UNITED STATES OF AMERICA

EASTERN DISTRICT OF LOUISIANA

NEW ORLEANS

IN RE: PROPULSID PRODUCTS LIABILITY LITIGATION

DOCKET NO: 1355
NEW ORLEANS, LOUISIANA
SECTION: "L"
APRIL 19, 2001

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TRANSCRIPT OF HEARING
BEFORE THE HONORABLE ELDON E. FALLON
U. S. DISTRICT JUDGE

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P-R-O-C-E-E-D-I-N-G-S

THE COURT: Good morning. Call the case, please.

THE CLERK: IN RE: MDL 1355.

THE COURT: Counsel, make appearances for the record.

MR. HERMAN: May it please the Court, good morning, Your Honor, Russ Herman of Herman Mathis. We are here on behalf of plaintiffs in this action this morning.

MR. IRWIN: Jim Irwin on behalf of the defendants.

THE COURT: Thank you. We are here assembled for the monthly meeting to receive reports from laison counsel as well as to hear argument on a motion before the Court, several motions before the Court. Let me hear from counsel first in connection with their monthly report and then we will go into the motions.

MR. HERMAN: Good morning, may it please the Court, its customary for a new member of the laison committee who has not been previously introduced to Your Honor to do so, Mr. Jim Caprotz of California is here today.

THE COURT: As I mentioned, on previous occasions, I'm interested in you all participating. Hopefully, the system, and the state and federal cases, will profit by your participation. If you have any questions or suggestions at any time, please feel free to state them.

MR. HERMAN: Your Honor, with regard to the virtual document depository, we are still discussing the issue. I'm pleased to report, however, that our continuing the discussions

have not delayed any production and have not interfered with any coordination. We may be able to reach a resolution. I don't think, frankly, we have made any progress in that regard, neither party has made any progress in that regard since the last meeting but we are paying attention to it.

THE COURT: As I understand it, you are all producing documents in electronic form and you are using them in that format?

MR. HERMAN: Yes, Your Honor, we have received, as of yesterday, another thirty-three disketts, we have about a million three hundred thousand images. What we do is download those into hard copy, they are reviewed, its an ongoing six day a week process at the plaintiffs' document depository and subjectively coded. I was out there myself yesterday for three or four hours. We had more than ten individuals from member firms coding and the operation is proceeding very smoothly and very well. The defense counsel have cooperated in the production and we have had very little problems.

THE COURT: Somebody ought to be keeping an eye on how you will deal with this during trial. With this many documents, it will be a monumental undertaking. Everybody's in the discovery mode, focusing on collecting the information and dealing with the information, but lets not lose sight of the fact that the whole purpose of this exercise is to get ready for the trial aspect of the case. And oftentimes it's helpful to have at

least someone, you know better than I, at least somebody, keeping an eye on how to present this information during the trial of the case. Its a monumental task and if you have two million documents you have to begin to focus on how to produce it at trial with a jury. So, in the formative stages of the matter, someone ought to keep an eye on that aspect of the case. Okay.

What is happening with the master complaint and answer?

MR. HERMAN: Your Honor, we presented a position paper on March 22nd to defense counsel regarding our concerns about master complaints, we expect to receive their reply and opposition paper, meet and confer on the issue, attempt to resolve the issue before our next monthly meeting.

I could report that there have been two additional class actions that I know was filed. One has been removed to a Tennessee class action, which I believe is conditionally certified. And frankly speaking, the recall or the withdrawal of the product from the market was July 2000 and I would expect that most of the issues that can be pled will be pled by that date. And we do have folks looking at the master complaint issue.

THE COURT: Anything from defendant?

MR. IRWIN: Yes, Your Honor. We agree with that and we would add that we appreciated the receipt of the position paper from the plaintiffs' steering committee. We plan on getting a response to them promptly. We will confer with them. I feel that we are going to disagree with this, I feel that we

are, and if we do, we would hope to present it to Your Honor next month.

THE COURT: Where are the potential areas of conflict, what's the area that you're concerned about?

MR. IRWIN: I think they are an interpretation of whether the class certification issue should be decided here or in the remanding courts. The implication of Lexicon, of which we disagree. The need to administratively resolve what we think is a question that is customarily resolved at the MDL setting, mainly a class action setting and I think we have philosophical disagreements with that.

MR. HERMAN: If I might expand on that very briefly. It may be helpful, once the defendants' position paper is in final form, that we present to you informally both position papers. I can say that philosophically I'm very sensitive to, PSC is very sensitive to depriving individuals of individual rights. The multi-state nature of this MDL, which now was eighteen states, I'm sure the defendants can fill the Court in during this hearing as to how many states now cases have been MDL, a number of states don't recognize medical monitoring, a number do, a number recognize different concepts of medical monitoring, although all are equitable in the nature of equitable relief, one of the problems with the master complaint is adjusting the preservation of individual rights to proceed at a home court as against the judicial economy and efficiency of a

master complaint. To that end, yesterday, in a telephone conversation we attempted to see if we could get together, and I think we can on some form of totalling agreement and filing process. It may resolve the issue in that we can in that respect file a master complaint. As Your Honor knows, Louisiana does not recognize totalling agreements, but most states do, that may ease the situation a great deal.

Rolling document production. As I indicated to the Court, the total number of documents produced on CD roam of the three million U. S. documents to be produced exceed one million five hundred thousand documents and an additional fifteen thousand documents produced in paper form in connection with depositions.

