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I 2 THE KASWAN IMBROGLIO

The year 2003 wasn't pretty for UGA President Michael Adams, as recent developments in the decisions he made that year in the Renee Kaswan case involving her patents to a medical breakthrough are making increasingly clear. The announcement that June of his decision to end Vince Dooley's career triggered an explosion of public rancor. Then in October, the Deloitte & Touche audit brought into question Adams's judgment as well as his ethics.

Moreover, the state was in an economic lull and lagging tax collections had caused Governor Sonny Perdue to order across-the-board budget cuts that reduced the university's funding by \$52 million. The Board of Regents ordered a 15 percent increase in tuition—the largest increase in two decades. And there was talk of another 5 percent budget reduction the next year. Politicians expressed concern that the state's lottery wouldn't produce enough profits to fully fund the popular Hope Scholarship program, which pays the tuition of virtually all UGA students.

Adams considered the situation desperate enough that he wrote a column in the *Atlanta Journal-Constitution* warning of the dire consequences of more budget cuts. "While money is not the sole determinant of quality in higher education, Georgians must recognize that there is no such thing as cheap excellence," he wrote. And he noted that Georgia isn't alone. Nearly every public university in the country faces the same financial worries. Government funding for public universities had been dwindling for years. The nation, Adams said, is "dangerously close" to a higher education system that offers

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1 top quality only in its private institutions.

2 But there was a ray of economic sunshine peeking through the
3 gloom. A University of Georgia veterinarian had come up with the
4 world's first medical treatment for "dry eye" in humans. It was a monu-
5 mental discovery with huge financial implications for the university.
6 The U.S. Food and Drug Administration—the FDA—in a surprise
7 decision on Christmas Eve of 2002, had approved the product, Resta-
8 sis, for widespread use. The giant pharmaceutical company, Allergan,
9 Inc., which held the license to produce Restasis had begun marketing
10 it in April 2003.

11 Restasis promised prestige and profits for the cash-strapped uni-
12 versity because UGA held the patents and was poised to reap millions
13 of dollars in royalty payments from Allergan. The treatment had
14 been pioneered by UGA veterinarian Dr. Renee Kaswan who, for a
15 decade, had pushed the FDA and pharmaceutical companies to bring
16 her invention to market. Although she had left her teaching position
17 at the veterinary medicine school in 1996, Kaswan too was in for a
18 big payday. Her contract with UGA would pay her 35 percent of the
19 royalties.

20 It should have been a glorious conclusion to a thirty-year effort.
21 Instead, it turned into a financial and legal nightmare that embroiled
22 the university in an ongoing legal battle and cost the school \$220
23 million in royalties. None of this was an issue in the Adams-UGA
24 Foundation contretemps or the resulting Deloitte & Touche audit.
25 But how it happened is a story of intrigue, manipulation, and another
26 secret deal orchestrated by President Adams, who also chairs the uni-
27 versity's research foundation.

28
29 THE RESTASIS STORY BEGINS in the 1980s when Dr. Renee Kaswan, then
30 in her final year as a veterinary student at the University of Georgia,
31 began experimenting with a treatment for "dry eye" in small animals.
32 The painful condition can lead to eventual blindness.

33 The only treatment at the time was an operation to reposition the
34 salivary duct from the mouth to the eye, allowing the animal to, in

effect, spit in its own eye for lubrication. While assisting her professor in the surgical procedure, Kaswan wondered if anyone had done a biopsy to try to discover the cause of dry eye in animals. Not that he was aware of, her professor said. They decided to send a sample of a diseased tear duct to the laboratory. The lab result suggested the condition was caused by an autoimmune response; this was also known to be the usual cause of dry eye in humans.

Kaswan made an instant decision to focus her career in ophthalmology. She persuaded the university to create a residency program in the field and to make her its first student. Here, she felt, was a chance to enter uncharted waters and possibly to find a cure for a common and painful condition afflicting thousands of animals and people worldwide.

