Kaswan Case Study
RESTASIS®

Restasis®, a topical treatment to remedy chronic dry eye disorder, was named one of the top "University Inventions That Changed the World" by the University of Virginia Patent Foundation. Originally developed as Optimmune® by Dr. Renee Kaswan in conjunction with The University of Georgia Research Foundation (UGARF) for the treatment of the disorder in canines, the drug was adapted and tested for human use, received FDA approval and was brought to market by Allergan in 2003.

As the most profitable and well-renowned invention to emerge from the University of Georgia (UGA), Restasis® has become a subject of litigation and controversy. Under the University's original contracts with Allergan, UGA would have realized an estimated $300 million in royalties from the drug's licensed sales. However, in secret meetings with the pharmaceutical company, excluding the inventor, the University agreed to a buy-down deal at a small fraction of that price.

Optimmune® is licensed solely to Dr. Kaswan, but nonetheless, the University of Georgia and the University of Georgia Research Foundation have filed multiple nuisance suits against the researcher and all but one minor claim were dismissed on summary judgment in her favor. The remaining claim is under appeal by Dr. Kaswan, who maintains that it is erroneous.

DISPUTE OVERVIEW

The Restasis® innovation dates back to 1983-1987. However, inventor's equity ownership rights at UGA didn't become public knowledge until 1996 when UGA published their 1995 Intellectual Property Policy. Dr. Kaswan claims that the UGA Intellectual Property (IP) Policy requires the UGA Research Foundation (UGARF) to reassign her patents to her. UGARF initially agreed with Dr. Kaswan's position and committed to reassign her patents to her, but back-pedaled when Restasis® won FDA approval on December 24, 2002, and the stakes changed.

Litigators immediately intercepted and stopped all direct communications between UGARF and Dr. Kaswan. They recommended an iron fist offensive-defense strategy and initiated a series of bad faith claims against Kaswan and her company KB Visions, Inc. within weeks of the FDA's approval of Restasis®. UGA's executive attorney blocked Dr. Kaswan's request for faculty peer review as prescribed in the UGA Intellectual Property Policy forcing her into protracted litigation to get her inventor's share of the vastly reduced net royalties, all the while subtracting UGARF's litigation expenses from net royalties.

Meanwhile, Allergan approached UGARF with a proposal for an upfront buy-down of their Restasis® royalty contract and proposed to co-defend the patent ownership dispute against Dr. Kaswan. Allergan insisted that UGARF prevent Dr. Kaswan from learning about their renegotiations until the buy-down deal was signed, which allowed Allergan to undervalue the Restasis® royalty stream owed to UGA and Dr. Kaswan. The deal UGARF accepted was well below market-rate and ultimately lost them over $220 million in royalty income they would have made if they had simply let the original Licensing Agreement executed in 1993 continue.

After years of negotiation and legal disputes, there are still fundamental questions regarding the ownership of the patents and therefore the right to license the treatment. Dr. Kaswan continues to pursue an appeal to have her case heard before a jury and to force UGA and Allergan to disclose the details of the renegotiated agreement that has been secreted from public scrutiny.

Additionally, Dr. Kaswan plans to encourage a call for reform of the standards of conduct associated with the Intellectual Property Policies of UGA.

What was about to become a UGA 'home run' became instead a bottomless pit of lost opportunity, expensive litigation and controversy. In closed-door meetings, absent both public and the inventor's input or oversight, Allergan allegedly enriched themselves by offering fraudulent information and inducements to UGARF to accept unreasonable new contract terms.

Resolution

The University left hundreds of millions of dollars on the table. These funds could have financed PhD students, built research laboratories, funded faculty salaries, financed other research projects, and generally bridged budget shortfalls. Instead litigators destroyed the mutually productive relationship with UGA's luminary scientist and distracted an innovative researcher from productive scientific endeavor. Beyond the loss of \$220 million dollars, UGA lost an invaluable opportunity for positive publicity and traded it for a publicity quagmire that will damage faculty recruiting efforts for the foreseeable future.