We are attempting to work on with the defendants on sequencing, which has been a problem, a mutual problem. There are some categories of documents subject to a motion to compel, defendants' objections --

THE COURT: Let me encourage both sides to give some serious thought to sequencing. That will be a time saver for both sides. To get the caboose before the engine doesn't make a lot of sense. If you can start and go from front to back or back to front in some logical order. Whatever way you are going, it's easier, and in the long run will be beneficial to both sides. A haphazard approach will likely result in requests to retake depositions and redo discovery and that causes a lot of

rescheduling problems as well as substantive problems. I know forensicly its often a knee jerk reaction to make discovery responses a little fuzzy around the edges; that's unfortunately the way we sometimes operate within our discipline; but in the long run you will save time and cost and it will be better for both sides to proceed in some rational order.

MR. HERMAN: Your Honor, I don't want to leave any inference that the defendants have not cooperated in sequencing.

THE COURT: I did not infer anything either way, I just see that sequencing is the way to go for both sides, and its the same way with the plaintiffs, I would expect the plaintiffs to cooperate with the defendants and the defendants to cooperate with the plaintiffs.

MR. IRWIN: Your Honor, may I make one comment?

THE COURT: Yes.

MR. IRWIN: I appreciate the remarks of plaintiffs' liason counsel, we had endeavored to address their sequencing request. As a matter of principle we tried to produce safety information up front. I know the Court knows that. There have been occasions where activities in some state litigations where sequencing have gotten a little bit out of wack, we were being requested to do something in a state setting that was not in order. here, and, of course, we have an agreement in principle with the plaintiffs' steering committee that whenever we produce something earlier on, in a state setting, we produce at the same

time to the steering committee.

Those have been some of the problems that we've encountered, but I'm happy to say that more recently I feel that there are fewer of those intersections of the state and federal sequencing problems. Maybe that's to the credit of our committee hearings, I hope so.

MR. HERMAN: With respect to the depositions, because various depositions have been noted in the state actions in addition to what we have noticed in the MDL, we have had participation by the laison committee members and PFC members attending those depositions, the defendant has agreed to reserve our rights to retake those depositions if need be. We don't anticipate a problem deposition-wise. First of all, we have attemted to resolve differences with the state lawyer so that we don't interfer with their depositions while still protecting the rights in the MDL. The defense has fully cooperated in that regard.

Your Honor, the next issue is electronic document production, which we addressed a motion briefing and hearing status right now, we have motions today, we have some -- another issue --

MR. IRWIN: On the joint report and I believe on the agenda, Your Honor, was a reference to electronic service and verilaw and I was hoping that we wouldn't have to spend any rocket fuel on that this morning. But just this week, Mr. Davis

and I were dealing with verilaw concerning an issue about the fact that some of our briefs recently have been filed under seal and questions about whether we need to take any more security measures. But I'm happy to know that verilaw can accommodate that. Mr. Davis and I do not know quite where that is right now, but I wanted to bring that to the attention of the Court.

MR. HERMAN: As Your Honor is aware, we have a motion set for hearing today. We -- with regard to electronic document production and protocol, we have a joint order to submit to Your Honor today, its been the subject of negotiation now for three months. We believe that it serves the Court and serves our clients mutually. It is the first electronic order to be submitted to a federal court that we know about. We are particularly pleased that through these very difficult negotiations the defendants and the plaintiffs have been able to arrive at an order which does not involve court time or magistrate time. We will present that to Your Honor during the course of the hearing.

There's one outstanding issue regarding software. We believe we are entitled to the software, the defendants object because the software licensor has a copyright and sometime next week we will have another meeting to confer on that issue pending receipt of the defendant's position paper.

MR. IRWIN: That is correct, Your Honor. We would, and I think this has been discussed with Mr. Davis in Mr.

Herman's office, we intend on supplying the Court and plaintiff's steering committee with our position paper next Tuesday with respect to the software issue. There is an issue concerning language in the electronic protocol involving the most favored nation status, I suspect we will be able to work that out, but we are pleased to submit this to the Court, we think that it can be finalized very soon and this will be the Court's opportunity to take its first look at it.

MR. HERMAN: Your Honor the 30(b)6 depositions regarding corporate organization have continued, it's another deposition scheduled, the defendants have consented to bring a representative from Beerse in Belgium to Philadelphia for that deposition. And the depositions that had been taken have proceeded without any conflict or problem

With respect to patients' profile forms and authorizations, we have had discussions recently about that, but I will turn that over to Mr. Irwin for his report.

MR. IRWIN: Your Honor, we, as the Court may see from the joint report, as of Friday April 13th, we had received one hundred and seventy-four patient profile forms, there were at that time by our count, two hundred and fourteen that were over due and ninety-four more that would become due within thirty days.

Now, there are some -- we have encountered some need to tweek some of our numbers as we started this program of trying to

tract the patient profile forms coming in and those due, there have been a couple of occasions where our information was not quite squared with the information of the plaintiffs' steering committee, but these numbers are close. We send a list once a week every Friday to plaintiffs steering committee and at this point in time, we are satisfied with how these patient profile forms are coming in. We will start looking at those that get to be older. So, for example, we are dealing with patient profile forms that are say thirty days old, we may put them in another category and we may send out a separate letter. If they get older than that, we will bring it to the attention of the plaintiffs' steering committee and so on. We will try to make the appropriate record, if it becomes necessary to present to the Court, to show that there have been ample notice to respond to the requirements of these orders to provide the patient forms.

I would mention one other thing, Judge, that is back on Roman VI of our joint report. This has to do with the submission of the names of the form operating company custodians. And I will have that list by the end of the day. We may still be missing names from three countries and I believe those countries may be Histonia, Bulgaria, and Viet Nam, and I would ask the Court's indulgence if I can not get those names to the Court by the end of the day, we would like permission of the Court, because we think these names are sensitive and its not necessarily been demonstrated that its necessary to disclose

these things at this time, we would like the permission of the Court to submit these names to Your Honor in camera.

