into the busy deposition season now, and I think this dispute primarily relates to a 30(b)(6) deposition that is coming up for Apotex, but I know we have other 30(b)(6) depositions coming up. We have fact witness depositions getting started. We have second levels of discovery going out. So, I recognize things are speeding up here in the litigation.

I just want to remind everybody and encourage everybody how important it is to leave enough time for the Court to resolve issues if issues arise, and to leave yourselves time to meet and confer. As you have seen both in this specific matter and in other matters, working with the special master, working with each other often leads to resolution.

I know some of the PTOs have specific deadlines where you have to produce documents X days in advance of the depo and you have to lodge your objections Y days ahead of the depo.

Those are there, those are the PTOs, and if you want to live on

the edge you can hold right to those dates and see where we end up.

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I think we will all be better served, and certainly my expectation and my hope would be that if you are going to object, object as fast as you can. You need some time to review, but generally speaking, in my experience if there is an objection to a deposition notice you know it relatively quickly. So, at least frame the issue, notify the other side that the objection is coming and start the process of resolution.

Likewise, on the flip side, if there is going to be a delay in producing materials, the sooner the information can be exchanged, the better everybody can plan. None of us likes to get bad news, none of us likes to deliver the news that something may be delayed or may cause a problem, but I think the sooner that information can get exchanged, everybody can work with it.

First of all, to be clear, not pointing fingers at the particular parties in this dispute. You have all acted very well, so I am not suggesting you are the impetus for those comments. I just happen to have everybody here today and this is an issue that I see coming, and as much as you all are feeling pressured by Judge Rosenberg to comply with certain deadlines, trust me, I am also getting pressured by Judge Rosenberg to make sure that you comply with your deadlines.

This is my transparent way to share with you kind of my thinking on that.

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Certainly if people have done things in the past, have given notices in the past, I am not retroactively trying to change anything or hold anybody responsible for maybe they could have done something sooner in the past. That is all water under the bridge, water over the dam, or both.

Just going forward, I would ask the parties, as you all have, in terms of professionalism and courtesy to each other, the sooner information can be exchanged, the sooner notices like that can be given, the more efficient we are going to be and the faster I can get involved and resolve your issues if you need me to get involved.

So, thank you for that.

Let me turn to the specifics of today. One last disclaimer before we actually do turn to the merits.

I understand there is in parallel to today's proceeding a motion relating to personal jurisdiction. That motion has not been referred to me, so I am not ruling or making any judgments about that. Frankly, given the Supreme Court's decision the other day, I am not quite sure what the law is on personal jurisdiction anymore, but I know at some level it involves contacts with a forum.

I know the issue that is before me today also relates in some respects to what is the foreign entity doing in the

United States, but in my view, the body of law that I need to apply in resolving a discovery question of whether entity one has possession, custody, and control of materials that may be housed by entity two, that question is an independent and completely different legal conclusion from whether entity two has sufficient — constitutionally sufficient contacts with the United States to invoke jurisdiction.

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I want to make very clear for the parties, I am not addressing or ruling on the personal jurisdiction question and no one should draw any conclusions about that from anything that I say today.

With that very long disclaimer, thank you for being patient, what I would like to do is, I am really interested in hearing from the parties at length today. This is, from my review of the case law, an extraordinarily factually driven conclusion as to whether Apotex U.S. has possession, custody, and control of documents that are housed by Apotex Canada.

I know I only gave you five double-spaced pages in the submissions to lay out for me what the law was. You all attached a number of materials which I have reviewed. I can't say that I have exhaustively read every word of every submission that you made, so it is not my intention to rule from the bench today.

What I want to invite you -- I know you both know me from other hearings, I generally have a lot of questions about

the issues in the case. I don't really have that many here today, other than I really want to give you the full opportunity to go through the evidence with me, point me to the exhibits you want to point me to, and make your best strongest arguments.

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I do think this is a very legally difficult question that is driven heavily by the facts, so I want both parties to know they have as much time as they want to really go through this in detail and help me as best you can.

Obviously, if I have questions, I will ask them, but at this point, I really am interested in hearing from you and not talking. So, in that regard, I will now shut up and turn to Ms. Goldenberg and allow her to argue whatever she would like to argue on behalf of the Plaintiffs.

MS. GOLDENBERG: Thank you, your Honor. With that helpful advice, what I would like to do is turn right away to the most important documents that we have cited and compare them to what the Defendants have put in their submission.

I want to walk through, starting with their Exhibit B, and what you will find in their Exhibit B is a list of their corporate officers as of the end of last year, which coincides with about the time we had our personal jurisdiction hearing, and what you will see there is that at that time Apotex appointed a new CEO.

What they didn't do, though, was get rid of any other

overlapping corporate officers. So, you can see that there are still corporate officers on this list who appear on Apotex's website as being officers who still serve in the capacity of an officer in both different bodies.

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I think it is telling, your Honor, that the declaration, or the affidavit that Apotex submitted in support of their position today came from their director of information technology, not from someone like Mr. Fahner or Mr. Bohling, for example, who were able to provide declarations as to other issues.

Mr. Porto's declaration is very carefully worded. If we look at paragraph three what he says is "I understand that each company has its own managers, executives, officers, and employees." I understand is very carefully chosen language, and again, this is not somebody who, in my opinion, should be giving this declaration because he is not an officer himself.

He also says that each company has its own. What he doesn't say is that no company shares any of those people because he can't say that because it is not true.

The best examples of this that we have put in our submissions are Exhibit O, which is Kiran Krishnan's LinkedIn page that shows that he works at Apotex Inc. and then our Exhibit L which is the screen shot of Apotex Inc.'s page where they list their corporate officers.

If we next turn to Mr. Fahner's declaration, in

paragraph four he says "Apotex, Inc. has no presence in the United States and has no office, facilities, leased or owned property. Employees, registered agent, local telephone listings or bank accounts in the United States."

