

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

FILED

FEB 15 2006

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WESTERN DISTRICT OF TEXAS
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IMMUNOCEPT, LLC,
PATRICE ANN LEE AND
JAMES REESE MATSON

Plaintiffs,

v.

FULBRIGHT & JAWORSKI, LLP

Defendant.

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CAUSE NO. A 05 CA 334 SS

PLAINTIFFS' MOTION TO EXCLUDE THE TESTIMONY OF JOHN R. KIRK

TO THE HONORABLE COURT

Pursuant to Federal Rule of Evidence 702, and this Court's Scheduling Order, Plaintiffs Immunocept, LLC, Patrice Ann Lee, and James Reese Matson ("Immunocept") hereby files their objections to the expert testimony proffered on behalf of Defendant Fulbright & Jaworski LLP ("Defendant") by John R. Kirk.

I. PRELIMINARY STATEMENT

Defendant's attempt to elicit improper expert testimony from its legal expert, John R. Kirk, should be rejected. As set forth below, Mr. Kirk will offer testimony wholly contrary to established law regarding two areas of patent practice: first, Mr. Kirk will assert that language included in the preamble of claim 1 of the '418 patent – "A method of treating a pathophysiological state caused by a toxic mediator-related disease" – cannot be limiting, and therefore could not have been used to distinguish the claim from a prior art reference; second, Mr. Kirk will assert that during the prosecution of the '418 patent it would have been impossible

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to include a negative claim limitation to distinguish the same prior art reference. Because Mr. Kirk's expert report and deposition testimony directly contradict the case law in this area, Mr. Kirk's opinions on these topics should be excluded. Finally, Mr. Kirk seeks to go beyond the written record and speculate as to the mental state of the Patent Examiner involved in the prosecution of the '418 patent. This speculation is beyond the scope of Mr. Kirk's (or anyone's) expertise, and should also be excluded.

A. **Mr. Kirk's Testimony That Contradicts Federal Circuit Precedent Should Be Precluded.**

1. **Standard for Admitting Expert Testimony.**

Federal Rule of Evidence 702, governing the admissibility of expert testimony, provides as follows:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training or education, may testify thereto in the form of an opinion or otherwise.

FED. R. EVID. 702. The Supreme Court defined the parameters of Rule 702 with its opinion in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 591 (1993). *Daubert* imposes a "gate-keeping" requirement on district courts, charging them with the duty to ensure that proffered expert testimony is both relevant and reliable. *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 149 (1999); *Daubert*, 509 U.S. at 597.

With regard to "reliability," the district court must be satisfied that an expert is sufficiently qualified to testify on a particular subject area, and that the reasoning or methodology behind the proposed testimony is scientifically valid. *Daubert*, 509 U.S. at 592-93; *Curtis v. M&S Petro, Inc.*, 174 F.3d 661, 668-74 (5th Cir. 1999); *Watkins v. Telsmith, Inc.*, 121 F.3d 984, 988-89 (5th Cir. 1997). The court must likewise be assured of the opinion's relevance

by ensuring that the expert's methodology or reasoning can be properly applied to the facts at issue in the case. *Id.* In sum, where an expert's factual basis, data, principles, methods, or their application are called sufficiently into question, the trial judge must determine whether the testimony has "a reliable basis in the knowledge and experience of [the relevant] discipline." *Kumho Tire*, 526 U.S. at 149.

The burden is on the party offering the expert opinion to prove by a preponderance of the evidence that the expert's proffered testimony satisfies Rule 702 and the *Daubert-Kumho* standard. *See Kumho Tire*, 526 U.S. at 147; *see also Mathis v. Exxon Corp.*, 302 F.3d 448, 459-460 (5th Cir. 2002).

2. Defendant's Main Argument Regarding the "consisting of" Language and the Nosé Plasma Filtration Patent.

Claim 1 of the '418 patent is reproduced below:

1. A method of treating a pathophysiological state caused by a toxic mediator-related disease consisting of hemofiltering blood with a filter, wherein said filter has a molecular weight exclusion limit of 100,000 to 150,000 Daltons and allows for passage of molecules with a molecular weight of about 70,000 Daltons in the presence of whole blood. (*See* Plaintiffs' Appendix ("Pls' Apx.") at 1, U.S. Patent Number 5,571,418.)

