IN THE COURT OF APPEALS FOR THE STATE OF OREGON

SUSAN LYNN BLAKE, personal representative of the Estate of Melissa Kay Blake, deceased, **Plaintiff/Appellant,** **v.** **CELL TECH INTERNATIONAL, INCORPORATED, a foreign corporation; and THE NEW ALGAE COMPANY, an Oregon corporation,** **Defendants/Respondents.**	**Multnomah County Circuit Court No. 0504-03928** **CA A135647**

RESPONDENTS' BRIEF AND SUPPLEMENTAL EXCERPT OF RECORD

Appeal from the judgment of the Circuit Court for Multnomah County, The Honorable Janice R. Wilson, Judge

R. Daniel Lindahl, OSB 84276
LINDAHL LAW FIRM, PC
121 S.W. Morrison Street, Suite 1100
Portland, Oregon 97204
503-241-4099

David R. Foster, OSB 80039
BULLIVANT HOUSER BAILEY, PC
300 Pioneer Tower
888 S.W. Fifth Avenue
Portland, Oregon 97204
503-228-6351
Attorneys for Respondents

George W. Kelly, OSB 82298
303 West 10th Avenue
Eugene, Oregon 97401
541-343-1884
Attorney for Appellant

June 4, 2008

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Pages

Cases

Rules and Statutes

STATEMENT OF THE CASE

A. Nature of the action.

This wrongful-death action was resolved by a stipulated judgment in favor of the defendants after the trial court ruled inadmissible the plaintiff's proposed expert testimony regarding the decedent's cause of death.

In this action, Plaintiff Susan Blake alleged that the decedent, Melissa Blake, died from consuming dietary supplements manufactured by the defendants that were contaminated with toxins called "microcystins."

Plaintiff's case was literally unique in two ways. First, if Plaintiff's factual theory were true and the decedent had died from microcystin poisoning, it would be the first known case in the history of medicine where someone in the United States died from microcystin poisoning.

To prove this unlikely occurrence, Plaintiff planned to rely on expert testimony from Dr. Daniel Dietrich, a toxicologist who tested the decedent's liver tissue for the presence of microcystins. Dr. Dietrich would tell the jury that his tests found microcystins in the decedent's liver, and that it was highly likely that the microcystins caused decedent's death.

But there was a problem with Dr. Dietrich's proposed testimony: Dr. Dietrich used immunohistochemistry to test for microcystins in the decedent's liver. Before Dr. Dietrich's experiments in this case,

immunohistochemistry had *never* been used in the manner Dr. Dietrich employed it here. As. Dr. Dietrich testified, "To my knowledge, this is the first time that immunohistochemistry has been used on liver sections in humans."[1]

Thus, Dr. Dietrich's testing methodology was just as unprecedented as the cause of death it claimed to prove.

The trial judge ruled that the proposed testimony was inadmissible because it lacked scientific validity. This appeal followed.

B. Nature of the judgment sought to be reviewed.

After the trial court ruled that Plaintiff's proposed scientific evidence was not admissible, Plaintiff reported that she was "unable to proceed to trial."[2] Consequently, Plaintiff stipulated that Defendants were entitled to judgment in their favor.[3] The court then entered a general judgment for Defendants.[4] The judgment said that Plaintiff reserved her right to appeal the judgment.[5] *See* ORS 19.245(3) (a party to a stipulated judgment may appeal the judgment

---

[1] Tr. 120:19-24.

[2] Trial Order and Stipulation Re: Judgment (circuit court docket entry 39).

[3] Trial Order and Stipulation Re: Judgment (circuit court docket entry no. 39).

[4] ER 9.

[5] ER 9.

if it specifically provides that the party has reserved the right to appellate review, and the appeal presents a justiciable controversy).

C. Statutory basis of appellate jurisdiction.

Defendants agree that appellate jurisdiction exists.

D. Timeliness of the appeal.

Defendants agree that the appeal was timely.

E. Questions presented on appeal.

Did the trial court correctly decide that Dr. Dietrich's proposed testimony concerning Decedent's cause of death was inadmissible because his proposed testimony was scientific evidence that lacked scientific validity?