MR. HERMAN: Candidly, I have a very weak objection to submitting any names of potential witnesses in camera, however, this was a request made by the Court and it may facilitate things not to have a motion on this issue.

THE COURT: Yes, the way I see it, I don't have any problems with it in camera. The purpose of getting the names is to make sure that the material is received. I think if the Court has a name then the chances are better that the materal will be forthcoming. Its not the intention of the Court to deprive any state liason counsel of an opportunity to know the names, if you need to know the names for some valid reason.

Okay, we're on depositions in state matters.

MR. HERMAN: They are proceeding. Members of the PSC and the laison counsel are contending with reservations rights. Plaintiffs have issued a subpoena to the FDA, a copy has gone to defense counsel, we are in negotiation with the FDA, we received a response yesterday afternoon from the FDA. The FDA, without getting into a lot of discussion, says that they are really over burdened right now, they have a Brady issue with two hundred and fifty thousand documents in some case, they have reslin, they have pulsa, they have P. P. A., etcetera. There are also some issues they take exception to. We are continuing our negotiation with the FDA and hope to resolve most of what's in contest

shortly. The only disturbing factor is that there was an indication in the FDA response that it might be six months before they can produce.

THE COURT: Bring that to my attention, if the Court can do anything to shorten that time, I'm interested in doing it, I don't want to wait six months.

MR. HERMAN: Your Honor, I would like to see what we can do in the next thirty days. If we can't, we will calendar it for the next monthly meeting.

THE COURT: Get a name of somebody that can be subpoenaed.

MR. HERMAN: Yes, Your Honor. Plaintiffs' time and billing matters, we will present that record to you at the bench before we conclude. The service list of attorneys' matters, we appreciate Your Honor's clerk in meeting with our folks, plaintiffs and defendants have made a lot of headway and we think that we will be able to resolve the service list point.

THE COURT: With regard to the future situation, I'm going to add to the consolidation order that counsel, meaning new counsel as they come in, is instructed to contact liason counsel as indicated in the attached order and the Court will send or attach to each consolidation order the names and telephone numbers and addresses of liason counsel so that new counsel will know who to contact and that they have some responsibility to contact those individuals. Hopefully that will help across the

board.

MR. HERMAN: We appreciate the Court's assistance in this matter. We turn this over to defense counsel, very simply the issue is there are other defendants, defense counsel that may be involved.

MR. IRWIN: Yes, Your Honor, we have -- as cases get docketed hear from around the country, we have a few more defense counsel who enroll. In some respcts for pharmacies, they are north large in number right now, but when we originally developed the electronic service protocol it provided that the plaintiff counsel were to submit the verilaw questionnaire and that would be the vehicle for them to be the recipients of electronic services. Now we are learning as we go, probably will do something like that with respect to defense counsel who are coming on board. And working with Miss Lambert yesterday in your office and trying to make sure we have the right list will help us to address this issue. I don't think it's a major issue, but we will be able to deal with it.

THE COURT: If we need some liason counsel we will give that some thought, we can create or if you need be additional people on your committee bring that to my attention, you would know befire I do.

MR. IRWIN: My wife would be most greatful to that, Your Honor.

THE COURT: Anything else on the report?

MR. HERMAN: Yes, Your Honor. Defense counsel in this case, in the MDL, have recently learned that there has been an ongoing study, post the withdrawal of the product, and we are attempting to negotiate an order as to what perimeters of our discovery will be with respect to the ongoing study. Of course, it would be a two-way street, plaintiffs have ongoing studies, we would have to also have to comply with the same order and expect, Your Honor, that we will have that to you sometime next week, presented to you with the electronic discovery order and the position papers as regard the copyright software issue. I have with me today our position paper on that issue and the proposed order. Would you prefer that we submit that today and then the defendants submit their position paper on this copyright issue next week and Your Honor can deal with the order or would you prefer that we wait?

THE COURT: I can do it either way, what's the best approach? Have you considered the procedures used in the Fen Fen litigation? I think they had some similar problems.

MR. HERMAN: I'm speaking now, I'm sorry, Your Honor, I wasn't clear. I'm not speaking now of the issue of ongoing studies, I'm speaking on the electronic discovery issue and the only thing that we have outstanding regarding that electronic issue is the defendants' objection to providing softwear because of the licensor's copyright. Should we present that material to you today or would you rather us wait until next week?

THE COURT: I have no problem either way.

MR. IRWIN: Neither do we, Judge. Whatever your preference is. We will meet next week on that most favored nation language and we are going to submit a response regarding the software.

THE COURT: I'm sensitive to the problems, the potential problems that producing software presents from the standpoint of the user of the software, but that ought to be able to be resolved. The problems ought to be able to be resolved by court order rather than your consent.

MR. IRWIN: We certainly do understand our position to Your Honor in that regard and we are satisfied for the plaintiffs to deliver it now or next week, either way.

THE COURT: Give it to me now.

MR. IRWIN: Would it be appropriate for me to respond to ongoing studies?

THE COURT: Yes, on ongoing studies, lets keep in mind that there have been some approaches utilized in other MDL cses that might be of help to you in this case. So, while it may not square with the problems here, at least there's some ground work laid that might save you some time and effort..

MR. IRWIN: You are correct, Your Honor, and on February 20th, we sent a letter to Mr. Herman's office on a number of matters, including the topic of ongoing studies, and suggested that we look at pretrial order 420 in Fen Fen as a

model for our discussions. And we think its a very good model and that's what we intended to talk to counsel about.