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I would like to compare that with footnote one to our brief which has a hyperlink to Apotex Inc.'s LinkedIn page where in the company section they say, and I quote, "Apotex Inc. exports to more than one hundred countries and territories" and the important part here is they say "operates in more than 45 countries with a significant presence in Canada, the U.S., Mexico, and India."

If we then look at Mr. Bohling's declaration, I would say we should compare that to Exhibit B, or compare that with Apotex's Exhibit B, with our Exhibit R, which is Bohling's LinkedIn profile that says that he has worked at Apotex Inc. for more than seven years.

So, if we use those facts and look at the case law on this issue that your Honor said that you are familiar with, so I am not going to delve into it too much, but I will say that the common thread across the case law is that if there is a shared employer or shared corporate officer, it is very easy for that officer to go and get those documents.

There is a lot in our briefs, and I am happy to go into all of it in greater detail, but if your Honor is asking for the greatest hits or the distillation of our argument, that

is it.

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If you look at all of these cases, the shared officer component is the one that is cited by Courts most frequently as the reason that one entity has possession, custody, or control over the other's documents.

THE MAGISTRATE JUDGE: Okay.

MS. GOLDENBERG: I will also note, I have to put this out there, in all of the other cases, too, it is not like these other entities or these other Defendants in the other cases didn't oppose these motions either, so the fact that they have a declaration that says we can't get access to these documents has never been dispositive on its own. Courts have looked at those and analyzed the facts and determined, over the objections cited in those declarations, that these companies nonetheless have possession, custody, and control.

THE MAGISTRATE JUDGE: Ms. Goldenberg, I don't want to limit you at all. I appreciate you distilling down your best argument, your most concise argument, but if you want to address the law or other legal arguments or factual arguments, I certainly did not mean to suggest you could not. I want to give you a full opportunity to argue anything you want to argue.

MS. GOLDENBERG: I appreciate that, your Honor. With that, then I will just point out that the Costa decision which -- and the Takata Airbag decision was to harmonize the

standard with the Searock decision, gives those three factors and it was determined that in almost every situation where you have an overlapping holding structure also, like what we have here where Apotex Holdings owns both companies, they say that virtually all of the published decisions have required production by the nonparty corporation.

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With that, I will wait to see what Mr. Henry has to say, but I will stop there for now.

THE MAGISTRATE JUDGE: Very well. Thank you very much, Ms. Goldenberg.

Mr. Henry, same invitation to you, I am happy to hear any and all argument you want to make, legal or factual.

MR. HENRY: Thank you, your Honor, I appreciate the opportunity. I want to start out today by making it crystal clear to the Court that Apotex Corp has produced and continues to produce and has committed to produce all documents in it possession, custody, and control, and that includes documents that were created by or at one time were held by Apotex Inc.

Those Apotex Inc. documents are documents that Apotex Corp has received or to which it has access in the normal course of its business dealings. Those have already been produced and we have committed to continue to produce those documents.

The Plaintiffs have served on Apotex Corp 111 document requests, but they haven't identified which documents are at

issue. Instead, they have make a broad and unlimited demand essentially saying that Apotex Corp is in possession, custody, and control of everything that Apotex Inc. has. That is not the standard for the analysis.

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The Plaintiffs also expressly stated in their PTO 32 submission that if they receive a ruling in their favor, they will require Apotex Corp to produce a witness to testify about these new documents that will be produced.

So, Apotex's argument on possession, custody, and control means these four things.

First of all, it disregards the formal arm's length corporate structure of foreign affiliates, which is contrary to how this Court ordered the parties to treat foreign affiliates under PTO 60. It also disregards the actual facts that show Apotex Corp and Apotex Inc. are formal separate legal entities performing separate business operation.

It also disregards this Court's clear guidance from March 4th, during our hearing, that a corporate party is not required to learn new facts in order to prepare for a corporate deposition.

And while we understand the Court's reluctance and refusal, actually, to address the jurisdictional issue, the relief the Plaintiffs here seek would erode Apotex Inc.'s due process protections against being forced to litigate in a foreign jurisdiction. Overall, their arguments are misguided.

So, the Plaintiffs have actually focused on alter ego here. They haven't focused on the legal requirement of possession, custody, and control, and it is because they have linked their argument to jurisdiction.

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The Plaintiffs have not presented any evidence that Apotex Corp actually possesses or has the legal right to any of the documents that they are seeking here and, frankly, again, documents that they have not identified, and it is incumbent upon Plaintiffs, it is their burden to identify which documents are at issue. That is both in the Pictet Overseas case and the Wiand case. Those Courts, when they analyzed this issue, did it request by request.

Thus, on the very face of their submission they haven't met their burden.

Now, the legal standard, as the Court knows, for possession, custody, and control is set by the Eleventh Circuit in both Searock and then more recently in Sergeeva, right, and that is the legal right to obtain documents upon demand.

Now, that can be established, and most often is as we'll see, when the affiliated corporations or the affiliated entities actually share responsive information and documents in the normal course of their business dealings. With that framework, I would like to address some of these factual issues.

The first one is the corporate structure issue.

Plaintiffs have alleged that they are intertwined; they are not. These is are two separate legal entities formed under the law of two separate countries, and that is an undisputed fact. They are not a parent subsidiary, they are affiliated companies with several intermediary entities between them.

Again, that is an undisputed fact both reflected in our Exhibit A and also page 7 on Plaintiffs' Exhibit B. So, they are affiliated, separated by several entities.

Again, they have separate business operations. Apotex Inc., the Canadian entity, is responsible for developing and then securing the right to market certain generic drugs, which it does, and it does spend millions of dollars in the U.S. on legal fees, as Plaintiff has alleged, in order to both secure the right to market those drugs, but also to defend the right to market those drugs. To defend its ANDA is what it spends the money for. So, that is Apotex Inc.'s role.