F. Summary of the arguments.

The admissibility of novel scientific evidence is governed by the application of seven factors derived from OEC 401, 403, and 702. The trial judge properly applied those factors and correctly ruled that Dr. Dietrich's proposed testimony was inadmissible because it lacked scientific validity. Multiple problems with Dr. Dietrich's testimony compelled the conclusion that it lacked scientific validity:

- Dr. Dietrich relied on immunohistochemical testing to establish the presence of microcystins in the decedent's liver. But immunohistochemical testing is not an accepted methodology for testing human liver tissue. Indeed, Dr. Dietrich's work in this case was the first time that anyone

tried using immunohistochemical testing on a human liver.

- Because immunohistochemical testing has never been tried on human livers, there is no scientific literature establishing standards or protocols for conducting such testing.
- Because immunohistochemical testing has never been used on human livers, the rate of error is unknown—except that it *is* known that Dr. Dietrich's testing in this case repeatedly produced inaccurate results, which caused him to adjust his protocols and repeat his tests.
- Immunohistochemical testing involves the application of antibodies diluted in the proper amount for the type of tissue to be tested. But since immunohistochemical testing not used on human livers, there are no standards for the proper dilution of the antibodies. To overcome this problem, Dr. Dietrich simply adjusted the dilution ratios as he went along.
- Immunohistochemical testing requires the subjective evaluation of ambiguous test results—adding to the uncertainty of an already uncertain methodology.

For all of these reasons, and others discussed in this brief, the trial court held that Dr. Dietrich's testimony was inadmissible because it lacked scientific validity. That decision was correct and the judgment should be affirmed.

G. Statement of facts.

Although Plaintiff's statement of facts is largely unobjectionable, it omits certain facts relevant to the issues presented. Accordingly, Defendants present this counter-statement of facts.

1. Plaintiff alleged that Decedent died because of toxins in Defendants' blue-green algae dietary supplements.

Plaintiff Susan Lynn Blake is the personal representative of the estate of Melissa Blake.[6] We refer to the personal representative as "Plaintiff" and Melissa Blake as "Decedent." Plaintiff brought this wrongful-death action on behalf of Decedent's estate against defendants Cell Tech International, Inc. and The New Algae Company.[7]

Decedent allegedly consumed blue-green algae dietary supplements manufactured by Defendants.[8] In early 2003 Decedent allegedly developed hepatorenal syndrome.[9] Hepatorenal syndrome involves kidney ("renal") failure caused by advanced liver ("hepato") disease.[10] The hepatorenal failure culminated in Decedent's death.[11] Plaintiff alleged that Decedent's liver damage

---

[6] ER 1, ¶ 1.

[7] ER 1.

[8] ER 2, ¶ 4.

[9] ER 2, ¶ 5.

[10] Tr. 45:5-20, 46:8-10. (All citations to the transcript refer to the transcript of proceedings on February 26, 2007.)

[11] ER 2, ¶ 5.

and resulting death were caused by toxins in Defendants' blue-green algae products.[12]

If Plaintiff's allegations were true, Decedent's death would have been an unprecedented event in the history of American medicine: according to Plaintiff's expert witness, never before has a person in the United States died from microcystin poisoning:

> "Q: [T]here has been no single death in the United States proven to be caused by microcystins poisoning; is that true?
>
> "A: Not that I am aware of."[13]

2. The trial court held a pretrial OEC 104 hearing for the purpose of evaluating the scientific validity of Plaintiff's evidence of causation.

At Defendants' request, the trial court ordered a pretrial hearing under OEC 104(1) (ORS 40.030(1)). That rule says:

> "Preliminary questions concerning the qualifications of a person to be a witness, the existence of a privilege or the admissibility of evidence shall be determined by the court, subject to the provisions of subsection (2) of this section. In making its determination the court is not bound by the rules of evidence except those with respect to privileges."

---

[12] ER 2-4, ¶¶ 6-9.

[13] Tr. 131:1-4.

(a) Plaintiff retained Dr. Dietrich to determine whether microcystins were present in Decedent's liver tissue.

At the Rule 104 hearing, Plaintiff's only witness was Dr. Daniel R. Dietrich. Plaintiff had asked Dr. Dietrich to examine Decedent's liver tissue for the presence of microcystins.[14]

(b) Dr. Dietrich's qualifications are not in dispute.