She reasoned that if dry eye was caused by an autoimmune response and the response could be interrupted, then perhaps the condition was reversible. She knew that immunosuppressant cyclosporine was commonly used to prevent organ rejection in transplant patients. Perhaps it could also reverse the autoimmune response that caused dry eye in animals.

While using cyclosporine eye drops to treat a dog for corneal inflammation, Kaswan noticed the drops caused an increase in tear production. She mentioned this observation to Dr. Keith Green, director of ophthalmic research at the Medical College of Georgia, who was taking Sandimmune, an oral cyclosporine, following a kidney transplant. Green said he'd noticed excessive tear production since his surgery but hadn't connected it to the cyclosporine.

Intrigued, Kaswan tried the drops on three more dogs with the same positive results. And when the university's famed football mascot Uga IV, developed dry eye in 1985, his owner, Savannah lawyer Sonny Seiler, brought the bulldog in for treatment. The treatment cured Uga IV and he returned to the sidelines and completed an illustrious 77-27-4 mascot career that included Vince Dooley's last game as head football coach. Without the treatment Uga IV would have gone blind.

In 1988 the university licensed KB Visions, a company owned by

1 Kaswan, to market her product for veterinary use. She sublicensed it
2 to Schering Plough, which marketed the treatment as Optimune.
3 Another seven years passed before Kaswan won FDA approval of
4 Optimune for widespread use on small animals.

5 Kaswan now had a nice steady income from royalties from Op-
6 timune, and she operated an animal hospital in Atlanta. However,
7 she continued her efforts to gain approval for a product that could
8 be used to treat dry eye in humans. A self-described “noodge” who
9 sometimes irritates people with her insistent behavior, Kaswan wasn’t
10 winning friends at the UGA Research Foundation or with the phar-
11 maceutical companies.

12 Zealously protective of her patent rights, Kaswan used her private
13 company, KB Visions, to file suit against pharmacy compounding
14 companies that were using her invention without paying royalties to
15 the university. Kaswan was trying to protect patents which the univer-
16 sity held and felt she was doing the university a favor. The pharmacies
17 responded to her lawsuits by challenging the validity of the patents—
18 standard legal responses in such cases. Kaswan maintains the patents
19 were never really in danger and that university lawyers were simply
20 trying to intimidate her.

21 Initially, the university favored Kaswan’s aggressive tactics in
22 defending the patents. The university’s lawyers sent out hundreds
23 of “cease and desist” letters to compounding pharmacies that were
24 distributing a generic version of Optimune. Eventually university
25 attorneys asked Kaswan to write the letters directly to the pharma-
26 cies. In the 1990’s it authorized her to sue pharmacies that were not
27 licensed to use Optimune and were not paying royalties to Kaswan
28 and the university.

29 Kaswan had pressured the university to sue outside patent lawyers
30 when they failed to protect her inventions in Pacific Rim countries.
31 The case was settled in 1997 with the university agreeing to increase
32 her faculty-inventor share of royalty on Optimune 25 percent to
33 35 percent.

34 While working to get FDA approval for Optimune, Kaswan had

been simultaneously pressing Sandoz Pharmaceuticals, the original licensee to complete human tests and gain FDA approval for human use. Between 1988 and 1992 she wrote 139 letters to the company prodding them to move faster. In 1993, she helped the university recruit and license Allergan to take over the study on humans. She collaborated with Allergan scientists on the human testing and when that effort faltered she talked university officials into pressing the company into giving her project a higher priority.

Still, they seemed to be making little progress and, in 1999 the FDA held up Allergan's application human eye drops. Frustrated with the bureaucracy, Kaswan began negotiation with the university's Research Foundation to assign her control of the patents so she could pursue an effort to win FDA approval. Negotiations dragged on for eighteen months until in late 2002 officials at the Research Foundation agreed in writing to assign her the patents. Assigning the patent rights to Kaswan meant that she would receive 75 percent of any future royalties should the product ever meet FDA approval. Draft contracts initiating the rights transfer were being completed when the FDA surprised everyone by approving Allergan's Restasis product for use on humans on December 24, 2002.

That's when things began to get ugly.