Apotex Inc.'s role is also to manufacture generic drugs, something that it does in Canada, and to the extent that it provides those generic drugs to Apotex Corp, the U.S. entity, Apotex Corp pays for those drugs. They are actually invoiced and there is payment exchanged.

Apotex Corp's responsibility here, separate business entity, is to commercialize, sell, and distribute generic drugs in the United States, completely separate operation.s Again, those are actually undisputed facts supported both by our

submission and the Plaintiffs' submission.

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There is an intercompany agreement that discusses how the companies will interact with each other, part of Plaintiffs' submission. So, it is important to understand that there is an agreement because it shows that these two entities, Apotex U.S. and Apotex Canada, respect the corporate formalities, and there are fees for services when one entity performs a service for the other.

For example, Apotex Corporation, Apotex U.S., is an FDA agent for Apotex Canada. Apotex Canada pays for that service as it would if it hired an outside vendor. In footnote two on page two of the Plaintiffs' submission there is a paragraph of services that Apotex Inc. may perform for Apotex Corp. That was from the 2005 agreement, and even at that time Inc. did not provide all of those services.

I represent to the Court today that Apotex U.S. pretty much provides those services for human resources, finances, etc. itself, but to the extent that there are services exchanged between the corporations, they respect the corporate formalities and those services are paid for.

Those distinctions are important because when Courts have found possession, custody, and control it is usually based on this close working relationship. Right?

For example, in the Batista case, we had -- Nissan North America was found to have a close working relationship

with Nissan Motors Limited, the Japanese entity. The reason was they worked together to both design and manufacture a transmission for the Nissan Pathfinder and the failure of that transmission was at the center of that case.

So, the Court found that of course Nissan North

America had possession, custody, and control of those design

and manufacturing documents because that was central to their

close working relationship on that project.

Here, there was no close working relationship on the manufacture of Ranitidine. That was solely within Apotex

Inc.'s responsibility, and it does not share that information with Apotex Corp or any of the other affiliated companies, so it is quite different from that close working relationship.

Similarly, in Mt. Hawley you had these nonparty foreign individuals essentially who were actually managing and operating the Defendant's business, and had communications that were at the very heart of that dispute. So, again the Court found that that was -- you know, gave the Defendant possession, custody, and control of the foreign affiliate's documents.

We don't have that here because Plaintiffs have provided no evidence that Apotex Corp or Apotex Inc. controlled the other's operations in that fashion. There is no intimate relationship here where Inc. controls what Apotex does. The actual facts are that they have two completely separate operations.

What we have here is akin to, or actually precisely like what we had in the Takata Airbag case. Right? We have two separate legal entities separated by multiple intervening entities with separate management structures and employees, no contractual right between the parties to demand documents; that there are certain documents that are not transmitted in the normal course of business, and Apotex Inc. — just like in the Takata case, Apotex Inc., the Canadian company, can decide in its sole discretion to provide documents or not provide documents.

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That is exactly the situation that we have here.

Those facts are not disputed. There is actually no evidence from the Plaintiffs on those facts, it is evidence that we have provided the Court, though. It is clear that these entities did not act as one and there was no close working relationship.

A related issue is the agency issue.

THE MAGISTRATE JUDGE: Before you shift to that -- MR. HENRY: Sure.

THE MAGISTRATE JUDGE: Sorry to interrupt you. Do you dispute the facts -- I understand you may dispute the legal significance of these facts, but do you dispute the facts that Ms. Goldenberg is pointing to about the same people being corporate officers of both entities, serving on the board of both entities, etc.?

MR. HENRY: I do dispute those facts. That is

after -- I can cover that now, if you'd like, your Honor.

THE MAGISTRATE JUDGE: Well, address it in the normal course of your argument. I did want to give you an opportunity to address that at some point.

MR. HENRY: Sure. I will actually talk about it now. They don't currently have overlapping officers. The one person who is really at issue here is Peter Hardwick. He is the CEO of Apotex Corp, but he also holds a senior management position. He is not an official officer of the corporation, but he holds a senior management position at Apotex Inc.

Now, what is important to understand is, he actually has two email addresses, and to the extent he provides services as the CEO of Apotex Corp, his salary is divided, but he is the one person that does span both.

Plaintiffs have asserted that Kiran Krishnan has dual roles. That is incorrect. Kiran Krishnan is an Apotex Corp employee, he is the vice-president for global regulatory functions. He does not have dual employment, he is employed only with Apotex Corp.

Now, his LinkedIn page is wrong, as is Mr. Bohling's. That is a simple explanation. For the longest time, when you go to LinkedIn and you select what company you work for, the drop down for Apotex, you had one option. Today there are more options, but many of these employees, like Kiran and Michael Bohling, did not go back and change them. A LinkedIn page is

not the same as a sworn declaration, which is what we have here.

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One final note on Mr. Krishnan as the vice-president of global regulatory functions. He does actually provide regulatory activities for other Apotex affiliates, including Apotex Inc., but to the extent he does so, his salary is reimbursed to Apotex Corp. Right? So it is another one of those services provided, services paid for, respecting the corporate formalities.

Mr. Bohling, vice-president for sales and marketing for Apotex Corp, he has no dual role, he is not an employee of Apotex Inc. The LinkedIn pages are wrong, and there actually is -- I just want to point out this other factual incorrect assertion. There actually is a web page for Apotex U.S. I am happy to provide to the Court.

So, one of the things the Plaintiffs suggest is that -- in their submission is that the Court ought to go back and take a look at a period of time when there were overlapping officers at Apotex, but that is not the test. The test is, what is the situation today?

We haven't seen any authority, and Plaintiffs have not pointed to any authority, that the Court can go back in time and say, well, you had overlapping officers five years ago, so I am going to find possession, custody, and control. That is not the test.