THE COURT: Okay. Some of those issues really are political more than they are substantive in the form, so lets not lose sight of the forest for the trees.

Anything further on the report?

MR. HERMAN: No, Your Honor.

THE COURT: How about from liason counsel, any issues that are concerning anybody?

NO RESPONSE

THE COURT: Lets go into the motions. I have before me two motions. First, plaintiffs wish to strike objections to discovery -- Rule 34 discovery. And second, the plaintiffs move to compel production of certain material from foreign operating companies associated with the defendant in this matter. I've had an opportunity to look at the materials submitted by both sides, extensive briefs and reply briefs, as well as the cases that were cited to me, but I will hear from counsel if they wish to add anything.

MR. HERMAN: May it please the Court, I'm going to try to synopsize views and add something additional.

There are two issues. The defendants raise an issue of relevancy of foreign discovery. Secondly, the defendants raise an issue of burden, economic burden and time burden.

As to relevancy, I don't think there's any question

that the documents are relevant and the discovery will lead to relevant information. When you have the nexus or center of litigation organized in one place and disseminated throughout the world as to efficacy and safety of a drug, then any information which relates to efficacy or safety when the same drug is distributed in the United States is certainly relevant. Not only is it relevant, its critical as to knowledge, foreknowledge, what was done, when it was done, and who did it. The fact is the drug was distributed beginning in 1988 but not in the U. S. until 1993, and not withdrawn from the market until the year 2000. So whatever they knew from 1988 forward, whatever they learned, it certainly is relevant.

It is the defendant who chose to distribute this worldwide. There are a number of infant deaths that have been alleged, attributed to this drug. This drug is under suspension and review in many European countries, even before it was distributed din the U.S. and while it was distributed in the U.S. There were certain inquiries going on as to both efficacy and safety.

Now, Your Honor, exhibits 9, 10 and 7, attached to plaintiffs' brief, indicate that more than a hundred companies and forty inter-related entities are responsible. The defendants have a double edged sword that cuts them both ways. On the one hand, on one edge of that sword, the defendants slashed with that says, oh, everything went to centralization in Beerse. On the

other hand the other side of that sword the defendants wheeled so well, they say well, each entity was responsible for collecting and deseminating and evaluating it's own information. And with this double edged sword its perched like the Sword of Damocles over our plaintiffs' heads, and that's just not fair. So, in addition to relevancy and burden, there has to be an issue of fairness.

Now, subsidiary information or information which is controlled under FRCP 33-A, 34-A, is certainly discoverable.

Now, let me get to burden. The published documents show that from Propulsid alone Johnson and Johnson and Jansen, just in the year 1999, have over five hundred million dollars in cash flow from this drug. And that while there were ongoing proceedings with the FDA, which the manufacturers delayed in the year 2000, while more infant deaths were occuring, and more QT heart problems were occuring they made an additional amount, exceeding five hundred million dollars. That's just in two years out of a span, a whole span of time that lasted more than twelve years. The figure for '99, I understated it, it was actually nine hundred and fify million dollars. For the defendants here to come in and say that it's costly or burdensome when they have withdrawn a drug from the market that they have profitted over a billion and a half dollars on in two years, that a million and a half dollars to gather the information that's relevant in this case is too burdensome, I don't think makes rational sense. It

just doesn't make sense.

The plaintiffs in this case, thus far, have borne all of the expense of their own medical care and their future medical care. The defendants in this case have not profitted one nickel out of the drug which the defendants manufactured, distributed worldwide, promoted worldwide, marketed worldwide, and from which they have recovered billions of dollars of profit.

As a matter of fact, if you take the million and a half dollars the defendants say is exorbitant or burdensome and you spread it over the number of claims just in the U, S., it is not an exorbitant amount, it's not an unreasonable amount and the fact that we do have an MDL, and we do have coordination, has lessened their costs, and their burden.

Should the burden be shifted to plaintiffs? Absolutely not. Just the ecomomics of it belie that. Your Honor, in the days of -- in the days when I was not only computer challenged, but computer ignorant, in days before fax machines, plaintiffs gathered up their briefcases, went to documents, looked through a million documents, selected fifty thousand or twenty thousand, those were copied and transported back. That is not an unreasonable burden, that is an alternative. We are willing to go where the documents are, review them, tag the onces we want, have them copied to image. Its not us whose placing this burden of having every document imaged, every document gathered, every document transported, because we are willing to just go and

select what we need. I don't see why that can't be done. Now if the defendants want, for their own organization, to image every document, bates stamp every document, you know, I think that this whole burden issue, and with all due respect, and I know the case law, some of it, developing case law talks about burden, I believe that this is a corporate fog, particularly in a case like this. And I have three, I did go to the document depository yesterday, I said, you know, look, just get me a couple of documents which show the problems with this foreign discovery. And we only have a million five hundred thousand documents of which only three or four hundred have been coded. I've given copies to defense counsel this morning. If we look at Bates number J-0218011, this is an investigation by the foreign inspection team of the FDA.

"Foreign serious, unexpected, adverse drug experience reports are not submitted in a timely manner."

Take a look at the propulsid, fifteen day follow-up reports, second page. "Serious A.D. reports are not being submitted." One of them -- Propulsid isn't submitted for three years until after the deadline. Are we to bear that burden of their poor reporting procedures, of their poor record keeping, of their poor monitoring, of these companies that they control from which they have made profit? I don't think so, Your Honor, I don't think we should.

