

# **Biotech** Daily

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## Daily news on ASX-listed biotechnology companies

## Fermiscan, Inventor Prof Veronica James Back In Court

Biotech Daily Editorial: Who Breaks A Butterfly On A Wheel?

Fermiscan is suing the inventor of its x-ray diffraction hair test Prof Veronica James claiming a new test using finger nails and skin is an improvement on their patent.

Prof James sold the 1998 hair x-ray diffraction patent to Fermiscan in 2004 and has been the subject of legal action brought against her by Fermiscan - including an Anton Piller order allowing the company to search and seize her private property.

Following the initial court action, the company and Prof James reached a settlement which included an agreement that Prof James would not disparage the company, which has been interpreted as a silencing order against the scientist.

Middleton's intellectual property partner Jane Owen is not bound by the settlement and told Biotech Daily there would be a hearing at the New South Wales Supreme Court on May 25, 2009.

Ms Owen said Fermiscan alleges that Prof James has breached the settlement clause preventing her from disparaging the company and that Fermiscan alleged that work Prof James had undertaken on x-ray diffraction of finger nails and skin was "an improvement" to the original patent they acquired from Prof James in 2004.

On January 3, 2008 Prof James filed international patent application PCT/AU2008/000005 entitled 'Biometrics Diagnosis' with the Australian Patent Office.

On July 17, 2008 the World Intellectual Property Organisation published the application on its website with the description: "The invention provides a method of detecting neoplastic or neurological disorders comprising exposing skin or nails to X-ray diffraction and detecting changes in the ultrastructure of the skin or nails, and also provides an instrument when used in the method of detection."

An adjunct professor at the Australian National University's Research School of Chemistry, Prof James article entitled 'Fiber diffraction of skin and nails provides an accurate diagnosis of malignancies' was published online in the International Journal of Cancer on February 3, 2009 by Wiley Interscience (<u>www.interscience.wiley.com</u>). The article says that an early diagnosis of malignancies correlates directly with a better prognosis, but for many malignancies there are no readily available, noninvasive, cost-effective diagnostic tests with patients often presenting too late for effective treatment.

"This article describes for the first time the use of fiber diffraction patterns of skin or fingernails, using X-ray sources, as a biometric diagnostic method for detecting neoplastic disorders including but not limited to melanoma, breast, colon and prostate cancers.

"With suitable further development, an early low-cost, totally non-invasive yet reliable diagnostic test could be conducted on a regular basis in local radiology facilities, as a confirmatory test for other diagnostic procedures or as a mass screening test using suitable small angle X-ray beam-lines at synchrotrons."

The abstract is at http://www3.interscience.wiley.com/journal/121664971/abstract.

Fermiscan alleges that x-ray diffraction of skin and nails is merely "an improvement" on Prof James's original patent for x-ray diffraction of hair to detect breast cancer.

Fermiscan managing director David Young told Biotech Daily that he was "prohibited from talking about it".

"We are not talking about it until it's resolved," Mr Young said.

"We hope one day she will win a Nobel Prize for the technology and [it will] make her very rich," Mr Young said. "She has a royalty stream for the product," he said.

Asked whether the matter could not be resolved without legal action, Mr Young said he wished it could be.

Prof James' solicitor Jane Owen said the skin and nail test was "absolutely a new invention".

"The diffraction process has been used since the 1930s to examine biological materials," Ms Owen said. "The difference is the use of different biological materials to test for cancers and different cancers to those in the 1998 Fermiscan patent."

"It's a complete over-simplification to think you can substitute a nail for a hair and then expect to automatically predict the results will be the same. The new patent application is for different biological materials for the detection of different and further types of cancer."

"If Fermiscan's claim was valid, it would be tantamount to saying that they own all x-ray diffraction processes for all biological material. Their patent simply doesn't go that far," Ms Owen said.

Prof James has an Order of Australia Medal for her services to the deaf and there is an annual two day camp called the Veronica James Science Challenge for Hearing Impaired Children supported by the University of Sydney's Faculty of Medicine through its department of pathology. Prof James has worked on breast cancer since the 1980s.

Fermiscan was down 1.5 cents or 7.89 percent to 17.5 cents.

#### **BIOTECH DAILY EDITORIAL**

Whatever the merits of the case Fermiscan is mounting against Prof Veronica James, it is simply bad for the biotechnology sector when a scientist is hounded by a company.

Fermiscan is spending its investors' money to take the most drastic action possible against the inventor of its technology and soon it will be requiring Polartechnics shareholders to follow suit.

It is not credible that the company cannot find a creative role for Prof James assisting in this most interesting method of non-invasively detecting very early cancer.

Together they could be saving women's lives.

It is most poignant when the circumstances of the plaintiff Fermiscan are compared with those of the defendant Prof Veronica James

Prof James is receiving legal assistance on a no-win, no-pay basis and is supported by women concerned with the high incidence of breast cancer. She should be allowed to retire in dignity and comfort, instead of facing endless court cases because she continues to research her life's passion. When she could not find suitable equipment, she designed and engineered it herself. She should be celebrated as a great pioneering scientist.

Fermiscan is spending investors' money, for what purpose? If Prof James disparages their test, originally based on her work, so what? This is science. Evidence rules.

The company has not explained why legal action is necessary. And to the best of Biotech Daily's knowledge neither Prof James nor Fermiscan have been able to clearly demonstrate superior results with the x-ray diffraction of hair process above the standard of care of mammography and biopsy.

If Prof James's skin and nail test does prove superior, Fermiscan could apologize, waive all previous agreements, pay a suitable fee and hire Prof James as a consultant.

Regardless of any facts and argument to be played out in court, one thing is clear, this case should never have begun and Biotech Daily strongly opposes the silencing of scientists with anything other than scientific evidence.

Biotech Daily believes that regardless of subsequent events, originating scientists should be celebrated by those who seek to capitalize on their creativity.

The Fermiscan Polartechnics merger will give the new company, Novus Diagnostics, an opportunity to reappraise the relationship with Prof James.

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