The downfall of UGA's home run invention was apparently the coincidence of two unforeseeable events: a covert corporate agenda, Allergan's "Florida Plan", to reduce all of their royalty expenses associated with Restasis®, concurrent to a furtive abuse of power by the UGA president who procured an instant burst in UGA discretionary income to secure his job.

Restasis® is a topical treatment to remedy chronic dry eye disorder (keratoconjunctivitis - KCS) in humans. Optimmune® is a topical treatment to remedy chronic dry eye disorder (keratoconjunctivitis - KCS) in canines.

Innovation And Patent Details

INVENTION/INNOVATION NAME

Restasis®, Optimmune®

INSTITUTION WHERE INVENTION/INNOVATION WAS DEVELOPED

University of Georgia

NAME(S) OF INVENTOR/INNOVATOR – TITLE – ADVANCED DEGREES HELD

Dr. Renee Kaswan, DVM, MS - Diplomate, American College of Veterinary Ophthalmologists

REVENUE GENERATED

Restasis®: Allergan began selling Restasis® in April, 2003. The following revenue numbers are annual, with all years containing four quarters of revenue except 2003, which contains three.

2003	$38,400,000	generated in Q2-Q4
2004	$99,800,000	24% quarter over quarter increase from 2003 to 2004
2005	$190,800,000	91.18% growth from 2004 to 2005
2006	$270,200,000	41.61% growth from 2005 to 2006
2007	$344,500,000	27.50% growth from 2006 to 2007
2008	$440,000,000	estimate provided by Allergan

Revenues for sales of Restasis® since it has been on the market have exceeded $1.5 billion. Annual sales have increased between $61-$91 million each year. This is a staggering growth rate. Restasis® was the first, and continues to be the only, treatment for chronic dry eye which helps to increase the eye's natural ability to produce tears.

PATENT NUMBERS, DATES ISSUED, PATENT HOLDER'S NAME

PATENT 4,649,047: Ophthalmic treatment by topical administration of cyclosporin; a method for the treatment of either phacoanaphylactic endophthalmitis or uveitis by administering at least one cyclosporin topically to the eyes. Topical application of cyclosporin provides cyclosporin to the anterior chamber, the posterior chamber and the vitreous body of the eye.

Filed: March 19, 1985
Inventor: Dr. Renee Kaswan
Assignee: University of Georgia Research Foundation
Commercial Name: Restasis®, Optimmune®

PATENT 4,839,342: Method of increasing tear production by topical administration of cyclosporin; a method of treating an aqueous-deficient dry eye state in a patient suffering there from, which method includes the step of administering cyclosporin topically to the patient's eye. The cyclosporin is administered as a solution, suspension or ointment in a pharmaceutically acceptable excipient.

Filed: September 3, 1987
Inventor: Dr. Renee Kaswan
Assignee: University of Georgia Research Foundation
Commercial Name: Restasis®, Optimmune®

PATENT 5,411,952: Ocular cyclosporine composition; cyclosporine compositions for topical ophthalmic use for treatment of immune disorders, to enhance or restore tear production, and to enhance or effect normal healing of the surface of the eye, containing cyclosporine dissolved in corn oil.

Filed: February 6, 1990
Inventor: Dr. Renee Kaswan
Assignee: University of Georgia Research Foundation
Commercial Name: Restasis®, Optimmune®

Dispute Details

These lawsuits are quite significant as they demonstrate aggressive behavior by the University of Georgia against one of their own inventors. Indeed, the Board of Regents of the University System of Georgia proclaimed in its meeting minutes of March 2005, "licensing income at UGA in fiscal year 2004 totaled more than $28 million, due in large part to the licensing of Restasis".

Policies of the Board of Regents of the University System of Georgia apply to all public universities within the state, including the University of Georgia. In Section 603.01 of the Board of Regents Policy Manual, it states:

"The rights and privileges, as well as the incentive, of the inventor or creator must be preserved so that his or her abilities and those of other faculty, staff or students of colleges and universities of the University System may be further encouraged and stimulated."

