MINUTE ENTRY
FALLON, J.
May 11, 2001

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: PROPULSID PRODUCTS LIABILITY LITIGATION	:	MDL NO. 1355 SECTION "L" JUDGE FALLON

THIS DOCUMENT RELATES TO ALL CASES:

Following the pretrial status conference on April 19, 2001, the Court heard argument from counsel on Plaintiffs' motions to strike objections to discovery and to compel production of documents from entities under the control of defendants Johnson & Johnson and Janssen Pharmaceutica. The Court denied Plaintiffs' motions. The reasons orally assigned for the Court's ruling at the conference are attached to this minute entry.

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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