The Sigman (phon) case is perhaps the only one we found that was kind of close on this issue. If you recall, in Sigman, which was out of the Southern District of Florida in 2016, the Plaintiffs were asking for board records from two individual Defendants. The problem they had was, these individual Defendants had left the board, and what the Court found was that these individuals could go to the board and ask for the documents, but they had no ability to compel the board to provide the documents even though back in time they were part of the board.

In that situation, the Court said these individual Defendants do not have possession, custody, and control of the board documents today, so they rejected the Motion to Compel. That is as close as we could get to say the test of time is today, and today we don't have this overlapping of officers.

These corporations respect the corporate formalities.

They have the intercompany agreement, they respect their roles, and on that point, I will touch on the agency issue because there are some cases on this agency idea. Right?

Apotex Corp does serve as the FDA agent for Apotex Inc., the Canadian entity. It is a legal requirement, a foreign drug manufacturer is required to have a U.S. agent. Apotex Corp's agency is limited to that one issue, it is not an agent for everything, and Apotex Corp charges Apotex Inc. for those services.

As I said before, there are other entities that actually provide that service, for example, Cosma Reg, or Regulatory Compliance Associates. These are independent companies and Apotex Inc. could have hired any one of those and that wouldn't make those companies intertwined. So, it is a limited agency.

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By the way, Apotex Corp has provided -- has produced and will continue to produce documents in its possession, custody, and control that were created by Apotex Inc. that were at one time in Apotex Inc.'s possession that are related to the agency issue.

For example, it has already produced four ANDAs, over 30,000 pages of documents, and supplements with those ANDAs. It has produced FDA correspondence related to Ranitidine and it has provided FDA correspondence related to the recall, and it will continue to produce documents in its possession, custody, and control from Apotex Inc. that it has obtained through its role as an agent.

That doesn't mean that because of that agency Apotex

Inc. -- I'm sorry, Apotex Corp now has access to all the

documents.

THE MAGISTRATE JUDGE: On that point, Mr. Henry -sorry to interrupt you -- if I could ask you, so, what is it -I understand you may not have access to all the records of
Apotex Canada, but at a category level, what is it that Apotex

Canada likely has that the Plaintiffs want that Apotex Inc. ——
Apotex U.S. says, we don't have it, we can't get it? Are we talking primarily about the manufacturing processes?

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MR. HENRY: I think manufacturing is one huge group, and within manufacturing it would be testing, quality assurance, the sourcing of API, like everything that happens on the manufacturing side, and then there is also a portion of the pharmacovigilance material related to drug safety and adverse event reporting that Apotex Corp does not have access to. I think those are the two biggest buckets.

THE MAGISTRATE JUDGE: Is there a storage and transport issue -- I can't keep track -- I apologize, I'll just call them U.S. and Canada.

Who is -- who would have access and have the ability to produce the storage and transport records, is that Canada or is that the U.S.?

MR. HENRY: So, it is actually mixed. One-third, I would say, of the storage and transport issue is the sourcing of API, where did you buy it from, how did it get here, how did you store it. Those are the documents to which we don't have access. Apotex U.S. would have access or information related to importing finished drug product, storage of finished drug product, and then distribution of finished drug product. That is what it has and we produced documents related to that.

By the way, there are some Apotex Inc. documents that

we have produced that we do have custody and control of.

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For example, there have been standard operating procedures that apply to the Apotex Inc. facilities. Now, we had access to those because we have access to a shared drive that has some of those SOPs on it. So, to the extent we have access, we have provided them, but, as I said, there is a whole category of information that Apotex U.S. is sealed off from that we can't access.

THE MAGISTRATE JUDGE: Got it. Okay.

So, looking at the issues that have been primary in this litigation, to the extent there is a theory by the Plaintiffs that after the finished Ranitidine product leaves the manufacturing facility and before it gets to the consumer there can be heat or other factors that cause cancer, or that increase the risk or the probabilities of cancer, that would all be sort of downstream from the factory and that the U.S. entity presumably would have most of, because they are the ones importing it, transporting it in the U.S., shipping it to whoever is going to get it.

Am I correct about that?

MR. HENRY: Correct, your Honor.

THE MAGISTRATE JUDGE: Now, upstream from that is, is there flaws in the manufacturing process, are there impurities in the API, are they doing batch testing, things like that. I assume you are going to tell me that is the stuff the Canadian

entity has and the U.S. entity can't get to primarily.

Am I correct?

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MR. HENRY: Correct, your Honor.

THE MAGISTRATE JUDGE: Okay. It sounds to me like pharmacovigilance may straddle the fence a little bit, because I am assuming if there is some sort of adverse event in the U.S. or relating to a U.S. distributed product, the U.S. entity probably gets notice of that, but if it occurs somewhere else around the world, the U.S. entity probably doesn't get access to that.

Again, am I close to the bull's eye on that?

MR. HENRY: You are close, your Honor. It is interesting because Apotex U.S. would have the intake information and it submits it to pharmacovigilance, and then it would have the output information. In other words, it has — whatever the finished adverse event report is has to be sent to the FDA.

What it doesn't have is the sausage making part of it, which is the investigation, the calls with the docs if that is what happened, the actual adverse event and drug safety aspect of it, which is within the pharmacovigilance responsibilities of Apotex Canada.

THE MAGISTRATE JUDGE: Okay. The reason I sort of focused on manufacture, pharmacovigilance, storage and transport -- I can't remember what the fourth -- those are the

four topics for these 30(b)(6) depositions, big picture. What is the one am I forgetting, Mr. Henry?

MR. HENRY: It's storage and transport, manufacturing, and pharmacovigilance. You got it.

THE MAGISTRATE JUDGE: Okay. I interrupted you, I apologize. I think you were just finishing up on agency and you were going to move to another topic and I interrupted, so I apologize.