The actions of the University of Georgia in its every dealing with Dr. Kaswan contradicted both the letter and spirit of this policy.

PRIMARY ISSUES ENCOUNTERED

Ownership of the Intellectual Property

Dr. Kaswan discovered an ophthalmic treatment for chronic dry eye which had applications in veterinary medicine as well as human medicine. Dr. Kaswan's innovations were not developed using Federal funds or corporate sponsorship, nor was the research specifically assigned to her by UGA. As such, in accordance with the University of Georgia's Intellectual Property Policy, the invention should have been classified as either IIC "University-Assisted Individual Efforts" or IID "Individual Efforts".

UGA CLASSIFICATION OF INTELLECTUAL PROPERTY

UGA classifies intellectual property according to the following four categories as defined in the UGA Intellectual Property Policy, Section II - Rights and Equities in Intellectual Property:

IIA. Sponsor Supported Efforts *– Supported by public or private grants*

IIB. University-Assigned Efforts *– Supported by UGARF grants*

IIC. University-Assisted Individual Efforts *– Significant use of University resources, staff, or paid employee time, but not grant supported.*

IID. Individual Efforts *– Unsupported and no significant use of University resources*

Though required by its own policies, the University of Georgia Research Foundation never did assign her invention a classification. Then, without notifying Dr. Kaswan, they altered their file documents by inserting "2A" into an Invention Disclosure Form Dr. Kaswan had submitted in 1983. UGARF relied heavily upon this altered document as "proof" that the University owned controlling rights to the invention.

Dr. Kaswan was denied the opportunity to appeal the ownership dispute to the UGA Faculty Intellectual Property Committee, which UGARF's Policy Section III.L. requires.

A classification of IIC or IID would put ownership and control of the patents and innovations in Dr. Kaswan's hands, while a IIA or IIB classification vested ownership in UGARF and allowed them control over the destiny of what was to become the most successful invention to emerge from the University of Georgia. When Dr. Kaswan attempted to appeal the classification of her invention, UGA's Executive Legal VP instructed the UGA Faculty Appeal Committee to refuse her request for a hearing, erroneously claiming that Dr. Kaswan forfeited her rights to appeal by choosing litigation. It was UGARF and not Dr. Kaswan that initiated litigation and at the time the appeal was made, Dr. Kaswan had yet to file even a counterclaim.

Dispute Details Continued

In 1987, KB Visions, a small business start-up incorporated in Georgia by Dr. Kaswan, contracted with UGARF for the exclusive license for veterinary use of the Kaswan patents. KB Visions sublicensed the veterinary field of use to Schering-Plough who produced Optimmune®. The FDA approved Optimmune® for veterinary use in 1995 and the royalties from this product have been significant to both Kaswan and UGARF ever since.

In 2001, domestic sales of Optimmune® were interrupted due to non-compliance at one of Schering-Plough's manufacturing facilities. Compounding pharmacies were eager to provide a replacement and supply the market but doing so violated the patents. UGARF directed KB Visions to downgrade the Schering-Plough license to non-exclusive and license compounding pharmacies to produce a generic equivalent of Optimmune®. UGARF also directed KB Visions to assume patent enforcement responsibility.

Allergan, who had obtained a sublicense for human use of the product from Novartis and UGARF, pursued FDA approval, but the FDA process stalled in 1999. Then Allergan invested in a partnership with Inspire pharmaceuticals to co-develop a different dry eye treatment, diquafosol and UGARF and Kaswan agreed that Allergan was no longer meeting its due diligence contractual requirements.

In negotiations in 2001-2002, UGARF verbally agreed to wholly assign the rights of the Kaswan patents to KB Visions in exchange for 25% royalties of the Restasis® income. UGARF concurred that this agreement would comply with IP policy classification, facilitate KB Visions authority to protect the patents for veterinary use, and release oversight of the Allergan issues to Kaswan who, as an individual, was more able to deal with them.