Seeing an opportunity for a new and significant income stream for the cash-strapped university, university officials immediately reneged on their promise to assign her the patents, informing her of the decision on January 6, 2003. Kaswan and her attorneys argued that the patent assignment to her was a "done deal" and threatened legal action.

Kaswan was hoping to avoid long legal entanglement. She appealed in a letter to research vice president Gordhan L. Patel to a sit-down to discuss a solution that would be agreeable to all. But the university was adamant. Patel responded in a January 13 letter telling Kaswan that, in effect, there was nothing to talk about "given the lawsuits in which the validity of our patents is challenged and the threats of future litigation." A copy of the letter was sent to Adams.

UGA then initiated a pitched legal battle against Kaswan and her

1 company. The hired the Atlanta law firm Sutherland Asbill & Brennan
2 to represent the research foundation. The university then intervened
3 on behalf of three compounding pharmacies in lawsuits that KB Vi-
4 sions had filed, one of which university officials had authorized in
5 writing. In February, 2003 research foundation lawyers opposed KB
6 Visions' motion seeking a summary judgment that the patents, which
7 were held by UGA, were in fact valid. This legal maneuver preventing
8 a declaration of validity gave the university cover to continue legal
9 claims against Kaswan and her company.

10 University lawyers initiated lawsuits against Kaswan over minor
11 violations of the veterinary license. They accused her of not properly
12 reporting quarterly income and not providing proper sublicensing
13 agreements although Kaswan said she had reported the information
14 in the same way for a decade. They filed suit in federal court accus-
15 ing Kaswan of invoking, without permission, the university's name
16 in patent enforcement letters to companies who were using her
17 veterinary medicine, Optimune, without paying royalties to her
18 and the university. The university acknowledged that the letters were
19 identical to letters the research foundation had itself previously sent
20 to formulators in an effort to enforce its patents.

21 Kaswan had left the veterinary school in 1996 to found a veterinary
22 hospital in Atlanta and was dependant on income from the hospital
23 and on the royalties from Optimune. She was, understandably de-
24 fensive of the patents and felt the university should share her concerns.
25 But UGA officials had bigger fish to fry. A 1993 agreement between
26 Allergan and the Research Foundation required the company to pay
27 the university 7 percent of its net sales through the end of 2009 when
28 the patent was due to expire. If the company was able to get the pat-
29 ent extended for an additional five years [which it did], the royalties
30 would drop to 5 percent.

31 In April 2003 Allergan had began marketing Restasis for dry eyes in
32 humans. The product, according to Allergan and UGA, had potential
33 annual sales of \$300-\$500 million. Sales at level would produce annual
34 royalties of between \$18 million and \$30 million. It almost certainly

would be the most profitable patent in the history of the research foundation. And with government support for UGA dwindling, the cash-strapped university was keen to exploit the invention.

Even before Restasis hit the market Allergan approached the university with an offer to buy out the royalty agreement with a one-time payment. But first, they wanted assurances from the university that UGARF had full authority to negotiate the buy-down agreement and that it would be kept secret from Kaswan. UGA agreed and the two sides began meeting.

Allergan officials noted the university was hurting for cash and also reminded research foundation officials that there were no guarantees that its patents would hold. Besides, company officials said, there was another product seeking FDA approval that could compete with Restasis. Accepting a deal would guarantee UGA a big payday immediately and remove uncertainties about the patent validity and the level of sales and royalties. Company negotiators brought up budget stresses affecting the university at the time.

“It was,” one observer said, “like waving a small carrot in front of a hungry rabbit.”

Allergan offered a one-time payment of \$13.8 million.

The university said “thanks but no thanks” and countered with a \$47.6 million offer.

On August 29, 2003 the research foundation’s executive committee, made up mostly of senior university officials, met to consider another Allergan offer—this one for \$22 million in lieu of all royalty payments. The executive committee, which Adams heads, has full authority to act on behalf of the entire research foundation board of directors. In 2003 the executive committee consisted of Adams as president; UGA Vice President for Research Gordhan Patel, executive vice president and chair; UGA Provost Arnett Mace, vice chairman; UGA Senior Vice President Henry Huckaby, financial vice president and treasurer; chemistry professor Charles R. Kotal; F. Abit Massey and Jane Willson. Five of the seven members answer directly or indirectly to Adams.