If we look at the next document JO-738765, it's labeled

exhibit E, we show that in Ireland, for example, there's a lack of support, and that they are having problems, if we turn to the second page, "We have incomplete information from some countries and if at all and we are aggressively implementing the stategy." Well, this isn't a document that stands alone, this is reflective and adds to a problem that was ongoing.

If we look at exhibit 7, two pages, July 2nd, 2000, this is a quarterly exhibit, this is a recent exhibit, this is an exhibit that coincides with them taking the product off the market.

In Europe, the European agency for the evaluation of medicinal products has initiated an article I procedure to refute the benefit risk of Propulsid. The product license has also been temporarily suspended in a number of European countries pending the outcome of the review." This information is necessary, it's relevant, it's discoverable and it does not place an undue burden.

Now, Your Honor, I don't have the document but I submit to you as an officer of the court, based upon information we have received, I did not have an opportunity to obtain the document, we have more documents to review, that there are unreported adverse event from foreign countries. And I think that I'm fully supported by that just in the evidence I was able to gather up yesterday at the depository from a limited examination of documents at the depository.

Therefore in sum, Your Honor, I say to Your Honor that Justice Brandise has a quote that I'm very fond of, "Sunshine is the best disinfectant," Sunshine removes suspicion, sunshine brings forth the truth, and the truth cuts both ways. Maybe we will find, if Your Honor allows this discovery, that there was a great reporting system, that there weren't adverse drug events reported in Europe, that the drug was found to be efficacious. And let me add, as to burden, no one knows how sweet the matter is until the well runs dry. We all want to get to the end of this case, digging a dry well when that sweet water has been denied us. We know now that there's an ongoing study, we suspect, although the defendants haven't reported yet, that that study that they are pursuing for their own defense purposes, far exceeds in cost the the million and a half dollars, the million and a half dollars that they say foreign discovery will entail.

Thank you, Your Honor, for the opportunity to argue.

THE COURT: Response.

MR. IRWIN: Yes, thank you, Judge. I'm going to try to make five points. One, touch briefly on what we believe is the applicable legal standard; two, an analysis of what is requested by this motion; three, a brief discussion of where the burdens are; four, some particulars with respect to the cost and benefits here; and five, our respectfull suggestions as to the appropriate Court relief.

I'll start off, I can't quote Justice Brandise, but I

can quote a respected Judge, and I will do so.

"Although the scope of discovery is broad, the Court may, and no question in my mind should, limit discovery where the burden of expense of the proposed discovery outweighs its advantage or the benefit that is likely to be derived from such discovery. The party requesting discovery, be it plaintiff or defendant, must be as specific as possible as to the nature, the extent, the feasibility, and, of course, the relevance of the discovery. The request must be as particular and specific as possible. General requests in this area are in themselves burdensome."

And those are the words of the MDL Judge, the MDL 1355 on February 20, 2001 in this case. I think that that legal standard sets forth the two basic principles that apply to this analysis here. The first is the cost benefit principle set forth in the first paragraph of that statement of the law. Where one has to balance the burden and expense against the advantage of the benefit.

And the second is the judgment about the request itself, is it specific or is it general. General requests are in themselves by nature burdensome. We think that Your Honor's analysis is totally consistent with the new Rule 26, the amendment to section B-1, which formally said that that which is discoverable is that which deals with the general subject matter of the case.

It was amended and now made more specific and it says, "It must relate to a claim or defense." And discovery of general subject matter is now only for good cause. So I think that the amendments to Rule 26 A-1 are reflected by Your Honor's statement of the law on February 20th. I think that what we need to focus here on is generality versus specificity first and then we will turn to the cost benefit analysis.

So then I turn to point two. When we look at the what is requested here, both generally and then try to judge it specifically, I think it's important to do so against the background of what is and will be produced in this case. Unlike the Bills versus Kennicot case, unlike the Brandname Prescription drug case, Bills involved five thousand dollars worth of costs in burden, and Brandname wasa fifty to seventy thousand dollars costs in burden, here we are talking about reaching into foreign outposts after an enormous amount of information has been produced. The value must necessarily deminish -- So then lets look at the analysis of generality versus specificity. This is what we see and I have extracted these words word for word from the plaintiffs' reply memorandum. They say this:

"These claims and defenses raise the core issues of knowledge, timeliness and action central to this litigation." what did the defendants know, when did they know it. They want to get inside of our heads, that's point number one.

Two, "If information did not flow from the foreign

subsidiaries to the central headquarter in Beerse questions then arise whether the defendants were negligent in the operation of their global pharmacutical enterprise."

They want to examine global information flow. Then they say,

"The information contained in the FOC files must be compared against what the defendants collected in their central system at Beerse."

And they are prepared to send lawyers and paralegals to Beerse or elsewhere to examine and mark for copying or imagining, produce documents or retrieving the electronic information. They want to get inside our heads, they want to audit what's inside our heads and examine the global information flow. I would suggest, Your Honor, with respect to my able opponent, that that is general, that that is burdensome. If we do the analysis by looking at the specifics, go behind the motion and look at the requests, what are we dealing with? Sooner or later you have to get to the nuts and bolts, I'll try to keep the specifics limited, but if you go to their requests for production documents, number 71, it ask for all the documents that you've got regarding direct to consumer advertising. And I will use that as an example for one of our foreign operating companies in Egypt.

73, give me all of your documents concerning meals and promotional expenses and golf outings with prescribers in

Columbia.

76, give me all of your sales training materials that you handed out to your sales people in China.

81, let us have all of your revenue projections in Africa.

And number 90, we would like all of your continuing medical education materials, your course programs, your attendance lists and your speaker evaluations.