Final revisions of the patent reassignment agreement were exchanged between legal counsel for UGARF and Kaswan on December 19, 2002, then UGARF staff dispersed for holiday. All parties received a Christmas surprise; FDA approval of Restasis® was granted to Allergan December 24, 2002. Lawyers for UGARF took immediate command even without consulting the UGARF director who, unbeknownst to Kaswan, was on a month-long vacation.

In January 2003, litigators reneged on the agreement to reassign the patents to Dr. Kaswan, threatened termination of the KB Visions' veterinary license, then filed a federal suit alleging trademark infringement and other claims against KB Visions and Kaswan.

UGARF granted an exclusive license in the field of human medicine to Novartis. Novartis later sublicensed to Allergan, who developed the medical breakthrough dry eye therapy, Restasis®.

Licensing Agreements

UGARF granted an exclusive license to Dr. Kaswan's company KB Visions (KBV) for the veterinary field of use of the invention. KBV registered the trademark Optimmune® and licensed the name and veterinary field of use to Schering-Plough Animal Health Inc. In 2001, Schering-Plough's human pharmaceutical corporation encountered FDA factory certification problems unrelated to Optimmune® and was forced to cease the manufacture of Optimmune® and several other products. At UGARF's urging, KBV issued non-exclusive licenses to compounding pharmacies and veterinarians to produce a generic equivalent of Optimmune®.

When they received notice of patent violations. UGARF sent out "cease and desist" letters, but later preferred Dr. Kaswan to take over this duty. When lawsuits were required, Dr. Kaswan informed UGARF. They replied with approval or no response at all. KB Visions was the petitioner, but UGARF occasionally had to be a co-petitioner as the assignee of the patents.

In the letter conveying the intent to recant on their agreement to revert patent assignment to Dr. Kaswan, UGARF complained about Dr. Kaswan's efforts to protect the Optimmune® patent, but did not invoke the notice/cure provisions of the licensing agreement. UGARF continues to collect royalties from KB Visions.

Major Issues

1. UGARF filed nuisance lawsuits against Dr. Kaswan to coerce her to relinquish her claims to controlling ownership of the patents. Coinciding with this, they threatened to terminate her veterinary field of use license agreement for Optimmune®. UGARF also suspended tender of her inventor's share of royalties on Restasis®.