One of the main issues in this legal malpractice case is whether inserting the language "consisting of" during prosecution of the '418 patent was an appropriate way to distinguish over one of the prior art references cited by the Examiner – specifically, U.S. Patent 4,966,709 to Nosé — in light of its extreme compromising effect on the scope and value of the patent. The essence of Defendant's argument is that a reasonable way that the Nosé patent (which discloses the addition of heat to plasma that is to be filtered) could be distinguished during the prosecution of the '418 patent was to add the radically narrowing term "consisting of" to claim 1 – this despite other readily apparent distinctions that would not restrict the patent's scope; for example, the Nosé patent teaches the treatment of high cholesterol (not toxic mediator-related diseases as

is taught and claimed by the '418 patent) by the filtration of plasma (not whole blood as is taught and claimed by the '418 patent) using a filter that will pass molecules that are much larger than those that can be passed by the filter described and claimed in the '418 patent.¹

3. Mr. Kirk's Statements that the Preamble of a Patent Claim Cannot be Limiting are Contradicted by Federal Circuit Precedent, and are Therefore Inadmissible.

One alternative to inserting the "consisting of" language, without sacrificing patent scope and value, would have been to rely upon the preamble language to distinguish Nosé. The dispute on this point relates to whether or not the language in the preamble of claim 1 – "A method of treating a pathophysiological state caused by a toxic mediator-related disease" – is a legally proper basis for such a distinction. In *Catalina Marketing, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002), the Federal Circuit explained the general principles used to decide if a claim's preamble is limiting:

In general, a preamble limits the invention if it recites essential structure or steps, or if it is "necessary to give life, meaning, and vitality" to the claim. *Pitney Bowes*, 182 F.3d at 1305. Conversely, a preamble is not limiting "where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention." *Rowe v Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997).

In both his expert report and deposition, Mr. Kirk argues that a claim preamble cannot be limiting, and cannot be used to distinguish over a prior art reference, even if the prosecuting attorney makes such arguments to the U.S. Patent and Trademark Office. Paragraph 9 of Mr. Kirk's reports states in part:

¹ Defendants' argument requires at least two related assumptions. First is the assumption that the Nosé plasma filtration patent discloses everything taught by the '418 patent with the addition of a heating step. The second assumption, which relies on the first, is that a claim using the restrictive "consisting of" language to exclude the heating step would be patentably distinct from Nosé. This is highly unlikely since Nosé also discusses cascade and double plasma filtration processes, "which operate at near ambient temperatures" (that is, without the addition of heat). See Pls' Apx. at 12, U.S. Patent Number 4,966,709 (the "Nosé Patent") at 1:49-58.

The language [A method of treating a pathophysiological state caused by a toxic mediator-related disease] appears in the preamble of the claim prior to the transition phrase and body of the claim and is thus merely a statement of purpose for the invention and adds nothing to the step of filtering and thus would not be considered a claim limitation. (See Pls' Apx. at 26, Expert Report of John R. Kirk at ¶ 9)

And in his deposition, Mr. Kirk stated:

Q. Okay. Could [the prosecuting attorney] have used the preamble language to distinguish the prior art in Nosé of the two-step process?

A. No, sir.

Q. Why not?

A. It's not a limitation of the claim.

* * *

Q. Why -- well, any other ways in which use the preamble can be used to distinguish prior art other than what you've told me?

A. I think there are a couple of other ways where the -- where the preamble can be a limitation.

Q. Is one of them that where you use the preamble yourself to distinguish prior art, it becomes a limitation?

A. *No, that doesn't become a limitation.* It becomes what you've done then in the prosecution of the application is created an estoppel in litigation later on. You haven't added a limitation to the claim.....

* * *

Q. Okay. So I -- I want to now return to what we were talking about just with respect to the preamble. If [the prosecuting attorney] had used the preamble to distinguish prior art, the examiner could consider that or could not consider that?

A. *Well, he shouldn't consider it, because it's not a limitation of the claim.* (See Pls' Apx. at 143, Deposition of John R. Kirk ("Kirk Depo").)