I think when you look at those specifics, you can see that that is not relevant and there is no value to it after what we have done and are doing so far.

Point 3, relevance and burden. We believe that the plaintiffs have the initial burden of establishing relevance for their entitlement to this information. Admittedly, Your Honor, it is not a hemolayon burden in the realm of discovery, but there is an initial burden. We take great issue with their argument in the brief and their reference to an exerpt in pretrial order number two, where they say that relevance is presumed. That quotation from pretrial order number number two was taken out of context, I believe, because that referenced the preservation order and it said that documents that are subject to the preservation order are presumed relevant for purposes of the application of the preservation order. It did not say that they are presumed relevant for purpose of Rule 26.

Point four. Costs benefit. In the United States,

these are estimated numbers and these are ballpark numbers, but they are so huge that ballpark or not, I believe that they make a point. I don't think there's any other cases reported any where where this record exists. In the United States there will be produced three point six million pages of documents. In Belgium, the projection is two and a half million pages of documents. That's roughly six million pages. The costs associated with the collection, the mingling, the numbering, the coding, and the review of these documents is projected to be conservatively in the United States five million dollars and in Belgium four million dollars.

There is, therefore, roughly six million pages of documents conservatively costing nine million dollars.

The burdens are not just cost burdens, they are burdens that deal with disruption of business, we are, as Your Honor pointed out shortly ago, dealing with foreign countries, we are dealing with people who speak foreign languages, these are unsophisticated employees by our standards, they don't watch Gretta Van Sustrine at night, many of them will be taking siestas during the day, they have different systems, they have different computer systems, all of us should be mindful of garus and the teaching of the aerostacial, which Your Honor alluded to, it doesn't control here, Your Honor has jurisdiction. But these are notions whose comedy bear examinations and special issues.

What is the benefit at the end of the day for doing

this audit of what's inside our heads on the global information flow, what is the benefit? After six million documents and after thousands of affidavits, which is unrebutted in this case, showing that the safety information, information involving safety of the product, is collected in Beerse and is being produced? I suggest that we look at the seven categories of documents that they -- that I and my side, we had to more or less devine from their motion. We alluded to it in our brief and our comment on it, and also with respect to any response that they made to it in their reply memorandum.

The first category that we thought they were asking for, under the heading of adverse events of reports and studies, we indicated that we are producing all of that, domestic and foreign. I saw no response to that in the reply brief. No quibble with that.

Pediatric licenses. We responded that we can not imagine the relevance of pediatric licenses in Italy, in France, and in South America. No response to our statement on that in their reply brief.

Forty international reports of QT prolongation. We indicated that we were producing that, it may already have been produced, no response to that in their reply brief. The Canadian and United Kingdom epidimiology study, we indicated that it was being produced, may have already been produced, a smaller version of it was attached to our memo, no response. Marketing and sales

data, no, no, a thousand times no. Of course, until Your Honor says yes. But we failed to every understand the relevance of a golf outing in Tangania. Labeling in foreign countries, we do not believe its relevant, nonetheless, since it was collected in Beerse, we are producing it. And finally, category number 7, the knowledge of affects, a broad category. If that knowledge means adverse events, if it means safety, we are giving it to them. If it means what you knew and when you knew it, then I come back to Your Honor's maxium, "The request must be as particular and specific as possible. General request in this area are in and of themselves burdensome."

Your Honor, the final point, number five. The relief that we would respectfully suggest is as follows. If Your Honor is inclined to strike our objection, we would ask that you permit us to substitute our memo in response for our objection because we believe that our memo in response illustrates in detail with affidavits the information that we are producing and how the design is collected and distributed.

With respect to the motion to compel, that aspect of the plaintiffs' motion, we ask that Your Honor dismiss that motion without prejudice at this time. We ask that Your Honor permit the production to proceed and we suggest that if the production proceeds further and if the plaintiffs require additional information from the foreign operating companies, that the parties be called upon to meet and confer as we have done so

successfully in this case so far. And so, for example, were it to come to the attention, as I was shown this morning, and for the first time, this document J0-218012, that there was a ADE event report that was three years old, which incidentally this information has been produced, and how much more information is out there about that, I don't know, but there was enough in this document apparently to satisfy the FDA, that it was late, we will sit down and talk about it before we start interrupting people's siestas at great expense.

And finally, Your Honor, failing an agreement on our ability to might and confer, we would suggest that it would be appropriate to submit it to Your Honor or Magistrate Africk and a decision be made in accordance with Your Honor's statement of law made on February 22nd. Thank you, very much.

THE COURT: Any response?

MR. HERMAN: Yes, Your Honor.

Lets talk about the standard first. Look at the commentator's remarks, the standard really hasn't changed, and even if it had changed as far as relevant discovery, in the words, defenses, we have the defendants here who are pleading negligence on the part of plaintiffs, learned intermediary defenses, safety and efficacy issues, and certainly all the information which we have requested relates to those issues.

Now, counsel next says what about, lets look at the particulars of what's requested. Well, that's interesting,

submissions to regulatory agencies, that's certainly particular and relevant. Propulsid's adverse experience, reported anywhere in the world. They say that they have an obligation to do that, so what's wrong with discovering it?

The next, was any testing done any where in the world regarding Propulsid, we are particularly concerned because we think there's two ongoing studies after this was withdrawn. One in the U.S. and one in Europe.

What about the premarket testing from 1983 to 1988 -- excuse me, 1981 to 1988 and then premarket testing before it got to the United States, some five years later in 1993, certainly relevant, certainly particular.