Again the executive committee said “no” to Allergan’s offer.

1 Committee members noted that Allergan's offer was based on sales
2 of \$200 million a year even though the company itself had projected
3 \$300 million to \$500 million in annual sales. Moreover, the offer was
4 based on a five-year period when they fully expected to get a five-year
5 extension on the patents. But even without the extension, university
6 officials noted that royalty payments would exceed Allergan's offer.
7 Finally, they said an agreement would have to include indemnification
8 for patent infringements and "other claims" that might be brought
9 against the university. University officials recognized the potential for
10 legal problems if they excluded Kaswan from the negotiations. They
11 wanted money for legal expenses and indemnification if Kaswan won
12 a lawsuit.

13 Negotiations between Allergan and the research foundation
14 continued through the summer and Allergan kept sweetening their
15 offers. Finally, on November 20, 2003 Allergan made another offer
16 to executive committee. They bumped the lump-sum payment up
17 \$1 million to \$23 million to cover the cost legal expenses if Kaswan
18 sued, which everyone considered likely. It also included \$15 million
19 in milestone payments. Allergan agreed to pay the University research
20 foundation the \$23 million within 30 days of signing the agreement
21 and another \$5 million the first year that sales hit \$275 million and an
22 additional \$10 million when net sales hit \$375 million. The agreement
23 cut UGA's royalty from 7% to 2% through 2009, and eliminated the
24 provision for an additional 5 year payment at 5% through 2014. The
25 committee decided to call a meeting of the full board the next day,
26 November 21, to vote on the offer.

27 One board member wondered whether it was ethical to exclude
28 Kaswan before agreeing to the deal. A Sutherland Asbill attorney
29 advised against it, saying that Kaswan would probably try to get a
30 temporary restraining order if they told her about deal before it was
31 signed. In that case Allergan may withdraw the offer, he said. If they
32 waited, she would probably sue but in either scenario the attorney said
33 the university would probably win. The board then voted unanimously
34 to accept the agreement.

Kaswan was dumfounded when she learned of the Allergan deal. Her attorney had been negotiating with Sutherland Asbill & Brennan lawyers all through the summer and fall to settle their disagreements.

“We even scheduled a mediator for December 16th. We each paid him \$10,000.

All the while they were negotiating with, and closing on their deal to sell my royalty stream to Allergan for an up front payment. UGARF had no intention to mediate. It was simply a distraction. Although attorneys for UGARF were asked direct questions about their interactions and communications to Allergan as late as Nov. 2003, they lied about the subjects of their meetings in depositions to conceal the deal from me. I thought they were negotiating in good faith, but they were simultaneously doing the Allergan buy-down deal,” said Kaswan.

The university’s public relations machine, which cranks out hundreds of “good news” stories each year about the most inconsequential of campus activities and discoveries was eerily silent about the agreement—the largest single royalty payment in the school’s history.

Kaswan was told of the agreement on December 12, 2003. She knew immediately it was a bad deal for the university. On December 15, 2003 she filed a lawsuit in Athens-Clarke Superior Court in an effort to stop the deal. Not only had she been the most actively involved in pushing her invention to market but she shared a financial stake in the deal. Moreover, she was more knowledgeable of the potential market value of Restasis than anyone at the university. That the university would exclude her from negotiations was not only unwise but personally hurtful.

Financial analysts hired by Kaswan for her court case project that UGA will receive \$72 million from the deal. It’s a nice payday. But under the original agreement, the university would receive \$294 million in royalties. The secret deal will cost UGA some \$222 million based on current projected sales. The figures are largely unchallenged by the university.

1 The lawsuit has been slowly winding its way through the court for
2 five years, much of it under a veil of secrecy. In an email response to
3 my request to open the files, Superior Court Judge David Sweat said
4 depositions and exhibits remain sealed because “they have not been used
5 by the court.” Thus, documents that may reveal the duplicity, perjury
6 and unethical behavior remain under seal by order of the court.