Mr. Kirk is simply wrong as a matter of law. A preamble will always be limiting *if the applicant argues that it is during prosecution of the patent.* As the Federal Circuit held in *Catalina Marketing*:

...[C]lear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention.²

The issue presented in this motion is whether the prosecuting attorney could have argued

that the language in the preamble distinguished over the relevant prior art reference (the Nosé

² *Catalina Marketing*, 289 F.3d at 808, citing *Bristol-Myers Squibb Co v Ben Venue Labs, Inc.*, 246 F.3d 1368, 1375, (Fed. Cir. 2001). In fact, during the prosecution of the '418 patent, the prosecuting attorney did argue that the language in the preamble distinguished the claimed invention over another patent – the Okamoto patent. See, for example, Pls' Apx. at 56, the June 17, 1996 Response.

plasma filtration patent). The Federal Circuit says the answer is yes, so Mr. Kirk should not be allowed to testify otherwise.

4. Mr. Kirk's Statements that the Prosecuting Attorney could not have Argued a Negative Limitation are also Contradicted by the Case Law, and are Therefore Inadmissible.

Another option to distinguish the Nosé Patent without sacrificing scope and value of the patent would have been to add a "negative" limitation to exclude a feature present in Nosé but not present in the claimed invention. As has been discussed above, there are many differences between the Nosé patent (which teaches, among other things, the filtration of plasma to treat high cholesterol) and the '418 patent (which teaches the filtration of whole blood to treat a toxic mediator-related disease such as sepsis). Defendant argues that despite these other differences, since the Nosé plasma filtration patent discloses heating plasma before the low density cholesterol is filtered, it was reasonable for the prosecuting attorney to add the restrictive "consisting of" transitional phrase to the claim language of the '418 patent.³ In Paragraph 14 of Alan MacPherson's report, Plaintiffs' legal expert stated:

...even if it is assumed that the Nosé et al. patent discloses every element of the '418 invention with the addition of a heating step, a reasonable patent attorney would understand how to amend the claim to exclude only thermofiltration (the heating step) and not all other additional steps that might have been employed with the steps recited in the claim. For example, claim 1 could have been amended with a negative limitation such as "without thermofiltration," or "without the addition of heat." (*See* Pls' Apx. at 40, Expert Report of Alan MacPherson at ¶ 14)

This is consistent with the Sheldon treatise, which endorses using negative limitations, in the very way recommended by MacPherson, to preserve valuable claim scope:

Negative limitations also provide a useful method for avoiding the limiting breadth of closed transition words like "consisting." For example, if it is nonobvious to eliminate the D from a prior art combination comprising A + B + C + D, a negative limitation could read "comprising A plus B plus C, and *absent sufficient D* to..."

³ See footnote 1, *supra*, regarding the assumptions required to support this argument.

Although the claim could be drafted as “*consisting of A + B + C,*” which would exclude D, only the prior claim would cover the combination A + B + C + E.⁴

The specification of the ‘418 patent at 2:27-35 describes the apparatus used to filter whole blood of a patient:

The hemofilter is part of a blood circuit. In passive flow HF, arterial blood flows through a large bore cannula, into plastic tubing leading to the filter; blood returns from the filter through plastic tubing to a vein. This is known as arteriovenous HF. Alternately, a blood pump is used so that blood is pumped from a vein to the filter and returned to a vein or venous HF. Ultrafiltrate collects in the filter jacket and is drained through the ultrafiltrate line and discarded. (‘418 Patent)

In both his expert report (at Paragraph 9) and deposition, Mr. Kirk disagrees with Plaintiffs’ expert. He argues that absent an explicit statement (or an inherent property of something explicitly disclosed) in the specification of the ‘418 patent to the effect that the method disclosed did not involve the addition of heat, a negative limitation would be improper:

Q. Okay. What’s the -- your understanding of the law with respect to being able to distinguish prior art on the basis of a negative limitation?

A. You mean placing a negative limitation on the claim?

Q. Yes, sir.

A. It has to have support in the specification.

Q. Okay. And does that support have to be explicit, or can it be implicit?

A. Unless it is inherent property of something that is explicitly disclosed, it must be explicit. (See Pls’ Apx. at 140, Kirk Depo.)

