UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

IMMUNOCEPT, LLC, PATRICE ANNE LEE, AND JAMES REESE MATSON,	§	
Plaintiffs,	§	
vs.	§	CAUSE NO. A O5 CA 334 SS
FULBRIGHT & JAWORSKI, LLP,	§	
Defendant.	§	

PLAINTIFFS' RESPONSE TO DEFENDANT'S MOTION TO EXCLUDE THE TESTIMONY OF MARTHA FELDMAN

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I
INTRODUCTION

This is a patent malpractice case, based upon defendant Fulbright and Jaworksi's ("F&J's) incompetent prosecution of a patent that was intended to cover plaintiff Immunocept's new invention for treating sepsis and septic shock, called Large Pore Hemofiltration. Through a wholly unnecessary amendment to the patent claims, F&J drastically shrank the legal scope, and thus the commercial value, of Immunocept's intellectual property rights. Now F& J seeks to minimize its damages exposure for its malpractice. F&J argues that no financial harm should be attributable to its errors, because the underlying technology is too unproven to provide a basis for assessing damages. Specifically, F&J urges two *purportedly distinct* questions as barriers to any damages award: 1) whether Large Pore Hemofiltration will prove safe and efficacious in the treatment of sepsis and septic shock, and 2) whether Large Pore Hemofiltration will receive FDA approval.

F&J presents those issues as if they were completely independent, hoping to inject the maximum possible uncertainty into the damages computation. Keeping the questions separate, however, depends upon F&J's ability to make the FDA approval process appear to be arbitrary, arduous, unpredictable, and unlinked to the medical merits of Immunocept's invention. F&J would have the jury believe that even safe and effective medical devices and treatments often fail to clear a thicket of thorns at the FDA, never to be approved for general use.

Martha Feldman, an FDA regulatory expert, will testify for Immunocept to rebut that suggestion. She will explain that obtaining FDA approval is not arbitrary. In this case, that means FDA approval will focus on whether Immunocept can show that Large Pore Hemofiltration is a safe and efficacious treatment. Her testimony is critical to establishing that

the two questions interposed by F&J actually collapse into one: is Immunocept's Large Pore Hemofiltration safe and efficacious?

In the current motion, F&J seeks to exclude Ms. Feldman's testimony. They object to her testimony because she is (admittedly) not an expert on the underlying science, and consequently must make assumptions about the efficacy of Large Pore Hemofiltration. Those facts do not in any way bar her testimony on the topics for which it is offered.

First and foremost, Immunocept will *not* offer Ms. Feldman as a sepsis expert, and will not elicit testimony requiring expertise in that field. Ms. Feldman will testify about the regulatory process. To the extent that predicate knowledge of the technical merits of Large Pore Hemofiltration is necessary, Ms. Feldman will rely upon Immunocept's sepsis expert, Dr. Rinaldo Bellomo. Dr. Bellomo has testified that Large Pore Hemofiltration is a safe and efficacious for the treatment of sepsis and septic shock. Just as the FDA does, Ms. Feldman is entitled to rely on the advice of subject area specialists such as Dr. Bellomo. She can testify that if Dr. Bellomo is correct, Large Pore Hemofiltration will be approved by the FDA.

II
LEGAL ANALYSIS

A court may admit expert testimony if (1) the expert is qualified, (2) the evidence is relevant, and (3) the evidence is reliable. *See Kunho Tire Co. v. Carmichael*, 526 U.S. 137, 147 (1999); *Watkins v. Telsmith Inc.*, 121 F.3d 984, 988-989 (5th Cir. 1997).

Here, there is no question that Ms. Feldman is an internationally recognized expert on FDA regulatory issues. She has been President of Drug and Device Development Co. Inc. ("DDD"), an FDA consulting company, since 1985. *See*, Feldman Report attached as Exhibit. B. Ms. Feldman has been an invited to speak on the FDA process to the New Zealand Trade

Association, Biotechnology Group, and the Canadian Government. *Id.* at 2-3. She teaches a course on the commercialization of medical devices at the University of Washington. *Id.*

Additionally, her testimony is clearly relevant to rebut F&J's "regulatory risk" defense. In deposition, Ms. Feldman testified that the FDA process is not arbitrary and that a device that works and is effective will obtain FDA approval.

> Q. (By Mr. Fielding) Would you -- do you consider the FDA process -- approval process to be in any way arbitrary?
> MR. GOLUB: Objection; leading.
> THE WITNESS: For devices, no.
> Q. (By Mr. Fielding) What do you mean -- what do you mean when you say it's not arbitrary?
> A. That the FDA publishes regular guidelines and guidances so everybody knows, if I can use the metaphor, where they are on the page so that the investigators, the sponsors and the reviewers all know what the FDA expects for certain types of products and certain situations.
> Q. So assume for a second, Ms. Feldman, that there is a device that works, that actually -- that actually is effective.
> A. Yes.
> Q. If that device was subjected to the FDA approval process, would you have any expectation about what the results of that process would be?
> A. Yes.
> Q. What would your expectations be?
> A. It would be that the device -- the advisory board would recommend approval and the FDA would approve it.
> (Feldman Dep. at pp. 302-303 attached as Exhibit C).