Dr. Dietrich's qualifications are discussed in Appellant's brief at pages 2-3 and will not be reviewed here because his qualifications were not a basis for Defendants' challenge to his proposed testimony.

(c) The mechanism by which microcystins can cause liver damage.

Dr. Dietrich began by explaining the mechanism by which microcystins can cause liver damage. The process begins when a person ingests algal material containing microcystins.[15] That material goes to the stomach and the intestine.[16] From there the microcystins enter the blood and are transported to the liver.[17] Upon reaching the liver, the toxins enter the liver cells.[18] The microcystins

---

[14] Tr. 35:2-4 ("Your office asked me to look at the presence of microcystins in liver tissue samples from Melissa Blake.").

[15] Tr. 42:13-17.

[16] Tr. 42:9-18.

[17] Tr. 42:19-21.

[18] Tr. 42:21-23 ("And in the liver, that is in the liver cells, which we call hepatocytes, these liver cells have an active uptake of these toxins.").

then bond to cell components and inhibit essential cell functions, causing cell damage.[19] As the damaged liver cells die, they are replaced by scar tissue, which sometimes appears as cirrhosis.[20]

A badly damaged liver causes increased amounts of proteins to be released into the bloodstream.[21] Kidneys are supposed to reabsorb proteins from the blood;[22] but ongoing liver damage causes the kidneys to be overwhelmed, resulting in kidney failure and death.[23]

(d) Dr. Dietrich used immunohistochemical testing to test Decedent's liver tissue for the presence of microcystins even though that testing methodology had never been used to test human liver tissue for microcystins.

As mentioned, Dr. Dietrich's assignment was to test Decedent's liver tissue for the presence of microcystins. The "gold standard" for analyzing human liver tissue is one of the "analytical methods," such as liquid chromatography/mass spectrometry or gas chromatography/mass spectrometry.[24] Such analytical methods both identify the presence of microcystins and quantify how much toxin is present.[25]

---

[19] Tr. 39-41.

[20] Tr. 43:2-8, 43:19-25, 44:1-5.

[21] Tr. 45:8-10.

[22] Tr. 45:10-15.

[23] Tr. 45:16-20.

[24] Tr. 148:20-25, 149:1-18.

[25] Tr. 149:19-25, 150:1-3.

But here Dr. Dietrich did not use one of the "gold standard" analytical methods. Instead, he employed immunohistochemical ("IHC") testing. IHC testing is not a new or novel methodology. Defendants do not quarrel with Dr. Dietrich's testimony that "immunohistochemistry is a very broad and a very common methodology used broadly in clinical medicine and oncology * * * as well as in research."[26]

But in the context of this case—testing for the presence of microcystins in human liver tissue—immunohistochemical testing is a novel and unproven technique; indeed, its use here was literally unprecedented. As Dr. Dietrich admitted during cross-examination, he was the first to even try using IHC to detect microcystins in human liver tissue:

> "To my knowledge, this is the first time that immunohistochemistry has been used on liver sections in humans."[27]

Because Dr. Dietrich's use of IHC in this case went beyond medicine's settled frontier, there are no scientific publications concerning the technique. For example, Dr. Dietrich admitted there are no publications discussing using IHC to detect microcystins in human livers; no publications establishing controls for using IHC to test for microcystins in human livers; no publications listing

---

[26] Tr. 33:10-13.

[27] Tr. 120:19-24.

protocols for using IHC to test for microcystins in human livers; and no publications reporting the error rate when using IHC to test for microcystins in human livers.[28] The only articles Dr. Dietrich could identify concerning IHC testing on livers involved animals.

Yet, despite the novelty of its application in this context, Dr. Dietrich set out to test for the presence of microcystins using IHC methodology.

(e) Immunohistochemical testing involves applying antibodies to tissue, with a resulting color reaction when the substance being tested for is present in the tissue.

Immunohistochemical testing is a method of detecting the presence of a substance—such as a toxin—in tissue.[29] IHC testing uses a two-step process. First, the tissue to be analyzed is coated with an antibody known to react to the substance being tested for.[30] This is called the "primary antibody."[31] If the substance being tested for is present in the tissue, the primary antibody binds to the substance.[32]

After the tissue is washed, a second antibody is applied; this "secondary" antibody is one that will recognize and bind with the

---

[28] Tr. 120:15-24, 121:10-24, 122:17-23.