Once again, Mr. Kirk’s understanding of the law is simply wrong. The relevant question here is whether the originally filed disclosure of the ‘418 patent specification would have conveyed to one of ordinary skill in the art the concept of performing filtration of whole blood to treat toxic mediator-related disease without the addition of heat – not whether the negative limitation is explicitly disclosed in the specification.⁵ As the Board of Patent Appeals and

⁴ Sheldon, *How to Write a Patent Application* (including release no. 16 April 2005) at §6.6.9; emphases in original.

⁵ The issue of whether the requirement for an adequate written description has been met is a question of fact that is driven by the exigencies of each case. *Wang Laboratories, Inc v Toshiba Corp.*, 993 F. 2d 858, 865 (Fed. Cir. 1993)

Interferences stated in *Ex Parte Parks*, 1993 U.S. Pat. App. LEXIS 27, 30 USPQ 2d 1234 (1993), “Clearly, the observation of a lack of literal support does not, in and of itself, establish a prima facie case for lack of adequate descriptive support under the first paragraph of 35 U.S.C. 112.”

The *Parks* case involved a claim that called for the generation of nitric acid “in the absence of a catalyst.” The Board found support for the negative limitation, even though the specification did not explicitly state that no catalyst was used. In support of this decision, the Board stated:

Throughout the discussion [in the specification that] would seem to cry out for a catalyst if one were used, no mention is made of a catalyst.

Moreover, according to two declarations by Wentworth, ... whose expertise in this particular art has not been challenged, one having ordinary skill in the art would have recognized that the reaction generating nitric oxide, according to the equation disclosed in the '562 patent, is conducted without a catalyst. See *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 19 USPQ2d 1111 (Fed. Cir. 1991); *In re Lemin*, 364 F.2d 864, 150 USPQ 546 (CCPA 1966). Thus, it cannot be said that the originally-filed disclosure would not have conveyed to one having ordinary skill in the art the concept of effecting decomposition at an elevated temperature in the absence of a catalyst.⁶

Mr. Kirk inexplicably rejects the correct test set forth in *Parks*, and would not rely on how one skilled in the art of hemofiltration would understand the specification of the '418 patent:

Q. ... Do you know if hemofiltration, that people skilled in the art, these types of medical devices and the process of medical filtration, do you know whether or not they would consider hemofiltration to involve heat?

A. I don't know that.

Q. Would that be an important factor to know in advising this particular client as to whether or not they could use a negative limitation such as our claimed invention doesn't involve heat?

⁶ *Id.*, footnotes and citations omitted. Significantly, citing *Parks*, the Manual of Patent Examining Procedure (“MPEP”) accords with this conclusion, stating “Note that a lack of literal basis in the specification for a negative limitation may not be sufficient to establish a prima facie case for lack of descriptive support.” (MPEP section 2173.05(i), Pls’ Apx. at 61.) Kirk quotes extensively from this same section of the MPEP in his report. (Kirk Report, Pls’ Apx. at 26.) Tellingly, however, he fails to include this language.

A. I don't think so, because the spec still won't support it. (*See* Pls' Apx. at 142, Kirk Depo.)

Since Mr. Kirk's conclusion that the prosecuting attorney could not have argued a negative limitation during prosecution of the '418 patent ignores the correct legal test, his testimony on this topic should be excluded.

B. **Mr. Kirk Should not be Allowed to Testify as to the Patent Examiner's Mental State.**

Again, Defendant's main argument in this case is that the prosecuting attorney appropriately sacrificed claim scope by adding the restrictive "consisting of" language to distinguish the Nosé plasma filtration patent. Here is the actual claim amendment as presented in the January 12, 1996 Response; the new language is underlined.

AMENDMENTS

In the claims:

1. (amended) A method of treating a pathophysiological state caused by a toxic mediator-related disease [by] consisting of hemofiltering [of] blood with a filter, wherein said filter [having] has a molecular weight exclusion limit of 100,000 to 150,000 Daltons and allows for passage of molecules with a molecular weight of about 70,000 Daltons in the presence of whole blood.