MR. HENRY: That is fine, your Honor, that is good data to have. I was actually just going to highlight some of the cases that define when the documents are in the possession, custody, and control, and one of the ones I want to highlight is this Cooper Industries case that the Plaintiffs cited.

It is actually an interesting case because what the Court there said was that the defendant, who sold and then serviced these aircrafts for a foreign nonparty, that defendant needed blueprints and service manuals of the nonparty in order to perform its duties, right, as the agent.

So, the Court said it would be inconceivable that you could perform your duties without having the blueprints, so you've got to go get them because that is what is required.

Right?

And in Sergeeva it was a similar situation where

Trident Atlanta was the defendant and Trident Atlanta said we

are not in the possession, custody, and control of our foreign

affiliates. The Court there said, yeah, but you are providing these financial services to your clients and it is impossible for you to do that unless you have access to and can obtain the documents form your foreign affiliates, so we are going to deem that you have possession, custody, and control of those documents.

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So, contrast both of those to the Takata Airbag case where in that situation, which is very much similar to this situation, BMW North America was fulfilling a statutory requirement to file documents from its German counterpart with the NHTSA. So, those are the documents that it was in the possession, custody, and control of. That did not provide access to all of the German affiliate's documents, particularly where that German affiliate protected those documents from disclosure to the North American defendant.

And that was a similar case in Wiand where the Court limited the production to what was available to the Defendant in the normal course as the agent, and refused to find possession, custody, and control to other documents that it didn't normally have access to in the normal course of the business.

That is the situation we have here where Apotex Corp
has already produced and will continue to produce documents
that it has in its possession, custody, and control as a result
of its normal business dealings with Apotex Inc., but it cannot

get or does not have access to other documents just generally.

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THE MAGISTRATE JUDGE: Let me ask you again, if I am hearing you correctly -- I am going to ask Ms. Goldenberg the flip side of this question, so I will alert her right now. I am going to ask you the flip side of this question.

Mr. Henry, you seem to be suggesting that you can have two corporate entities and that entity number one could have possession, custody, and control of some of the documents of entity two, but not all of those documents, that it is not a full matching.

I think what you are saying is, Apotex U.S. doesn't manufacture anything, therefore, they have no need to and no ability to access the manufacturing data, but they might have the ability to access invoicing materials, import/export, and all that because that is what they do.

So, the question I am going to flip to Ms. Goldenberg eventually is — it sounds to me like their position may be the opposite, which is, once you have a corporate relationship such that the materials of one entity are within the possession, custody, and control of the other the subject matter doesn't matter, it is a binary. You either have possession, custody, and control or you don't.

Am I correctly interpreting your analysis, Mr. Henry, that you can carve that up into subsets?

MR. HENRY: You are, your Honor. In fact, I'd say it

is not just my analysis, that is the proper analysis, that is what these Courts have done, particularly the ones I just went through, that it is limited to the documents that you have access to or the documents that you can demand in the normal course of your business dealings.

THE MAGISTRATE JUDGE: Right. I guess to follow through, then, the argument would be that the reason you can demand them is that there is a business reason, you are involved in that aspect of — the two entities are jointly involved in some aspect of the business, and therefore both entities have a need and an ability to access those materials, but, for example, the U.S. entity may have no need or ability to access Canadian tax records that are held by a chief financial officer, which has nothing to do with the U.S. entity, and vice versa.

MR. HENRY: Correct, your Honor.

THE MAGISTRATE JUDGE: I understand the argument. I thought that's what you were saying, I just wanted to give you an explicit opportunity to clarify that. Go ahead.

MR. HENRY: In fact, this last fact issue that I want to cover is exactly that, which is the data sharing. It is true that Apotex affiliated companies have data sharing services, undisputed. Plaintiffs talk about this application called Trackwise, and it is a fact that these companies interact and do share data.

Again, to the extent that Apotex Corp has that data or is able to access it, Apotex Corp has produced it.

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Your Honor, this is 2021, the data sharing services are ubiquitous throughout the commercial environment. Related companies and unrelated companies collaborate to increase efficiencies, save costs, and data sharing is a key component of that.

One example would be Apotex U.S. maintains EDI services, an electronic data interface, that allows its customers to order medicines. So, when Rite Aid goes on to the EDI website to order more medicine for its pharmacies it is interacting with Apotex U.S.'s information. Right? It goes in, it places its order, it can go back in and check the order, it can change the order. It can look for the delivery dates, it can change the delivery date or delivery conditions.

So, it is accessing and they are exchanging that information, but that doesn't mean the two corporations are intertwined, and it also doesn't mean that all of a sudden Rite Aid now has access to all information that Apotex U.S. has.

That is the kind of situation you have where you have these two corporations that have separate responsibilities, that also have separate operations, they share data, but on a limited basis.

As described in Mr. Porto's declaration and on these aspects, right, how the environment is set up, there is no

dispute. He carefully talks about how Apotex has structured its information technology environment to allow sharing for business operations, but also to preclude sharing where documents and information require protection.

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So, to get to the Court's question about what documents does Apotex U.S. not have access to, he explains that in paragraph five, and he mentions — these are broad categories, manufacturing, testing, drug safety, some packaging information, and pharmacovigilance. That is generally information that, as a drug distributor, Apotex U.S. would not be able to access, and Apotex U.S. does not have the right to demand those documents at all.

So, it's Plaintiffs' burden to demonstrate that these data sharing services allow Apotex U.S. to have access, which they simply haven't done.

Now, since I have been talking for quite awhile, I will try to wrap it up.

So, we think the authorities show, and as the Court has recognized, the possession, custody, and control analysis is very fact specific.

Plaintiffs offer incorrect LinkedIn pages, websites that are not correct, and years old legal filings to try to support their position, but we have shown, you know, both through the documents that we have attached and the sworn declarations what the facts actually are.