[29] Tr. 33:22-25.

[30] Tr. 46:25, 47:1-6.

[31] Tr. 47:1-9.

[32] Tr. 47:6-9.

primary antibody if the primary antibody found the desired toxin and, therefore, remained on the tissue.[33] The secondary antibody produces a color reaction if it recognizes the presence of the first antibody.[34]

In summary IHC testing involves applying two antibodies to the tissue, with the result that the antibodies produce a color reaction if the toxin is found.[35] If the substance tested for is not found, then ideally there is no color reaction. But sometimes there is a "background" color reaction even when the substance tested for is not present.[36] Therefore, part of IHC testing involves deciding whether a color reaction is a true positive or merely "background." Dr. Dietrich conceded that deciding whether a tissue had changed color, indicating the presence of a toxin, or merely contained "background" color, was a subjective evaluation:[37]

> "Q: Now, the interpretation of your pictures, the slides that you have sent showing the pictures --
>
> "A: Uh-hum.
>
> "Q: --is dependent, to a significant degree, on a subjective interpretation of the presence of red colors in positive slides or rose colors in

---

[33] Tr. 47:5-11.

[34] Tr. 47:17-22.

[35] Tr. 67:19-25.

[36] Tr. 55-56, 66:14-21, 66:25, 67:1-11.

[37] Tr. 125:19-23.

positive slides; is that correct?

"A: That is correct."

(f) Dr. Dietrich performed three sets of tests—each of which used different protocols and each of which produced false positives—then he stopped.

Using IHC methodology, Dr. Dietrich performed three sets of tests on Decedent's liver tissue.

The first tests were performed January 25, 2007, and the results are summarized at Supp ER ??, which is a slide Dr. Dietrich used in connection with his testimony.[38] The first set of tests used a single primary antibody, called #824.[39] The test was designed to cause tissue to turn red if microcystins were detected.[40]

When the primary antibody and the secondary antibody were applied to a positive control (fish liver that had been exposed to microcystins), the tissue turned red, indicating the presence of microcystins.[41] And when the antibodies were applied to a sample of Decedent's liver tissue, the tissue also turned red, indicating the presence of microcystins.[42]

There was, however, a problem. A control test using a sample of Decedent's liver tissue that was treated with only the secondary

---

[38] Tr. 69:4-25, 70:1-6.

[39] Supp ER 1.

[40] Tr. 72:18-25, 73:21-22.

[41] Supp ER 1, 3.

[42] Supp ER 1, 4.

antibody also turned red, producing what Dr. Dietrich called a "false positive" result.[43] The false positive can be viewed at Supp ER 4. On the left are photographs of Decedent's liver tissue stained with both antibodies; on the right are photographs of Decedent's liver tissue stained with only the secondary antibody. If Dr. Dietrich's testing methodology were valid, and microcystins were present, the photographs on the left should show red staining and the photographs on the right should not. Instead, both photos reflect red staining.

Because Dr. Dietrich was dissatisfied with the test results—and, in particular, the false positive result on sample A6—he changed procedures and performed a second set of tests.[44]

The results from the second set of tests are summarized at Supp ER 5. The second set of tests involved three changes from the first round of tests:

- Dr. Dietrich added a commercially-obtained human liver as a negative control. (It was a "negative" control because Dr. Dietrich assumed the control liver had not been exposed to microcystins and, therefore, should have tested "negative" for microcystins.)[45]

---

[43] Tr. 77:8-22, 129:21-25.

[44] Tr. 77:17-22, 136:12-19, 137:5-16.

[45] Tr. 78:18-20.

- Dr. Dietrich added a second primary antibody, known as antibody #2.[46]
- Dr. Dietrich tested a sample of Decedent's kidney.[47]

The testing produced positive results in the fish liver that had been exposed to microcystins.[48] And the testing produced positive results from Decedent's liver tissue.[49] Again, however, Dr. Dietrich was dissatisfied with the test results.[50]

One problem was that the kidney produced a false positive because it turned red, reflecting the presence of microcystins, even though the kidney was not treated with a primary antibody and, consequently, should not have stained.[51] A second problem was that the human control liver—which Dr. Dietrich assumed would not stain because it had not been exposed to microcystins—produced a false positive when tested with antibody #824.[52] The false positive can be seen vividly at Supp ER 6, which is slide 17 from Dr. Dietrich's testimony. The photographs on the left are of Decedent's liver tissue treated with primary antibody #824. The photographs on

---

[46] Tr. 78:10-17; Supp ER 5.