Marketing initiatives, yeah, it sounds trivial to say that Gary Player in South Africa took a group of representatives, perhaps some from the United States, on a golfing tour of three or four golf courses to discuss the wonderful drug Propulsid and the representations to whoever went. Do I know that happened, no, I'm using it as a metaphor. It's certainly a stronger metaphor then just saying what do they need to know about a golfing tour, we don't even know if there was a golfing tour, or what the perimeters were. I think the defendants have attempted to shift the focus and very adroitly, I congratulate them, from this case to some atherial case that doesn't exist. This isn't a burden that we are placing go on foreign countries, this is a foreign country that manufactured this drug, distributed it

everywhere else and then brought it to our country. This isn't where you go out and you say okay, foreign country, we are going to subject you to our jurisdiction. This is a foreign corporation in the true sense, a Belgium corporation controlling forty other companies, doing business in the United States and the international arm is housed in Titusville, here in this country. So this whole argument about imposing some burden on foreign countries, I mean literally is a buggabo, it begs the entire issue.

Costs benefits at the end of the day. They said they will produce six million documents, well, that's wonderful, we only have a million five. And we only had a million two before yesterday, and they had almost two years of this information gathering from the time the first suit was filed. And now, the suggestion that this process ought to be delayed so we can meet and confer and meet and confer and bring it back and go to the Magistrate, and then come argue to Your Honor about an issue that's ripe right now. Mr. Klousen's affidavit? No, we didn't put an affidavit against Klousen, we don't control their corporate employees. But I tell you what, I reserved the right to take Dr. Klousen's deposition and Dr. Klousen's own sworn testimony to date contradicts defense counsel's statement that gee we are dealing with foreign languages and forty countries and Dr. Klousen, under oath in deposition, in this case, has stated the language of propulsid is English.

For defendants to come here and say, you know, we've got unsophisticated people in these forty countries who are looking at this drug and making report on effacacy, we've got people that take siestas in foreign countries, and they're so undependable, Judge, how can you make us produce documents from people that are unsophisticated, who hates the essence, we can't be responsible for the people we hired and trained and what they produced. And that is the problem. If you've got unsophisticated people who are sleeping on the job, how do we know that the captain of the ship is replacing those oars people with people that can pull the ship, that will comply with what their obligations are. And the only way to test that, the only way to test that is through the light of day. And I don't blame them for saying we want to get into their head, we have an obligation to get into their head. Motive is whatever juror looks for. Motive is something the judges consider. And how do you get motive if you can't get into somebody's head? And where in the rules or in what case has it every been a bar to plaintiffs' discovery that we can't determine what the mind set of some corporate giant in Belgium, whose making billions of dollars promoting a drug in the United States, what their mind set is.

Now, with regard to pediatric licenses, of course we are entitled to that. There are more than two thousand reported SIDs deaths, alleged in some of them in medical journals to be

caused by Propulside. This drug was never approved for pediatric use in the United States.

What did the pediatric licenses in Tanganika say, or in China about what representations were made. Aren't our people in the United States entitled to know that, doesn't it form the nexus of relevant information and what they knew in their mind and when they knew it?

The foreign international reports of QT prolongation proves a point. At that point in time they only reported sixty adverse events in the United States, but there were forty reported internationally. We don't know what the unreported census is, and these defendants admitted, they are not as sophisticated in what they do. And the only way we will find out how many real adverse events there were is by getting into the documents.

Now, marketing and sales documents are always important, every product case that's disseminated to consumers on a worldwide basis and promoted with million dollar budgets, multimillion dollar budgets certainly is discoverable and relevant. Its not just what they represented here, it's what they represented their, and any conflicts in those representations.

And what the defendants want us to do is go through their six million documents, oh, gee, Your Honor, go to them and say, you know, we found in your documents that you have posession

of, that you've coded, that you've been working with, that you have knowledge of, we found in the country of China that there were sixty adverse events that were never reported to Beerse and you never reported to the FDA, and then we will meet and confer. And then we will come to Your Honor and Your Honor is going to say, okay, now go to China, or bring it to the Magistrate and then we're going to argue and brief before the Magistrate and then come back here on the same issue.

I just don't think that the remedy that the defendant suggest is reasonable in this case or in any case given these circumstances. We have no objection to the defendants submiting their briefs and the Court utilizing that as their objections. Of course, we agree to that.

To strike our motion to compel, we think our motion to compel is compelling. to proceed as we are now, its one thing to deal with sequencing, it is another thing to say, hey, we are not going to get this discovery. The defendants want to meet and confer with us about allowing us to look at the documents in these foreign countries to some where down the line, that's a matter we can meet and confer on, but not whether we have the right to do it.

So most respectfully, Your Honor, the standard relates to their defenses. We did request particulars. The burden was not created by us and indeed it is not burdensome in terms of the overall case. In terms of benefit, where is the defendants'

crystal ball that there is no benefit at the end of this. I would like to defend a case and say, you know, if I produce documents I want the Court to accept that at the end of it there will be no benefit to the case.

And lastly, Your Honor, most respectfully, we believe that this is an issue that both sides have worked hard to resolve, we have reached a matter that we bring to Your Honor's attention, it is one of the key issues in this case. And we thank Your Honor for your attention to this matter.

THE COURT: Thank you. Both sides, as I have said, have favored me with thorough briefs, and I have profitted from the oral arguments. I'm ready to rule on the motions.

The plaintiffs in this particular case submitted a Rule 34 merits request for production of documents. The request contains over one hundred requests with over one hundred subparts. The plaintiffs' request for production defines the defendant, that is to say the party or parties who are to furnish the response, to respond to the response, to include, "every company affiliated with each such company by common ownership or control."

