

A RAW DEAL, IN A RESEARCHER'S EYES

Dispute over an invention highlights problems in technology transfer

By Goldie Blumenstyk | From the issue dated August 8, 2008 | <http://chronicle.com/free/v54/i48/48a00101.htm>

The University of Georgia and a former faculty member there stand to make some \$70-million from a license on an invention used for the popular eyedrops Restasis, sold by Allergan Inc.

Sound great? Not to Renee L. Kaswan, the former professor of veterinary medicine who for more than a decade has been prodding the institution to be more aggressive in commercializing the invention.

She contends the university would be entitled to substantially more — as much as \$230-million in additional cash — were it not for the deal its research foundation cut with Allergan behind her back in 2003, a deal she calls naïve and shortsighted.

"They got suckered," says Dr. Kaswan.

The 2003 deal allowed Allergan to reduce the royalties it was obliged to pay to the university, in exchange for an upfront payment of \$23-million and additional payments later.

Sales of Restasis have taken off, but the university is not getting the full benefit because of the 2003 agreement. University leaders have said that their arrangement with Allergan guaranteed the institution a lucrative payday even if the prescription product was later found to be unsafe or was overtaken by a competing drug.

The dispute that is now slowly working its way through a state court in Georgia shows why so few university inventions become blockbusters for their institutions.

Documents in the case depict a university with the faults that often undermine academic commercialization ventures: timidity about enforcing patent rights for fear of bad PR, a lack of sophistication in negotiating with savvier corporate partners, and a failure to properly vet lawyers and consultants.

The documents also highlight the difficulties inherent in university technology transfer when the interests of faculty members passionate about their inventions clash with the more cautious culture of the university ultimately responsible for the intellectual property.

In court hearings and pleadings, University of Georgia lawyers have acknowledged that the institution's leaders had become upset with some of Dr. Kaswan's combative tactics — and said that Allergan "had From the issue dated August 8, 2008 experienced Dr. Kaswan's hostile and harassing behavior." In the 1990s, she sued alleged infringers of her patent when the university would not, and later battled with the university itself. Because of that, the lawyers said, the university and Allergan became wary of involving her, despite her expertise.

Dr. Kaswan says the university "didn't have the backbone" it needed when tangling with a big company like Allergan.

LOST OPPORTUNITY

Allergan began selling Restasis in 2003. In the most recent quarter for which figures are available, it reported sales of \$100-million, up 28 percent from the same period a year earlier. The company, based in Irvine, Calif., predicts sales of \$375-million to \$405-million in 2008.

Dr. Kaswan says the deal keeps the university from fully profiting from the sales growth that Restasis has enjoyed. The arrangement, she says, benefits the company "at the expense of the university and the public" that supports the state institution. The deal also substantially shortchanges her; she is entitled to 35 percent of what the university earns from Restasis.

She contends that Allergan understated the sales potential for Restasis and overstated the possibility of long-term financial risks with the product and the patent to get the university to sign on. She also contends that the company the university hired to help it evaluate the deal did not do a good job researching the product's market potential.

Court transcripts and other evidence in the case show that board members of the University of Georgia Research Foundation decided to keep the deal secret from her — a move she calls a mistake because she understood Restasis's market potential better than they did. Faculty members who develop valuable intellectual property, she says, deserve better from their universities. "It's just not the way you treat your inventors," she says.

In April 2007, Georgia Superior Court Judge David R. Sweat ruled that the research foundation, which manages patents for the institution, had the right to act without consulting its inventor, although "no doubt many faculty and staff may be dissatisfied" with that finding." The judge did acknowledge that the foundation "made a bad deal."

Dr. Kaswan plans to appeal. She wants the 2003 deal invalidated to allow the university to revert to its original agreement with Allergan, which provided for royalty payments of 7 percent on Restasis sales through 2009 and then 5 percent through 2014. Those terms could provide hundreds of millions of dollars more to the university, assuming sales remain strong.

Dr. Kaswan, who left the university in 1996 and now owns an animal clinic outside Atlanta, is not the only one challenging the university's actions. One influential Georgia lawmaker has questioned the "grossly inept" consultants the university hired to help it evaluate the Allergan deal. In a letter to Michael F. Adams, president of the university, State Rep. Steve Davis, a Republican who is deputy majority whip, demanded an explanation.

A spokesman for Mr. Adams said the president, who also chairs the foundation, had responded privately to Mr. Davis and would not elaborate.

He said the university's policy was to not discuss pending litigation. An Allergan spokeswoman cited a similar policy. One of the university's consultants declined to comment, and another did not respond to an interview request.