Now, Plaintiffs' PTO 32 submission is, I think, as we hit on earlier, far more than just about the documents, they seek to undermine the jurisdictional issues by avoiding these due process protections.

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Their argument amounts to alter ego here, your Honor, but they haven't pled any of these facts in any of their amended pleadings under Rule 11 or Rule 12, but they come here on an informal discovery situation and have asserted these facts. They haven't shown that one company is using another company for an improper purpose, and that is a substantive element of the alter ego analysis that is required to reach the personal jurisdiction issue.

Again, I understand that the Court is not going there, but the ultimate effect could be to undermine that jurisdictional issue.

So, what really causes us concern is this idea that if the Court determines that Apotex U.S. has the possession, custody, and control of, for example, manufacturing documents that it has never seen, the Plaintiffs will interpret that as saying you now have to produce a witness that knows all about those documents.

So, Apotex U.S. is going to be faced with the unrealistic and unfair burden of having to prepare a witness on 23 years of manufacturing four different forms of Ranitidine in order to present a witness, or the alternative would be to

concede and put up an Apotex Inc. witness when there has been no showing of jurisdiction.

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So, we wanted to put this out there because that is really what the effect of Plaintiffs' petition is. So, for that reason, as well as because Plaintiff has not met their burden to establish possession, custody, and control, we are asking the Court to reject the petition and deem that Apotex Corp does not have possession, custody, and control of all of Apotex Inc.'s documents.

THE MAGISTRATE JUDGE: All right. Thank you. I'm sorry.

MR. HENRY: No, I was going to say that is it.

THE MAGISTRATE JUDGE: Okay. Let me ask you kind of procedurally. I usually start here and I didn't. I am not quite sure exactly the procedural posture in which this issue comes before the Court.

Is it what you just said, which is, you are preparing for the 30(b)(6) deposition and the Plaintiffs are insisting that you produce a witness who can testify to these things and you are objecting to having to produce that witness on the grounds that you don't have possession, custody, and control of those documents, or did the Plaintiffs propound requests for production, and in the requests for production it requires you to produce materials form the Canadian entity and you are objecting to the definitions used in the requests for

production?

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So, the issue ends up in the same place from a legal perspective. I am just trying to make sure procedurally I understand how we get here.

MR. HENRY: Ms. Goldenberg may have a different view, but our understanding is, this is essentially Plaintiffs' motion to compel certain responses to requests for production of the documents. There are a lot of categories that we have said we just don't have the documents because they are in Canada.

Now, although this issue of the 30(b)(6) deposition was out there, it wasn't really crystalized until it ended up in the request for relief the Plaintiffs submitted to the Court yesterday morning.

So, in our view, it is Plaintiffs' motion to compel responses to requests for production of documents.

THE MAGISTRATE JUDGE: Just to make sure I understand it correctly, they served you with a request for production and you responded in part and you objected in part on the grounds that some of the materials called for in the request for production would have required you to obtain documents from Apotex Canada, which you do not have possession, custody, and control of.

MR. HENRY: Correct.

THE MAGISTRATE JUDGE: I understand. Thank you, Mr.

Henry. Let me turn back to Ms. Goldenberg.

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You can respond to any and all of what Mr. Henry just said.

MS. GOLDENBERG: That's good because I was short winded before and I think I am going to make up for that now. I will try to address the issues at least somewhat in reverse so that the issues that are fresh in our minds get answered first.

Procedurally, yes, what we are talking about here are the requests for production. My understanding is that Mr. Maderal on our team and Mr. Henry yesterday had a meet and confer about the depositions and agreed that the depositions would not implicate this issue. So we are talking about documents.

I also wanted to bring up that this issue was expressly contemplated in PTO 60. If we look at that pretrial order, there is an express provision, I think it is section 1(b)(2), if I remember right, where that PTO says that these Defendants are going to produce documents within their possession, custody, and control.

We knew we had a dispute then. Mr. Henry was involved in those negotiations, so there is no surprise here, but this was always something that was going to be teed up because we need these documents not just for depositions, but our experts need to get going on this stuff and have to write reports based

on different documents from 20 plus Defendants here. So, I wanted to clarify that.

Moving on to your other --

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THE MAGISTRATE JUDGE: Before you move off of that -- and I appreciate that. Whatever order I write -- at the end of it I have to order something, I have to rule on something.

What I would be doing is either I would be sustaining the Defendants' objections to the interrogatories -- or to the requests for production, or I would be overruling the Defendants' objections and granting the motion to compel the production of the documents. That is all, I just wanted to frame that.

MS. GOLDENBERG: That is a fair clarification and that is right, your Honor.

I also wanted to answer your question about whether or not this is a piecemeal, can Apotex U.S. have access in part only to Apotex Canada's documents. We don't really need to answer that question in a vacuum and we don't need to talk about some theoretical context because here what we are talking about are the documents that you and Mr. Henry just discussed, manufacturing documents, pharmacovigilance, and all the other documents that are the subject of our requests that are closely tied to what we have in our complaint relating to Ranitidine. Right?

And what we also know is that Apotex Corp is the U.S.

FDA agent for Apotex Inc. for Ranitidine. We also know that, as the agent, if the FDA ever said, hey, we want these documents, whatever they were, whether they were manufacturing batch records, pharmacovigilance records, adverse events, storage and transport, they would have to go and get them, and they could go and get them because that is a business need.

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We also know that there is the deferred prosecution agreement that is referred to, and I think it is footnote two in our brief, where Apotex has agreed with the United States Government that their corporate officers, which include shared corporate officers like the ones we just talked about, can and will provide information to the United States Government on behalf of Apotex.

And it is difficult to believe that they would make these same distinctions for the U.S. Government that they are trying to draw here when they have a shared corporate officer who clearly can go and get these documents from either entity.

What that also tells us is that -- you know, Mr. Henry hasn't produced any evidence because that there needs to be some kind of a board vote in order to do this. It sounds like that not only can, but has already has been done for the United States Government in relation to that deferred prosecution agreement.