The following facts are undisputed:

- When the "consisting of" amendment was made, the prosecuting attorney did not discuss it in her submission to the Patent Office; however, in the "Remarks" section of the Response, the prosecuting attorney presented three pages of arguments to distinguish three prior art references; [*See* Pls' Apx. at 62, January 12, 1996 Response to PTO Office Action; Kirk Depo]
- The Examiner did not mention the "consisting of" language at any point during the prosecution of the '418 patent; [*See* Pls' Apx. at 67, '418 file history; Kirk Depo]

- Several amendments to the claim language were made at the time the “consisting of” language was added. [January 12, 1996 Response]

Despite this, both in his report (at paragraph 8) and in his deposition, Mr. Kirk argues that the Examiner must have relied on the “consisting of” amendment to distinguish the Nosé plasma filtration patent:

Q. Okay. And you're drawing the conclusion that that's what the examiner must have thought from just the obvious nature the change "consisting of." Right?

A. The familiarity that an examiner has with that language, yes, sir.

Q. But there's nothing in the response by the examiner saying that he relied on or was basing any action on the "consisting of" amendment. Correct?

A. That's correct.

* * *

Q. Is there any other basis other than just that "consisting of" is obvious to the examiner that leads you to your opinion that the examiner must have used that as the basis for overcoming the two-step process identified in the Nosé patent?

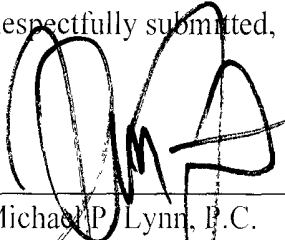
A. At the moment, I can't think of anything. (*See* Pls' Apx. at 139, Kirk Depo.)

Any testimony as to the Examiner's mental state that departs from the written record is speculation and should be excluded. *See, e.g., Lewis v Terrebonne*, 894 F.2d 142, 145 (5th Cir. 1990) (holding that an expert's opinion must be preceded by facts in evidence and cannot be based on speculation and conjecture); *see also Randolph v. F. Laeisz*, 896 F. Supp. 964, 968 (5th Cir. 1990); *Viterbo v. Dow Chemical Co.*, 826 F.2d 420, 422 (5th Cir. 1987); *Eastern Airlines, Inc. v. McDonnell Douglas Corp.*, 532 F.2d 957, 1000 (5th Cir. 1975); FED. R. EVID. 702.

II. CONCLUSION

For the reasons set forth above, Plaintiffs respectfully request that the Court sustain Plaintiffs' objections and exclude the proffered testimony of Mr. Kirk pursuant to Federal Rule of Evidence 702.

Respectfully submitted,



Michael P. Lynn, P.C.
State Bar No. 12718500
Jeffrey M. Tillotson, P.C.
State Bar No. 20039200

John Volney
State Bar No. 24003118
Jeremy A. Fielding
State Bar No. 24040895

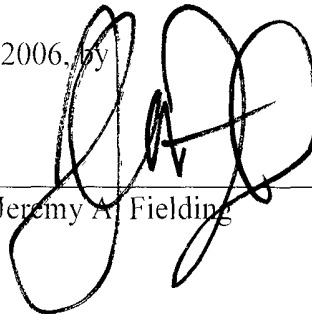
LYNN TILLOTSON & PINKER, LLP
750 N. St. Paul Street, Suite 1400
Dallas, Texas 75201
(214) 981-3800 Telephone
(214) 981-3839 Facsimile

ATTORNEYS FOR PLAINTIFFS
IMMUNOCEPT, LLC
PATRICE ANN LEE
JAMES REESE MATSON

CERTIFICATE OF CONFERENCE

Counsel for movant and counsel for respondent have personally conducted a conference at which there was a substantive discussion of every item presented to the Court in this motion and despite best efforts the counsel have not been able to resolve those matters presented.

Certified to the 13th day of February, 2006, by



Jeremy A. Fielding

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the above and foregoing document has been served as shown below on this the 13th day of February, 2006:

Via Cert. Mail, RRR

David J. Beck, Esq.
Geoff Gannaway, Esq.
BECK, REDDEN & SECREST, L.L.P.
One Houston Center
1221 McKinney Street, Suite 4500
Houston, Texas 77010
(713) 951-3700 Telephone
(713) 951-3720 Facsimile
Attorneys for Fulbright & Jaworski, LLP



Jeremy A. Fielding