[47] Tr. 78:20-25; Supp ER 5.

[48] Tr. 80:2-6; Supp ER 5.

[49] Tr. 79:1-5, 18-21; Supp ER 5.

[50] Tr. 80:10-25, 81:1-10.

[51] Supp ER 5; Tr. 129:17-20.

[52] Tr. 129:12-16; Supp ER 5.

the right are the human control liver treated with primary antibody #824. Both turned red, indicating the presence of microcystins, even though the control liver presumably had never been exposed to microcystins. Thus, the second group of tests produced false positives in two of the six control tests.[53]

Unhappy with the second set of tests, Dr. Dietrich again adjusted his procedures and performed a third set of tests.[54] Explaining the change in protocol for the third test requires a brief digression. Antibodies used for IHC testing are diluted before being applied to the tissue. Commercially-available antibodies come with instructions for the proper dilution ratio for the particular type of tissue to be tested because the manufacturer has already determined the optimal dilution ratio.[55] Here, however, Dr. Dietrich did not use antibodies obtained from a commercial manufacturer of antibodies for IHC testing; instead, Dr. Dietrich made the antibodies himself.[56] Consequently, there was no established and standardized dilution of antibodies #824 and #2 for testing human liver tissue.[57] That means

---

[53] Tr. 129:12-20.

[54] Tr. 80:15-19 ("However, as we see, the control human liver, bottom right-hand corner, does show a background. We were not happy with this, so we started changing some of the –or start optimizing some of the staining procedures for the next stain * * * ."); Tr. 99:3-9.

[55] Tr. 101:6-14.

[56] Tr. 101:24-25, 102:1-3.

[57] Tr. 102:4-6.

Dr. Dietrich was experimenting with finding the proper dilution at the same time he was testing Decedent's liver tissue for microcystins.

For the third set of tests Dr. Dietrich reduced the dilution for antibody #2 because he felt the staining was too faint in the second set of tests.[58] The results from the third set of tests are summarized at Supp ER 9. Once again the testing produced positive reactions when antibodies were applied to Decedent's liver tissue. But also, again, the tests produced a false positive among the control samples, this time when antibody #824 was applied to the human control liver.[59]

Dr. Dietrich did not repeat the protocols used in the third set of tests, and he did not continue testing to resolve the false positive he got during the third set of tests. Dr. Dietrich also did not perform a cross-check by using an independent form of testing to verify his results.[60] Instead, the third set of tests was the last.

---

[58] Tr. 76:23-25, 77:1-2, 80:10-25, 81:1-24; 100:19-25, 101:1-14.

[59] Supp ER 9; Tr. 130:1-4 ("Q: Then on page 20, table C, there is another reported false positive in the human control liver, slide No. C3; is that correct? A: Yes.").

[60] Tr. 106:7-25.

(g) Dr. Dietrich testified that his tests provided clear evidence of microcystins in Decedent's liver tissue, and that there was a high likelihood that microcystins caused Decedent's death.

Dr. Dietrich testified that his tests provided clear evidence of the presence of microcystins in Decedent's liver tissue.[61] He also testified to his opinion that there is a "high likelihood" that microcystins caused Decedent's liver damage and death.[62]

3. The trial judge ruled that Dr. Dietrich's testimony was inadmissible because it lacked scientific validity.

After the Rule 104 hearing, Judge Wilson issued a letter opinion ruling that Dr. Dietrich would not be allowed to testify "about the immunohistochemical (IHC) testing he performed on the slides of liver tissue from Melissa Blake, and his conclusion that the testing showed the presence of microcystins was 'highly likely' the cause of her death."[63]

The court identified several reasons for its decision to bar the testimony, including:

- The use of IHC to detect microcystins in human liver tissue has never been done in any other instance;
- The technique has never been tested or corroborated by other means;

---

[61] Tr. 86:19-24.

[62] Tr. 95:15-25, 96:1-15.