I then wanted to talk about Mr. Henry's suggestion that these are two completely separate entities and that they

don't work closely together on this specific product. They do.

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Apotex United States would have no reason for existing but for being the U.S. FDA agent for Apotex Inc., and they wouldn't sell any Ranitidine if they didn't get it from Canada. So, the sole reason that they exist is to sell a product that was made by another Apotex entity.

If we look then at -- I am jumping around a little bit, but I want to make sure I respond to everything that Mr. Henry said.

He also mentioned alter ego and personal jurisdiction. I agree and I have heard, your Honor, that that is not what we are here for today and it is not what we are asking for. The reason that all of this information was included here is just to show that Apotex U.S. does in fact have access to the documents for Apotex Canada.

So, we are not asking your Honor to rule on personal jurisdiction today, and we are on the same page that that is not what we need.

I did, however, want to say that Mr. Henry also made a point about if somebody had a shared corporate officer, I think he said five years ago, we are here today to talk about the here and now, so let's talk about that. They had the same CEO up until December of 2020, and that is in their Exhibit B.

That was while this case was pending, that was while we were asking Apotex for documents from Apotex Canada, and

during that time, even while they had the same CEO, they were maintaining that they were not going to and could not go and get this stuff.

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Again, the case law is very clear, and I think we have already touched on that, that these shared corporate officers, particularly one who is at the top of the company, has the power to go and get the documents, and they have refused to do that in this case.

We also talked -- we touched on Batista, and again, you know, that case I actually think is supportive for our position for the reasons that I just outlined, because these companies did work so closely together on marketing Ranitidine and distributing it into the United States, and it would not have made it from Canada into the United States but for the assistance of Apotex in the U.S.

That is also supported by the NAFTA petition, which is cited on page two of our brief, where Apotex wrote themselves that Apotex Corp exists for the very purpose of allowing Apotex Inc. to operate in the United States.

We have talked about Mr. Hardwick, and again, Mr. Henry has agreed that he holds a senior management position at Apotex Inc. You don't have to be at the top to go and ask for documents, even though we have someone at the top who was there up until the end of last year, as we just talked about, but there are shared corporate officers here, and we also now know

1 that Mr. Krishnan has the ability to go to different 2 companies -- or to both entities and to get regulatory documents. 3 So, for all of these reasons, there is significant 4 overlap between these companies and there is really no reason 5 6 to find that they operate entirely separately. 7 Beyond that, I know that Mr. McGlamry is coming on the screen right now, he is really anxious to talk about the NAFTA 8 9 petition, so I am going to let him chime in and do that for a 10 minute. 11 THE MAGISTRATE JUDGE: One second. For purposes of 12 the record, what is the exhibit number for the --13 MS. GOLDENBERG: For which? 14 THE MAGISTRATE JUDGE: For the NAFTA petition that Mr. 15 McGlamry wants to talk about. 16 MS. GOLDENBERG: It is Plaintiffs' Exhibit B. 17 THE MAGISTRATE JUDGE: Thank you very much. 18 Mr. McGlamry, I'm happy to hear from you. 19 MR. McGLAMRY: Thank you, your Honor. Mike McGlamry 20 on behalf of Plaintiffs. The reason I was so sort of excited to get in here was 21 22 that you started this with saying, one, you had the law 23 covered, you wanted to hear about the facts. For me, I don't

know much about the law, but I do think I know about facts and

I know about common sense and I know what smells like a rat.

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If you look at the NAFTA documents, what that process was, was that Apotex Inc. Canada was seeking to obtain jurisdiction in a dispute about NAFTA by telling, and supporting it with evidence, including Mr. Fahner and Mr. Krishnan -- and Mr. Krishnan at that time was an employee, according to them, of Apotex U.S. and Fahner was an employee of Apotex Canada, even though both have switched over and right now Mr. Fahner is a director of U.S., although he was an officer and director until about a month or two ago.

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But the point that Apotex Inc. was trying to make was -- to get jurisdiction was, look at how invested, and that is the word they used under NAFTA, in the United States.

What they submitted was statements, which we have asked them to give us and they have said no, and this intercompany agreement that Mr. Henry referenced that we cited. We have asked for it, and although he cites to it, he has never provided it, which does apparently lay out the relationship and the who does what sort of stuff, but what we know they told NAFTA, and not just argued because they presented evidence — and unfortunately, in this kind of scenario we don't have a chance to generate evidence like they do.

So, their evidence that they generated there, which I think it is important, we can only see now what they said it said, which is Mr. Krishnan, as an employee of Apotex U.S., was put there by Apotex Canada along with six other people to work

for them in the U.S., for their business in the U.S, and they were telling NAFTA, or this process, that they were investing — and they blanked it out, and it is in their exhibit, they blanked out the millions of dollars that they had invested in the United States in litigation. That is part of their model, and what they told NAFTA was, Apotex Corp was put here by us to litigate.

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Now, I know that is not talking about manufacturing, which I will get to in just a second, but in terms of what the relationship is and who has access to it, the NAFTA stuff, if you look, because I have, their statement, which was only 179 pages about how invested they are in the United States, it goes on because the United States responds and says, wait a second, everything we have ever seen you say in litigation is you all don't do anything here in the United States, the same sort of thing we are getting here, yet elsewhere they are saying just the opposite. I think factually the tie goes to us because we can't generate evidence.

If you talk about manufacturing, Apotex U.S. is licensed in the State of Florida as an over-the-counter manufacturer, and if you look at those statutes and regulations associated with that, and their application, they are bound by manufacturing guidelines.

I think that is what Marlene was essentially saying is, look, you can say we don't have it, that does not mean you

are not responsible for it or you can't get access to it. The fact that they have a system that could easily click a button and open it up to anybody they want to, they set it up in a certain way. That happens in every system and that's probably true in my office and I don't know what I can get access to, but if I ask somebody, I be damn well sure I get those documents.