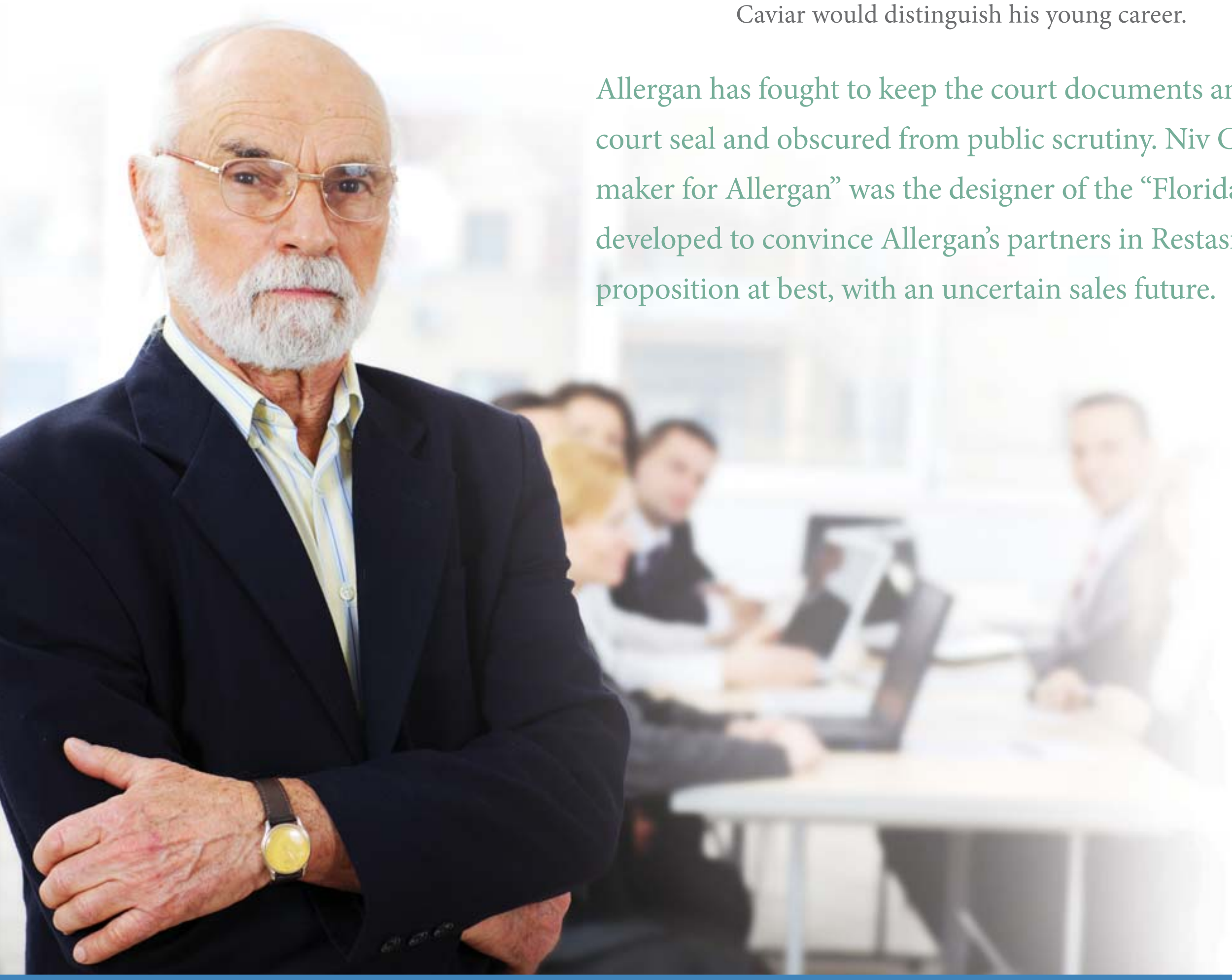
2. Allergan and UGARF conducted closed-door secret negotiations for a lump sum buy-down of future royalty payments that was substantially less than market value. As part of the deal, Allergan would give UGARF $1 million toward its legal fees and assign Allergan's expert legal counsel to control the legal strategy to defeat Kaswan, and ultimately UGA's best interests.

Dispute Details Continued

Allergan's Actions

There were several parties due royalties from Allergan based on the future sales of Restasis®. UGA and in turn, Dr. Kaswan were due royalties, Novartis, the initial licensor of the patent and also Inspire Pharmaceuticals had royalty arrangements with Allergan tied to future Restasis® sales. Niv Caviar, self-styled "deal maker for Allergan", was the architect of the secret "Florida Plan," the strategy developed to buy out royalty obligations at a huge discount by convincing Allergan's partners that Restasis® was a risky proposition at best, with an uncertain sales future. By obtaining a deeply discounted buy-down agreement with UGARF and their other partners, Allergan would avoid hundreds of millions, perhaps a billion dollars in future royalty payments that would have otherwise been due to their Restasis® development partners, and Caviar would distinguish his young career.

Allergan has fought to keep the court documents and records under court seal and obscured from public scrutiny. Niv Caviar, self-styled "deal maker for Allergan" was the designer of the "Florida Plan," the strategy developed to convince Allergan's partners in Restasis® that it was a risky proposition at best, with an uncertain sales future.



Allergan delayed the roll out of the consumer targeted television commercials in order to keep 2003 revenues in the “underperforming range” to support the grossly underestimated sales projections Caviar suggested to UGARF during the buy-down negotiations.

> Caviar falsely informed UGARF that Allergan and Inspire’s competing product, diquafosol, would be FDA approved imminently and urged UGARF to sign before Allergan executives could recant the offer. This misrepresentation caused analysts for UGARF to include erroneous risk factors in their sales projections, as well as false urgency to seal the deal.