The foundation maintained in its court pleadings that the hiring of an outside consultant to help it evaluate the deal and the months of bargaining with Allergan were evidence that the foundation "did use 'reasonable diligence.' "

The foundation's responsibility, it argued, "excludes the idea that it had the duty to consider — and then defer to — Dr. Kaswan's opinion as to what she may deem possible or desirable, or the ways and means her judgment might dictate."

Documents that could shed light on the decision-making remain under seal. The university and Allergan contend that making them public would betray the company's trade secrets and violate the parties' confidentiality. Dr. Kaswan says university officials fear unsealing them because they will show that Allergan was "pulling the wool over their eyes."

AN UNREPENTANT NOODGE

By her own description, Dr. Kaswan has been more pit bull than puppy dog in publicizing her story and exploiting her invention. The treatment got its start as a drug called Optimune, for dry eye in dogs.

"I nag people. I'm a noodge," she says unapologetically. "That's the only way things get done."

At first her aggressive posture suited the university. In the mid-1990s, it authorized her, through her company, KB Visions Inc., to sue pharmacies for patent infringement for making the animal eyedrops when commercial production of Optimune was temporarily halted.

Later, however, when pharmacies began to protest, the university became uncomfortable. Officials also grew concerned that her lawsuits could put the patents in peril because the pharmacies accused of infringing responded by challenging the validity of her patents. Dr. Kaswan, noting that such an argument is a standard defense, asserts that the patents were never really in danger.

She was similarly aggressive in protecting her rights when she learned that the university's outside patent lawyers had failed to secure patent protection for her inventions in some foreign countries. She pressed the university to sue its law firm for redress. The case was settled in 1997 (full terms of that settlement are part of the sealed record), with the university agreeing to increase her faculty-inventor share of royalty income from the usual 25 percent provided for by university policy to 35 percent.

Dr. Kaswan also took an active role in commercializing her invention into a dry-eye product for people. She helped the university recruit Allergan in 1993 to take over the work when the initial licensee appeared to be making little progress. And later, when Allergan appeared to be faltering, she worked with the university to press that company to give the project a higher priority.

Dr. Kaswan, who was named Inventor of the Year by the university in 1998, says those dealings show that she and the university were often allies, though she says she was often the more-assertive party.

"I would tell them, They're my patents, not wallpaper," she recalls. "My patent is not a trophy on the shelf."

In 1999 the Food and Drug Administration put off Allergan's application for human eyedrops, and for a period after that, court documents show, it appeared even to the university that little was being done to bring a product to market.

During that time, Dr. Kaswan began negotiating with the research foundation for the right to own the patent herself. By late 2002, the parties were closing in on a deal that would have assigned patent rights to a company controlled by her. Under this arrangement, the university would have given Dr. Kaswan a greater share of any future proceeds from the patents, according to documents that Dr. Kaswan kept.

A SURPRISING TWIST

On December 24, 2002, in what Dr. Kaswan says was a surprise to both her and the research foundation, Allergan won FDA approval for Restasis.

The approval triggered a chain reaction between Dr. Kaswan and the university that brought the parties to their current impasse. Over her objections, the university called off the plans to transfer the patents to her. It then sued her in federal court over patent issues related to her actions in connection with the veterinary eyedrops. (That case was later dismissed.)

By the summer of 2003, discussions between the research foundation and Allergan over the royalties were under way. Although several research-foundation staff members opposed Allergan's initial proposal, they later backed off from that position when Allergan sweetened the deal by offering to continue to pay a royalty of 2 percent, through 2009, on top of the \$23-million, and additional one-time payments of \$5-million and \$10-million if annual sales exceeded \$275-million and \$375-million, respectively.

Some in the foundation favored the new deal because they worried that an agreement requiring Allergan to pay royalties to the university beyond 2009 could be challenged.

The research foundation, which feared that Dr. Kaswan would sue over the deal and hold it up, according to evidence introduced in the lawsuit, decided to approve it without telling her about it. The agreement was signed in November 2003.

When Dr. Kaswan learned about it, she sued the university, seeking to have the deal invalidated.

Since Judge Sweat's ruling in 2007, the university and Dr. Kaswan have negotiated over the amounts due her. She cannot pursue her appeal until those matters, which were part of the judge's decision, have been resolved.

Financially secure thanks to the income from her veterinary clinic and her share of the millions earned from Optimune, Dr. Kaswan says she is pressing the Restasis issue not only to help herself, but also to help the university get its due.

And, she says, she wants to make a point. "It's really important to me that this becomes a lesson for the university system," she says. If she prevails, she plans to use some of her proceeds to create a forum to educate faculty members and universities throughout the country on how to protect themselves when licensing their patents to corporations.

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