[63] ER 6.

- The technique has not been subjected to peer review or publication;
- The error rate is unknown;
- There are no established standards or protocols;
- The technique relies on the subjective interpretation of stained tissue;
- No protocols exist for the proper use of the antibodies that Dr. Dietrich employed;
- The first two sets of tests performed by Dr. Dietrich were deemed unsatisfactory by him; the third set of tests was never replicated.

The court then entered judgment for Defendants and this appeal followed. There is no cross-appeal.

FIRST ASSIGNMENT OF ERROR

A. First assignment of error.

1. The circuit court's decision.

Plaintiff challenges the trial court's decision to not allow Dr. Dietrich to testify to his opinion about Decedent's cause of death.

2. Preservation of error.

Defendants agree that the claimed error was preserved below.

3. Standard of review.

Whether scientific evidence is admissible is reviewed for errors of law.[64]

ARGUMENT

A. The trial court correctly ruled that Dr. Dietrich's proposed testimony was not admissible because the basis for his testimony was not scientifically valid.

1. The admissibility of scientific evidence is determined by evaluating the proposed testimony in light of seven factors derived from OEC 401, 403, and 702.

This case involves the standards for admissibility of scientific testimony. In *State v. Brown*,[65] the Oregon Supreme Court said that "scientific evidence" refers to "evidence that draws its convincing force from some principle of science, mathematics and the like.

---

[64] *Jennings v. Baxter Healthcare Corp.*, 331 Or 285, 299, 14 P3d 596 (2000).

[65] *State v. Brown*, 297 Or 404, 407, 687 P2d 751 (1984).

Typically, but not necessarily, scientific evidence is presented by an expert witness who can explain data or test results and, if necessary, explain the scientific principles which are said to give the evidence its reliability or accuracy."

Here it is undisputed that Dr. Dietrich's testimony was "scientific evidence"; Plaintiff has not argued either in the trial court or on appeal that Dr. Dietrich's testimony was not scientific evidence. Therefore, the admissibility of Dr. Dietrich's testimony is governed by the standards for admissibility of scientific evidence.

The Oregon Supreme Court has laid out the analytical framework for the admission of scientific evidence in three cases: *State v. Brown*,[66] *State v. O'Key*,[67] and *Jennings v. Baxter Healthcare Corp.*[68] (At the time this brief was prepared, *Marcum v. Adventist Health System/West*[69] was pending in the Oregon Supreme Court but had not been decided.) In addition, in *O'Key* the Oregon Supreme Court adopted aspects of the United States Supreme Court's analysis in *Daubert v. Merrill Dow Pharmaceuticals, Inc.*, 509 US 579 (1993). Consequently, those cases guide the analysis here.

In Oregon, the admissibility of scientific evidence is governed by

---

[66] *Id.*

[67] *State v. O'Key*, 321 Or 285, 899 P2d 663 (1995).

[68] *Jennings v. Baxter Healthcare Corp.*, 331 Or 285, 14 P3d 596 (2000).

[69] *Marcum v. Adventist Health System/West*, 215 Or App 166, 168 P3d 1214 (2007), *rev allowed*, 344 Or 194 (2008).

traditional standards in the Oregon Evidence Code.[70] The court should first assess the proffered evidence under OEC 401 and 702.[71] Rule 401 is entitled "Definition of Relevant Evidence." It says:

> "'Relevant evidence' means evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence."

Rule 702 is entitled "Testimony by experts" and says:

> "If scientific, technical or other specialized knowledge will assist the trier of fact to understand the evidence or to 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."

O'Key[72] says that if the proposed evidence is relevant under OEC 401 and helpful under OEC 702, then it should be admitted unless its probative value is substantially outweighed by one or more of the countervailing factors set forth in OEC 403, which provides:

> "Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay or needless presentation of cumulative evidence."

"In applying OEC 401, 702, and 403, the court must identify and evaluate the probative value of the proffered scientific evidence,

---

[70] *Brown*, 297 Or at 408.

[71] *O'Key*, 321 Or at 297-98.