Days after execution of the buy-down agreement, the FDA denied approval of diquafosol based on poor efficacy results that Allergan and Inspire had jointly submitted and discussed with FDA. Stockholder class actions suits subsequently waged against Inspire, but not Allergan, alleged public misrepresentation of the anticipated FDA diquafosol approval.

Allergan was well aware of the poor clinical trial results of diquafosol, and its imminent rejection for FDA approval. In fact, in January 2002, Inspire Pharmaceuticals, Allergan’s partner in the development of diquafosol saw a nearly 75% plunge in stock price when the company reported poor results in their first set of clinical trials. Subsequent clinical trials fared no better; the treatment was apparently no more effective than placebo.

Allergan’s CEO, David E.I. Pyott stated, “Given the challenges associated with the research, development and regulatory approval of dry eye pharmaceuticals, we have always taken a conservative approach and have not included diquafosol in our strategic plans. Instead, our strategic plans have focused on vigorously building Restasis®, the only pharmaceutical approved by the FDA for the treatment of chronic dry eye disease.”

Allergan has staunchly litigated to keep their UGA contract and legal proceedings secreted from public review and under court seal. However, Georgia Sunshine Laws require contracts between state agencies and private corporations be made public.

Dispute Details Continued

UNIVERSITY INVOLVEMENT

For a long period of time, UGARF worked cooperatively with Dr. Kaswan and KB Visions to protect the veterinary use patent rights. Concerned about damaging their image among Georgia pharmacists, UGARF eventually withdrew from the process and requested that Dr. Kaswan solely assume compliance efforts.

After FDA approval of Restasis®, UGARF's interests changed substantially. UGARF initiated legal action against Dr. Kaswan, falsely alleging that she was acting against their instructions, outside of the terms of the licensing agreement and announced intent to retract her patent license agreement. Additionally, UGARF suspended royalty payments from Dr. Kaswan from January 2003 through July 2005, and September 2008 to present.

In an August 2003 deposition taken by defendants in the UGARF initiated lawsuits, UGA President Michael Adams, who also serves as UGARF President, pleaded complete ignorance of the legal controversy surrounding the licenses and the lawsuits, stating that they did not rise to the level of an "institutional concern." Yet also in August 2003, the same month he gave his deposition, he presided over an executive session of the UGARF board, where he presented these issues and recommended the dual course of action taken: secretly accept Allergan's royalty buy-down proposal and continue litigation against Dr. Kaswan for the purpose of distraction and coercion.

Adams' harmful decisions as President of UGARF coincided with his rivalry with a hugely popular football coach whom he summarily fired in 2003, an action which triggered statewide calls for his dismissal. Official notes from the closed UGARF executive board meeting, produced in discovery and kept under court seal until made public by Pulitzer Prize winning journalist Richard Whit contradict President Adams' testimony in his deposition and reveal his decisions and motives.

At Adams' direction, UGARF acted in bad faith violating UGA Intellectual Property Policies and Georgia Sunshine Laws to the ultimate detriment of UGA and benefit of Allergan. Questions remain as to why UGARF went forward without this valuable information.

In court, UGARF's defense of its actions amounted to innocence based on naiveté. Remarkably, Ed Tolley, one of UGA's attorneys in the proceedings, said the University's actions were "stupid" but not illegal. When it became impossible to continue insisting the secret royalty buy-down was financially advantageous for UGA, confessing to 'poor judgment' was preferable to abuse of power, perjury, and illegal conduct in violation of Georgia's Sunshine Laws. There are very few exceptions to Georgia's Open Meetings/Open Records Laws and the agreement between Allergan and UGARF does not meet those criteria.

LEGAL FINDINGS/PROCEEDINGS

2003: UGARF sued KB Visions for trademark infringement for using the name "UGARF" in legal notices. Dismissed in a Summary Judgment.

2004: UGARF sued KB Visions to have the court escrow royalties due KB Visions. Dismissed in a Summary Judgment.