F&J challenges Ms. Feldman based on the incorrect assertion that she is making "a series of *unfounded* assumptions." Defendant's Motion at 6, emphasis added. However, that is not the case. Certainly, Ms. Feldman makes foundational assumptions, as experts routinely do. Whether or not they are well founded, however, is another matter. Ms. Feldman relies on Dr. Bellomo, one of leaders in the field of sepsis and sepsis treatment. Fed. R. Evid. 703 allows this kind of testimony:

> . . . If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence in order for the opinion or inference to be admitted.

As an FDA expert, Ms. Feldman can rely on medical experts such as Dr. Bellomo.[1] That is precisely what she does.

> Q. Now, Ms. Feldman, have you ever reviewed the CV of Dr. Reynaldo Bellomo?
> A. Yes, I have.
> Q. Okay. And what is your impressions -- what is your impression of Dr. Bellomo's CV?
> A. It is incredible. He's very knowledgeable. He's had a lot of relevant experience in this area. He's published a lot of books. He has a lot of articles. He's an invited guest speaker. He's faculty at a lot of major universities. Sepsis is his game.
> (Feldman Dep. at pp. 298-299, attached as Exhibit C).

Indeed, while F&J argues that Ms. Feldman assumes that clinical trials on humans would prove successful (F&J Motion at p. 7), this is not an arbitrary unfounded leap made by her without basis. Dr. Bellomo states:

> There is a clear case for large randomized controlled trial in septic patients to test whether [Large Pore Hemofiltration] can improve survival and/or other important clinical outcomes.
>
> On the basis of all the available evidence, the probably that this trial would demonstrate such a clinical benefit is clear, real and substantial. Bellomo Report at p. 13, attached as Exhibit E.

Thus, Ms. Feldman's testimony is not based on guesswork or unfounded assumptions. It is based on the testimony of a leading medical authority.

Ms. Feldman's testimony will be subject to cross-examination to the same extent as any other witness. If F&J chooses to do so, they may confront her as to the workings of the FDA approval process. They may demonstrate that her testimony is dependent upon the veracity of the testimony of Dr. Bellomo. They may rigorously cross-examine Dr. Bellomo when he testifies if they wish to attack the foundation for Ms. Feldman's testimony. They may not, however, have her entirely excluded merely because she is not a universal expert, well versed in

[1] Indeed, F&J's expert, Phillip J. Phillips discuss how the FDA uses scientists in the approval process. *See* Phillips report at p. 9 attached as Exhibit D.

every pertinent field, and able to address all possible topics solely from within her own personal expertise.

IV
CONCLUSION

Ms. Feldman is an FDA expert. As such she may properly rely on Dr. Bellomo, a medical expert who specializes in treating sepsis and septic shock. Therefore, this Court should allow Ms. Feldman provide her opinion that 1) the FDA process is not arbitrary and it will approve devices that prove to be safe and efficacious, 2) based on Dr. Bellomo's opinion, the FDA will approve Large Pore Hemofiltration for the treatment of sepsis and septic shock.

Respectfully submitted,

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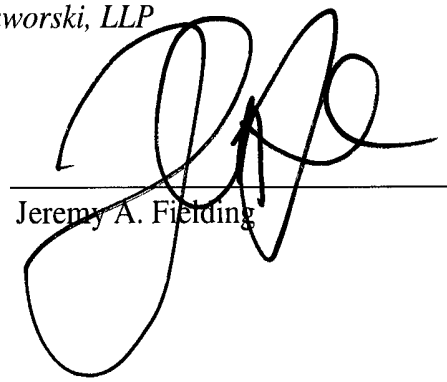

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Fulbright.	§	

APPENDIX TO PLAINTIFFS'OPPOSITION TO DEFENDANT'S MOTION TO EXCLUDE MARTHA FELDMAN

EXHIBIT A: Affidavit of Jeremy A. Fielding

EXHIBIT B: Expert Report of Martha Feldman dated December 19, 2005

EXHIBIT C: Deposition Excerpts from the deposition of Martha Feldman taken February 10, 2006

EXHIBIT D: Expert Report of Philip Phillips dated January 9, 2006

EXHIBIT E: Expert Report of Rinaldo Bellomo dated December 17, 2005

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Notice of Document/Attachment(s) Not Imaged but Stored with Document in Case File

See Original File to View/Copy Document/Attachment(s)

Civil Case No. A:05-CA-334 SS

Immunocept, LLC, et al.

VS.

Fulbright & Jaworski LLP

Attachments to Document #: 69

Description: Plaintiffs' Response to Defendants' Motion to Exclude the Testimony of Martha Feldman

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