[72] *Id*. at 298-99.

consider how that evidence might impair rather than help the trier of fact, and decide whether truthfinding is better served by admission or exclusion."[73] To assist courts in performing this analysis, the Oregon Supreme Court has identified seven factors potentially relevant to the admissibility question:

1. The technique's general acceptance in the field;
2. The expert's qualifications and stature;
3. The use which has been made of the technique;
4. The potential rate of error;
5. The existence of specialized literature;
6. The novelty of the invention;
7. The extent to which the technique relies on the subjective interpretation of the expert.[74]

"The existence or nonexistence of these factors may all enter into the court's final decision on admissibility of the novel scientific evidence, but need not necessarily do so."[75] The ultimate inquiry concerns the scientific validity of the proposed evidence.[76] The proponent of the scientific evidence has the burden of establishing its validity.[77]

---

[73] *Id.* at 299.

[74] *Id.*

[75] *Brown*, 297 Or at 417 (footnote omitted).

[76] *O'Key*, 331 Or at 304.

[77] *Id.* at 303.

We now consider each factor in the context of this case.

2. Application of the seven factors to the evidence in this case.

(a) The technique's general acceptance in the field.

Immunohistochemistry is not an accepted method for testing for microcystins in human livers or determining whether a human death was caused by microcystin poisoning. Dr. Dietrich admitted that this case was literally unique: **"To my knowledge, this is the first time that immunohistochemistry has been used on liver sections in humans."**[78] Dr. Dietrich also admitted that immunohistochemistry had never before been used to determine the cause of death in humans:

> "Q: And would it also be true that this technique [i.e., immunohistochemistry] has never been used to determine a cause of death in humans?
>
> "A: That is also true."[79]

Therefore, IHC is not *generally accepted* for the purpose to which it was applied in this case; indeed, it is not accepted *at all*. That is not to say that IHC is quackery; it is not. As Defendants' expert, Dr. Carmichael, testified, "immunohistochemical assays are accepted assays"—but not in this context.[80] IHC is an accepted technique in

---

[78] Tr. 120:19-24.

[79] Tr. 118:10-13.

[80] Tr. 151:15-17.

some medical applications, and Dr. Dietrich identified some articles discussing IHC as applied to animal livers. But as it was used here—to detect the presence of toxins in a human liver and ascribe a cause of death—immunohistochemistry is not an accepted methodology.

(b) The expert's qualifications and stature.

Defendants acknowledge that Dr. Dietrich is a qualified toxicologist.

(c) The use that has been made of the technique.

Immunohistochemistry is an established and reliable methodology—in certain contexts. But its application here is entirely novel, even unprecedented. Through the work of Dr. Dietrich and others, perhaps someday IHC will develop to the point where it is a scientifically valid method for testing human livers; but that day has not arrived.

Because no one has ever employed IHC to analyze human liver tissue, there are no standards for such testing. Dr. Dietrich conceded there are no published protocols or standards whatsoever for conducting such testing. There are not even any standards for preparing the antibodies for application to the liver tissue—which is why Dr. Dietrich was experimenting with that aspect of the testing at the same time he was examining Decedent's liver tissue.

Dr. Dietrich's work could prove valuable to future efforts to hone and refine IHC so that it is a proven and reliable method for testing human liver tissue. But at this point Dr. Dietrich is merely a pioneer in an unproven application of IHC; he alone applies IHC in this

context; no other scientist in the world stands with him.

(d) The potential rate of error.

The potential rate of error is unknown except for the results in this case—and they are not encouraging.

First, Dr. Dietrich testified that because no one uses IHC to test human livers, the error rate is unknown:

> "Q: And would it follow from that then that there are no scientific papers concerning immunohistochemical testing that exist, which establish an error rate for human tissue with microcystins exposure; is that true?
>
> "A: That is true.
>
> "Q: That would mean no standards exist for—in the scientific literature for establishing how often you could be in error in the detection of microcystins in human tissue, true?
>
> "A: That is true."[81]

Thus, the error rate could be 5 percent, 25 percent, 75 percent, or 95 percent—no one knows.

What we do know is that Dr. Dietrich's testing consistently produced inaccurate results. Each series of tests had at least one false positive out of the small number of tests conducted. And even the third, and final, set of tests produced a false positive. As the trial judge noted, the *lowest* rate of error that Dr. Dietrich achieved was more than 16 percent.[82] These error-laden results do not permit

---

[81] Tr. 121:15-24.