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Just like Mr. Fahner and Mr. Krishnan and all these people that won't tell you the truth because -- Terry has never answered this question, and we have asked it: Have you all asked Canada for this material? Have you asked for access?

Because the answer to that is absolutely.

I will end with this piece about, well, this will impact our obligation. I hear that, that is not our cross to bear. If it changes their obligation, that is the position they have taken from the beginning. They have known what the position is.

More importantly, just like we worked with them to say, okay, we will do these 30(b)(6)s without going into these documents if we get with them, we also worked with others who said, okay, we are going to put up somebody from the parent, from the foreign entity that does know all of this stuff because we are technically, and from a legal obligation, bound by -- we sell this stuff, so we are responsible for it. We may not do it ourselves, these 12 people in the office, but we are

part of it, so we will bring Mr. Smith down from Canada, and he can explain it.

The obligation doesn't, to me, affect what the facts are. Look, to me, we are sort of dancing on the head of a pin about what they can do and what they can't do. How their systems are set up, that is fine, and if that is saying that's the only thing in the ordinary course of business means, and even though I don't think the law supports that limitation, but you know that better than I do.

The reality is, they have access to this stuff, you know, and the reason I believe that is because we have asked for the evidence that would support that that is already generated by them and they won't give it to us.

That is all I have, your Honor. Thank you.

THE MAGISTRATE JUDGE: Thank you very much, Mr.

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McGlamry.

All right. Ms. Goldenberg, anything else on behalf of the Plaintiffs?

MS. GOLDENBERG: I am happy to answer any questions, your Honor, but I think I have gotten through my list.

THE MAGISTRATE JUDGE: Let me double check my notes here. No. I will turn back to Mr. Henry -- since I let Mr. McGlamry speak, I will let Mr. Henry or his colleague speak if they want to speak.

Before I forget, though, I don't know if it was in the

cover email you sent or it was in one of the pleadings, but the parties indicated some of the materials that were appended to the submissions to the Court are marked either confidential or attorneys' eyes only. I will grant you leave to file those under seal. I don't remember which ones they are, but I will grant leave to file any exhibit under seal that is marked confidential or attorneys' eyes only under the appropriate PTO.

Back to Mr. Henry, or his side, if there is anything -- I will give you the last word.

MR. HENRY: Just a few points to address some of the things Ms. Goldenberg and Mr. McGlamry raised.

Our view of PTO 60 is this: It laid out clearly how foreign defendants are supposed be treated, separate, arm's length, but it also did put on the U.S. affiliates an obligation to respond, to produce documents in their possession, custody, and control even if those documents were from a foreign entity. We have done that, that is what we have fulfilled.

Since I was involved in negotiating that portion of the PTO and the prior generic discovery agreement, that was certainly our vision of what those words meant.

Plaintiffs' discussion about the deferred prosecution agreement, again, an irrelevant piece of litigation, but more to the point, that was about pricing. Right? And it also was a deferred prosecution agreement as to only Apotex Corp.

Apotex Inc. wasn't involved in that at all, so it has absolutely no relation to anything that is at issue before the Court on possession, custody, and control.

Ms. Goldenberg suggested that it was Defendants' burden to demonstrate that Apotex Corp could not enforce a demand for documents. Right? That is not the standard. The standard is, it is Plaintiffs' burden to show that we have access to the documents, and I think we have demonstrated that we don't.

Finally, to address Mr. McGlamry's conclusory remarks about the NAFTA submission, I will only say that Mr. McGlamry makes numerous unwarranted leaps of logic based on the actual assertions in the NAFTA petition.

So, we have reviewed that, and we actually find it very consistent with the facts that we talked to the Court about today, that these are separate entities, they each have their own role.

Mr. Krishnan, as the vice-president of global regulatory, is here to perform regulatory activities for all Apotex affiliates. So, what is in the NAFTA petition is not a surprise.

As part of that investment that Apotex Inc. has made in the U.S., it is to compensate Apotex Corporation for providing those services and for providing other services, which is what separate corporations that maintain corporate

formalities, that is what they do.

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So, there is no untoward conclusion to take away from how these folks have structured their businesses. It is perfectly normal and it is what they do in the normal course of their business, and it does matter, based on the case law on possession, custody, and control, what an entity has access to and what it doesn't have access to, and I think we have laid that out today.

With that, I will rest, your Honor.

THE MAGISTRATE JUDGE: Thank you very much. Very well argued on both sides, very well briefed, interesting topic that I am going to spend some time taking under advisement. I will try to get an order out quickly. I know you have matters that need to move forward based upon the decisions that I am going to make and I will try to get an order out quickly.

Unless there is anything else from either side, we will be in recess. Thank you very much.

Was there somebody else who had something? Yes.

MS. GOLDENBERG: I apologize. To the extent that Mr. Henry is taking the position that the two individuals we discussed are not currently officers of Apotex, Ms. Finken was kind enough to email me in the background the Canadian corporate registration information that does list both of them as corporate officers of Apotex Inc., and with your permission, I would like to supplement our submission with that.

THE MAGISTRATE JUDGE: Show it to Mr. Henry. If there is no objection, you can submit it as a supplemental exhibit. If there is objection, you can submit it noting his objection, and I will determine whether I should consider it or not. MS. GOLDENBERG: I appreciate it. THE MAGISTRATE JUDGE: Thank you very much. Have a good day, everybody. (Thereupon, the hearing was concluded.) I certify that the foregoing is a correct transcript from the record of proceedings in the above matter. Date: April 10, 2021 /s/ Pauline A. Stipes, Official Federal Reporter Signature of Court Reporter

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45/4 46/21	number [5] 2/2 3/2 6/20 27/7	ordinary [1] 43/7
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