2004: Kaswan sued UGARF to enforce the unsigned contract to reassign the patents to Kaswan. Dismissed in a Summary Judgment.

2004: Kaswan sued UGARF and Allergan for breach of contract and Allergan for fraudulent and tortious interference with her employment contract. All but one claim, failure to pay inventor's share of royalties, were dismissed in a Summary Judgment. Disputes over interest and unreasonable deduction of legal fees are currently being adjudicated. Breach of contract claims will be eligible for appeal following written court order on the non-payment claim.

2004: UGARF sued KB Visions for breach of patent license contract, KB Visions countersued. Currently in litigation.

2008: UGARF sued KB Visions to escrow inventor's share of royalties. Currently in litigation.

AWARDS/LEGAL RULINGS

UGARF v. KB Visions/Renee Kaswan: KB Visions was awarded a Summary Judgment dismissal and legal costs.

Kaswan v. UGARF/Allergan: UGARF/Allergan awarded Summary Judgment on all claims except one. The claim for payment of inventor's share, interest and restoration of legal expense deductions is being adjudicated following which an appeal of the Summary Judgment dismissal of additional claims is anticipated.

PERTINENT DOCUMENTS

Many of the case documents are still under court seal at the insistence of Allergan and UGARF. After years of haggling over discovery disputes, Allergan's evidence was produced "for attorney's eyes only" and has not been publicly examined, nor examined even by Dr. Kaswan. Most court documents were unsealed in 2008 at Pulitzer Prize winning journalist Richard Whitt's request.

IPADVOCATE.org

Analysis

Unequivocally, the litigious aftermath that incessantly shadows any inventor's 'home run' debilitates American entrepreneurial productivity for mankind.

IMPLICATIONS OF CASE

Impacting all university inventors, the implications of this case are far-reaching. Many schools follow the advice of their IP attorneys who often take the 'iron fist' approach to patenting. Students and faculty are compelled to sign, under substantial duress, a complete assignment of sole ownership and control of their patent applications to their university. This essentially grants the university sole discretion over all future decisions for their invention over a 20-30 year lifecycle of the proposed patents. Combine the anticipation of large profit potential, staff turnover, selective memory, and an abundance of overzealous IP litigators representing the University and not the inventors, the opportunity for abuse of sole discretion should be quite obvious. Additionally, adversarial litigation, unaccountable research foundation budgets, discretionary spending, and closed executive research office board meetings will only repress innovation in our universities.

While some leading research universities invite and encourage inventor participation in licensing and commercialization negotiations, many institutions still choose to act behind a veil of secrecy. When commercialization efforts are not conducted transparently, accountability is sacrificed.

When universities abuse the efforts of their intellectual workforce, the spirit of research will dwindle and the drive for innovation will die. Therefore, if discussions are not transparent, then poor intentions, incompetence, and naiveté can be shrouded by a lack of disclosure. No one will prosper under these conditions - not the university, not its researchers and not the public.

It is incumbent upon universities and their technology transfer offices to establish policies of transparent negotiations and communications, inventor involvement and a review and oversight process that ensures the future of the pursuit of knowledge and innovation for the betterment of all mankind.

The actions of the University of Georgia, the University of Georgia Research Foundation and Allergan are a worst-case example of the need for reform in the academic intellectual property arena. Using the combined coercion tactics of financial stricture, nuisance litigation, bottomless legal funds and the abuse of the name of a well-respected university, this behemoth sought to crush one of its foremost researchers.

FUTURE ACTIVITY ANTICIPATED

Dr. Kaswan plans to appeal the summary judgment dismissal of breach of contract claims and present her claim before an Athens, Georgia jury that Allergan fraudulently induced UGARF to breach the UGA Intellectual Property Policy and Georgia Sunshine laws for Allergan's undue enrichment. Additionally, Dr. Kaswan sponsors www.IPAdvocate.org as a forum for reform of the standards of conduct associated with the Intellectual Property Policies of all American universities.

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