[82] ER 7.

any court to conclude that IHC is a scientifically reliable technique in this context.

(e) The existence of specialized literature.

There are *no* scientific publications concerning using IHC to analyze toxins in human livers. Although Dr. Dietrich could identify a few articles about IHC testing of animal livers, apparently not even a single doctor or scientist has written an article about using IHC to analyze human livers.

(f) The novelty of the invention.

Because this point has been discussed in connection with other factors, it will not be belabored here—as applied here, IHC is not merely novel, it is unprecedented and wholly unproven.

(g) The extent to which the technique relies on the subjective interpretation of the expert.

IHC testing comes down to the expert's subjective interpretation of the data.

As Dr. Dietrich explained, deciding whether a result is positive (indicating the presence of toxins) or negative (indicating the absence of toxins) is a product of comparing the tested tissue with a control tissue. And as Dr. Dietrich testified, that comparison involves a subjective interpretation of the tissues:

> "Q: Now, the interpretation of your pictures, the slides, that you have sent showing the pictures--
>
> "A: Uh-hum.
>
> "Q: --is dependent, to a significant degree, on a subjective interpretation of the presence of

> red colors in positive slides or rose colors in positive slides; is that correct?
>
> "A: That is correct."[83]

The court can assess for itself just how subjective the evaluation is by examining Dr. Dietrich's slides, which appear in the supplemental excerpt of record to this brief. It is apparent that the difference between a "positive" result and mere "background" is not manifest and depends, to a significant degree, on subjective judgments about inconclusive evidence.

3. IHC testing is not a scientifically valid method of detecting microcystins in human livers or ascribing a cause of death from such exposure.

"Evidence perceived by lay jurors to be scientific in nature possesses an unusually high degree of persuasive power."[84] Consequently, the Oregon Supreme Court has said that "trial courts have an obligation to ensure that proffered expert scientific testimony that a court finds possesses significantly increased potential to influence the trier of fact as 'scientific assertions' is scientifically valid."[85] This duty is especially acute where the proposed evidence is "innovative, nontraditional, unconventional, controversial, or close to the frontier of understanding."[86]

---

[83] Tr. 125:19-23.

[84] *O'Key*, 321 Or at 291.

[85] *Id.* at 293.

[86] *Id.*

Here, the trial court decided that Dr. Dietrich's proposed testimony was inadmissible because it was not based on scientifically valid methodology. That decision was correct.

There are proven, reliable methods for testing human liver tissue for toxins. But Dr. Dietrich did not employ any of those methods. Instead, he took a proven methodology and attempted to use it in a wholly novel context. It is as if Dr. Dietrich used a thermometer to measure blood pressure. While a thermometer is not a novel device, and is a perfectly reliable and valid method for measuring a person's temperature, it has never been proven to be a reliable or valid method for measuring blood pressure.

Similarly, IHC has an established role in medicine—just not in the way it was used here. Consequently, the trial court correctly held that Dr. Dietrich's testimony was inadmissible.

CONCLUSION

This court should affirm the judgment for Defendants.

DATED: June 4, 2008.

David R. Foster, OSB 80039
BULLIVANT HOUSER BAILEY, PC
300 Pioneer Tower
888 SW Fifth Avenue
Portland, Oregon 97204

R Daniel Lindahl, OSB 84276
LINDAHL LAW FIRM, PC
Suite 1100
121 SW Morrison Street
Portland, Oregon 97204

By_____
R. Daniel Lindahl
Attorneys for Respondents

CERTIFICATE OF SERVICE

I certify that on June 4, 2008, I served two true copies of this RESPONDENTS' BRIEF AND SUPPLEMENTAL EXCERPT OF RECORD on the following person by United States Postal Service, ordinary first class mail:

George W. Kelly
303 West 10th Avenue
Eugene, Oregon 97401

CERTIFICATE OF FILING

I certify that on June 4, 2008, I filed the original and 20 copies of this RESPONDENTS' BRIEF AND SUPPLEMENTAL EXCERPT OF RECORD by United States Postal Service, ordinary first class mail, addressed to:

Records Section
Oregon Court of Appeals
Supreme Court Building
1163 State Street
Salem, Oregon 97301-2563

Dated: June 4, 2008.

R. Daniel Lindahl