The defendants object to the production of the documents from any foreign facilities other than the documents from Jansen Pharmaceutica N.V. in Beerse, Belgium. Such documentation the defendants claim are neither relevant nor reasonably likely to lead to relevant discoverable material.

Therefore, the defendants, in essense, decline to produce documents created, or for that matter, located at other foreign operating companies, [FOCs, as they term them] affiliated with Jansen, even though these companies may have had something to do with Propulsid.

It should be noted, however, that the defendants have agreed to produce, and are actually producing, or will produce all potentially relevant documents located in any Jansen or Johnson and Johnson in the United States as well as the Jansen Pharmaceutica N.V. in Beerse, Belgium. These documents are being provided in CD ROM format with sortable index of objective coding and searchable OCR text for unredacted documents.

The plaintiffs move to strike the defendants' objections and seek also to compel production of the documents from all foreign entities affiliated by common ownership or control. The plaintiffs claim that the information is relevant and necessary to the preparation of their particular case. Defendants, on the other hand, respond that the requests are overly broad, they also argue the requested material is irrelevant and that the requests are burdensome.

The defendants' claim of irrelevance does have some merit. There has been some change in the definition of "relevance". For over five decades Rule 26 defined the scope of discovery as, "Any matter not privileged which is relevant to the SUBJECT MATTER involved in the pending action." On December the

1st of 2000, the rule was amended to limit discovery, "to matters relevant to the CLAIM OR DEFENSE OF THE PARTY," except for good cause. The thrust of the change seems to be to reign in discovery, or restrict it somewhat and to give the Court a greater hand in deciding the scope and nature of the discovery. Moreover, some of the requests call for information which is or may be specific to the location or locality. For example, the application requirements to regulatory agencies may be different; also, stress, diet, custom usage, and other factors may well differ greatly from country to country. All of this supports a claim of irrelevancy.

However, the defendants arguments attacking or seeking to debunk relevancy is substantially weakened when the nature of the plaintiffs' claims is scrutinized. The plaintiffs contend that the defendants designed, manufactured and marketed an unsafe product. That they misrepresented the safety of the product, which they knew or should have known was unsafe. That they failed to warn of known risks of the product. What the defendants knew or what they should have known, and when they knew it, or when they should have known it is an "issue" in the plaintiffs' claims.

In this regard, it is significant to note that the plaintiffs claim that there is some evidence to indicate that Propulsid was marketed for years abroad before approved in the United States. The drug was introduced in Europe in 1988 and was

placed on the market in the United States in 1993. Plaintiffs suggest that there may have been some side affects or adverse reactions before 1993, the time it was introduced in the United States and perhaps as far back as 1981. If so, the foreign subsidiaries, so say the plaintiffs, may be the warehouse or the repository of such information. Therefore, the relevance requirement, even under the most conservative or restrictive view of the present Rule 26, may be satisfied.

However, relevancy is not the only factor to be considered, particularly in a manner of this nature. An MDL case involving perhaps several million documents, costing many millions of dollars to produce, with potential likelihood of business interruption presents peculiar problems. The court, according to the cases, is authorized to limit discovery if it determines that, (1) the discovery sought is cummulative or duplicative or is obtainable from some other source that is more convenient, less burdensome, or even less expensive. Or where the burden or expense of the proposed discovery outweighs its likely benefit, taking into account the needs of the case, the Court may consider the amount in controversy, the parties resources, the importance of the issues at stake in the litigation, and the importance of the proposed discovery in seeking to resolve the issues.

Moreover, in this particular case, we are confronted with foreign discovery which adds an additional element. The

cases seem to make some distinction in foreign discovery as it relates to non-foreign or United States discovery. The seminal case on this issue is Societe Nationale Industrielle Aerospatiale v. United States 482 U. S. 522 (1987), which the Fifth Circuit picked up in In Re Anschuetz and Co 838 F.2d, 1362, (1998).

The Court in Aerospatiale suggests that American courts in supervising pretrial proceedings involving foreign entities should exercise special vigilence in order to protect foreign litigants from the danger of unnecessary or unduly burdensome discovery. Objections to discovery that foreign litigants advance should receive most careful consideration. The exact line, the Courts say between reasonable and abusive discovery must be drawn by the trial court based on the particular facts of the case and the foreign interest involved.

Foreign discovery, it seems to me, as articulated in the cases that I have reviewed, imposes issues of comity between nations and also key issues of enforceability. Neither issue is insurmountable, but does require a cautious, deliberate and specific approach.

After considering all of the above matters and balancing the benefit with the burden of the discovery of the records of these FOCs, other than Beerse, it is the conclusion of the Court that it is not appropriate to conduct the broad based discovery that the plaintiff now seeks. At this time, discovery should be limited to the United States and Beerse, as well as

those FOC documents which are being produced and that are traditionally sent to the FDA in the United States and those matters dealing with labeling or scientific safety data, or adverse event evaluation material.

Accordingly, the plaintiffs' motion to strike the objections and the motion to compel production are denied. But let me say this: the problem that I see with the current status of the discovery request is it's broad nature. The broad nature of the requests, in themselves, as I said once before, make it overly burdensome, difficult and in the long run complicates matters more than it helps. The requests are too general and lack any reasonable specificity.

If the parties, in the future, reach the point in discovery where certain specific items, specific locations, specific references in depositions focus on areas which can be defined with more certainty, with greater specificity, then this material or some material from the FOCs may well be not only relevant but also produceable.

Hopefully, learned counsel for both sides will know whether or not this occurs and will act appropriately and it will not be necessary for the Court to take action or even consider the matter.

Thank you, gentlemen.

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