7 In April 2007, Judge Sweat granted summary judgment in favor
8 of the research foundation after sorting through dozens of motions
9 and hearing months of legal arguments. Kaswan’s contract with the
10 university gives the institution complete control over the patent and
11 had the authority to negotiate the deal without informing the inventor.
12 The fact that the university made a bad deal with Allergan is relevant,
13 Sweat said in his summary judgment, which is not under seal.

14 At the hearing on summary judgment, Kaswan’s attorney Foy
15 Devine pointed out that Allergan acknowledged that it would have
16 been willing to pay the university up to \$71 million, more than three
17 times the amount of the contract. In one exchange with Kaswan’s
18 attorney, Foy Devine, Judge Sweat left little doubt about what he
19 thought of the university’s actions.

20 THE COURT: *But you’re—They made a bad deal.*

21 DEVINE: *Pardon?*

22 THE COURT: *UGARF made a bad deal.*

23 DEVINE: *They not only made a bad deal, you honor, and they made*
24 *a horribly bad deal.*

25 THE COURT: *That doesn’t make it illegal.*

26 DEVINE: *Not in. . .*

27 THE COURT: *It may be stupid.*

28 Nevertheless, Judge Sweat ruled against Kaswan’s claim that the
29 research foundation and Allergan conspired to committed fraud. He
30 said the university’s policies vest wide latitude in how it administers
31 patents and inventions created by the faculty and staff.

32 “No doubt many of the university faculty and staff may be dis-
33 satisfied with those provisions that limit their ability to direct devel-
34 opment of products that may become commercially viable based on

the inventions, Sweat said, “but these agreements leave little question that the employees assignment of the patent vests the decision making authority to the University of Georgia Research Foundation.”

Adding further insult, Judge Sweat ruled that the university could withhold part of her share of the royalties to pay for the legal costs of the research foundations. Essentially, Kaswan is paying the research foundation’s legal bills as well as her own. Nevertheless, Kaswan vows not to go away.

Adams brushed aside the entire episode as not rising to the level of “institutional concern.”

In a sworn deposition in the federal suit on August 13, 2003 Adams claimed to have learned of the possible lawsuits a couple of months earlier at a research foundation board meeting. As for Kaswan, who was named UGA’s “inventor of the year” in 1998, Adams first full year at Georgia, Adams didn’t recognize the name at the time. However, court documents suggest otherwise.

Judy Curry, the research foundation’s legal counsel, wrote Adams January 21, 2003 regarding the FDA approval of Restasis. “*You may have heard the news that Allergan’s dry eye product, Restasis, has received FDA approval,*” Kaswan wrote. “*This is very good news because UGARF holds the patent on which the product is based and will receive royalties on sales thorough the life of the patent. . . Based on annual gross sales of \$100 million, UGARF’s royalties would be about six million. As you know the inventor on this product is Dr. Renee Kaswan.*”

In March Curry again wrote the president updating him legal action the research foundation had taken against Kaswan. Both letters were marked “attorney client privileged.”

Kaswan is convinced that Adams orchestrated the deal to make himself look good without regard for the long-term damage to the university. Even if it weren’t a horrible financial deal for the school long-term, such treatment of a researcher and inventor will damage the school’s reputation and make recruitment of top researchers more difficult, she says.

“Michael Adams lies so smoothly and automatically it’s frightening,”

1 Kaswan said. “What he did in this situation was so underhanded that
2 it’s hard for people to conceive that a president of a major university
3 would behave this way. It is deeply disturbing that UGA’s defense
4 in the Restasis buy-down case, which cost the University over \$220
5 million, hinged on the legal argument that the school’s Intellectual
6 Property Policy, which all employees are required to sign as a condi-
7 tion of employment, is so severely one-sided that the inventor has no
8 rights,” Kaswan said. “UGA lawyers claimed the UGA Intellectual
9 Property policy evades even the usual requirements for good faith and
10 fair dealing inherent in all other employment contracts.”
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