



1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

CHAMBERS OF
U.S. DISTRICT COURT
ELDON E. FALLON
UNITED STATES OF AMERICA
EASTERN DISTRICT OF LOUISIANA
NEW ORLEANS

IN RE: PROPULSID PRODUCTS DOCKET NO: 1355
LIABILITY LITIGATION NEW ORLEANS, LOUISIANA
SECTION: "L"
APRIL 19, 2001

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

APPEARANCES:

FOR PLAINTIFF: RUSS HERMAN, ESQ.
LEONARD A. DAVIS, ESQ.
HERMAN, MATHIS, CASEY &
KITCHENS, LLP
820 O'KEEFE AVENUE - SUITE 100
NEW ORLEANS, LA 70113
504-581-4892

FOR DEFENDANT: JAMES B. IRWIN, ESQ.
IRWIN FRITCHIE URQUHART &
MOORE, LLC
TEXACO CENTER
400 POYDRAS STREET
SUITE 2700
NEW ORLEANS, LA 70130
504-310-2100

1 PLC: JAMES DUGAN, ESQ
2 HIAWATHA NORTHINGTON, II, ESQ.
3 LYNN SWANSON, ESQ.
4 ROY AMEDEE, ESQ.
5 JAMES HATCH, ESQ.
6 JAMES CAPROTZ, ESQ.
7 CARLA PERRON, ESQ.
8 JIM ROY, ESQ.
9 BARRY HILL, ESQ.
10 RICHARD ARSENAULT, ESQ.
11 WALTER C. DEMAS, ESQ.
12
13
14
15
16
17
18

10 PSC: REBECCA CUNARD, ESQ.
11 CHRIS SEEGER, ESQ.
12 JULIE JACOBS, ESQ.
13 KIM EVERS, ESQ.
14 GORDON RUDD, ESQ.
15 ARNOLD LEN, ESQ.
16 FRED S. LONGES, ESQ.
17 CHARLES F. PREUSS, ESQ.
18 CARLOS PRIETTO, ESQ.
19 DANIEL BECNEL, JR., ESQ.
20
21 CHARLES V. TAYLOR, ESQ. - COLLINS
22
23
24
25

19 REPORTED BY: PATRICIA DURONCELET-RALPH
20 CERTIFIED COURT REPORTER
21 501 MAGAZINE STREET
22
23 NEW ORLEANS, LA 70130 (504) 589-7781
24
25

23 RECORDED BY MECHANICAL STENOGRAPHY, TRANSCRIBED BY CAT
24
25

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 liaison 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 liaison 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

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

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

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

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

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

7 What is happening with the master complaint and answer?

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

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

20 THE COURT: Anything from defendant?

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

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

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

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

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

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

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

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

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

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

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

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

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

15 THE COURT: Yes.

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

1 time to the steering committee.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

14 Okay, we're on depositions in state matters.

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

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

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

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

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

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

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

1 board.

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

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

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

23 MR. IRWIN: My wife would be most grateful to that,
24 Your Honor.

25 THE COURT: Anything else on the report?

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

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

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

1 THE COURT: I have no problem either way.

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

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

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

14 THE COURT: Give it to me now.

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

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

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

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

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

6 Anything further on the report?

7 MR. HERMAN: No, Your Honor.

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

10 NO RESPONSE

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

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

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

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

1 that the documents are relevant and the discovery will lead to
2 relevant information. When you have the nexus or center of
3 litigation organized in one place and disseminated throughout the
4 world as to efficacy and safety of a drug, then any information
5 which relates to efficacy or safety when the same drug is
6 distributed in the United States is certainly relevant. Not only
7 is it relevant, its critical as to knowledge, foreknowledge, what
8 was done, when it was done, and who did it. The fact is the drug
9 was distributed beginning in 1988 but not in the U. S. until
10 1993, and not withdrawn from the market until the year 2000. So
11 whatever they knew from 1988 forward, whatever they learned, it
12 certainly is relevant.

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

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

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

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

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

1 just doesn't make sense.

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

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

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

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

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

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

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

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

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

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

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

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

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

17 THE COURT: Response.

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

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

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

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

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

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

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

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

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

25 Two, "If information did not flow from the foreign

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

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

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

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

24 73, give me all of your documents concerning meals and
25 promotional expenses and golf outings with prescribers in

1 Columbia.

2 76, give me all of your sales training materials that
3 you handed out to your sales people in China.

4 81, let us have all of your revenue projections in
5 Africa.

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

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

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

25 Point four. Costs benefit. In the United States,

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

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

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

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

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

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

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

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

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

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

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

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

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

15 THE COURT: Any response?

16 MR. HERMAN: Yes, Your Honor.

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

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

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

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

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

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

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

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

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

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

1 caused by Propulsid. This drug was never approved for pediatric
2 use in the United States.

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

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

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

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

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

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

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

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

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

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

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

13 The plaintiffs in this particular case submitted a Rule
14 34 merits request for production of documents. The request
15 contains over one hundred requests with over one hundred
16 subparts. The plaintiffs' request for production defines the
17 defendant, that is to say the party or parties who are to furnish
18 the response, to respond to the response, to include, "every
19 company affiliated with each such company by common ownership or
20 control."

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

23 Thank you, gentlemen.

24 * * *

25