Townsend Case Study

PET/CT SCANNER

What do a British particle physicist working in Geneva, Switzerland and an electrical engineer from the Deep South have in common? The answer: a landmark medical innovation that has saved the lives of countless people worldwide.

By combining a computerized axial tomography (CT) scanner with a positron emitting tomography (PET) scanner into one imaging device controlled from a single console, Dr. David Townsend and Dr. Ronald Nutt have enabled oncologists and other doctors to more accurately diagnose cancer in earlier stages and precisely pinpoint the location of even the smallest of tumors.

In 1993, the University of Pittsburgh hired Dr. Townsend away from the University of Geneva to run the physics and instrumentation program at their PET facility. A key part of their interest in Dr. Townsend over other PET specialists was his collaborative relationship with Dr. Nutt. The two had conceived the combined scanner in 1991 and were discussing how their idea could be reduced to practice when the University of Pittsburgh came knocking at Dr. Townsend's door.

After dedicating ten years helping to develop Pitt's PET facility into a state-of-the-art program, Townsend resigned in late 2002 when the University suggested he should abandon Dr. Nutt, his long time collaborator, and begin working with rival firm GE who had signed an agreement with the University of Pittsburgh Medical Center.

Then, in early 2004, the University of Pittsburgh filed a lawsuit against the two inventors alleging the University owned the intellectual property and patents on the combined scanner and seeking millions of dollars in damages.

DISPUTE OVERVIEW

Before relocating to the University of Pittsburgh, Dr. Townsend signed a consulting agreement with Dr. Nutt's Knoxville based company, CTI. This agreement gave CTI rights to Dr. Townsend's interest in any patent secured as a result of his collaboration with them.

In 1986, CTI formed a joint venture with Siemens called CTI PET Systems (CPS) in order to build a prototype of the PET/CT combined scanner. CPS applied for a patent in October of 2000, listing Drs. Townsend and Nutt as the inventors and themselves as the assignee. Even prior to the invention reaching the market, it was recognized by Time Magazine as its *Medical Invention of the Year* in 2000.

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DISPUTE OVERVIEW CONTINUED

In May 2001, GE launched the first PET/CT scanner, called the Discovery PET/CT. Siemens followed in August of 2001 with the introduction of their Biograph system. When these manufacturers went to market with their devices, the Townsend/Nutt patent had yet to be approved. The patent was not approved until 2002, well after the two companies were competing in the marketplace.

Today, GE, Siemens and Philips all market combined PET/CT scanners based on a similar concept, but with each machine differing somewhat in the actual technology. None of these companies relied on patent protection for their devices. It was the uniqueness of their systems that differentiated them in the marketplace, not the concept or method patents.

Pitt's Office of Technology Management wanted a share of the $1.5-$2 million dollar sales price of the combined scanner. In January of 2004, Pitt representatives, along with university attorneys, met with the two inventors.

The meeting ended with the inventors optimistic that a compromise had been reached, but the next day Pitt's attorneys filed a lawsuit against Townsend, Nutt and CPS charging them with conspiracy, fraud, conversion of property and other serious allegations.

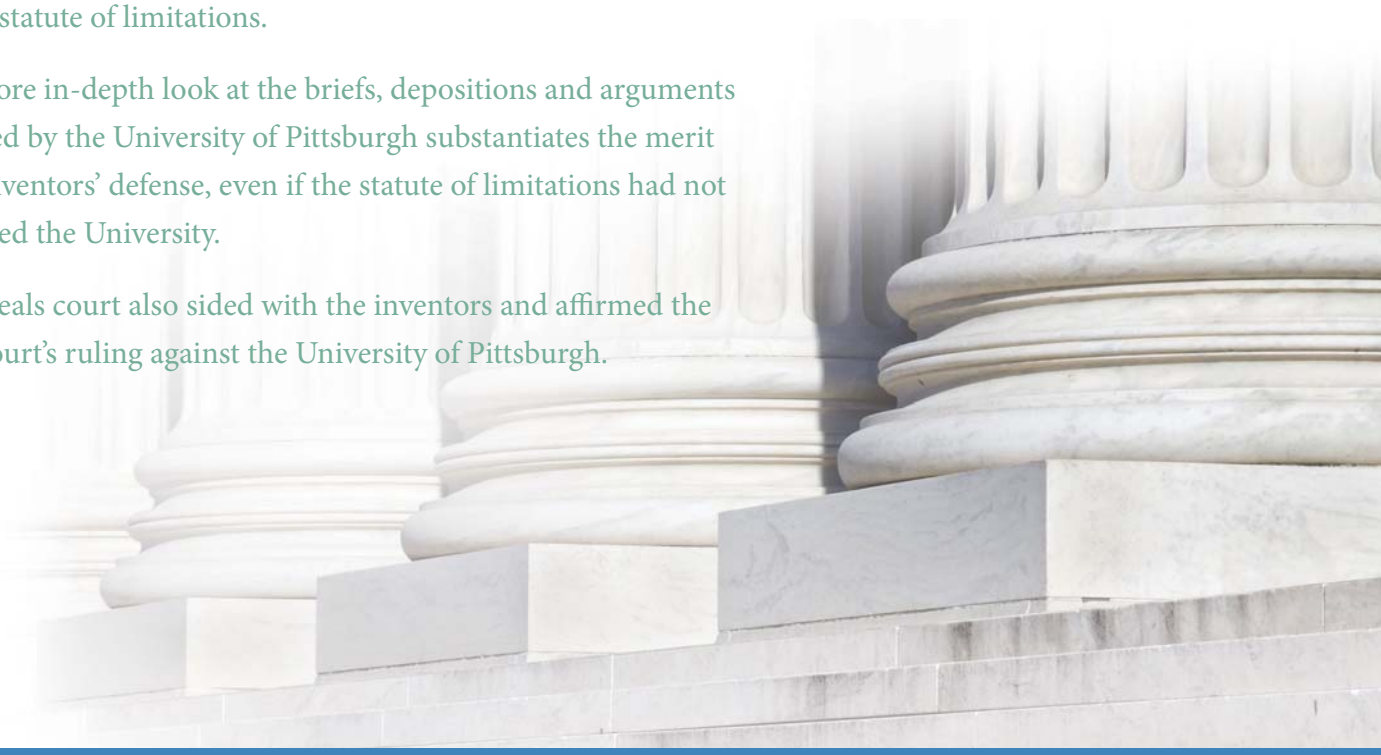
Resolution

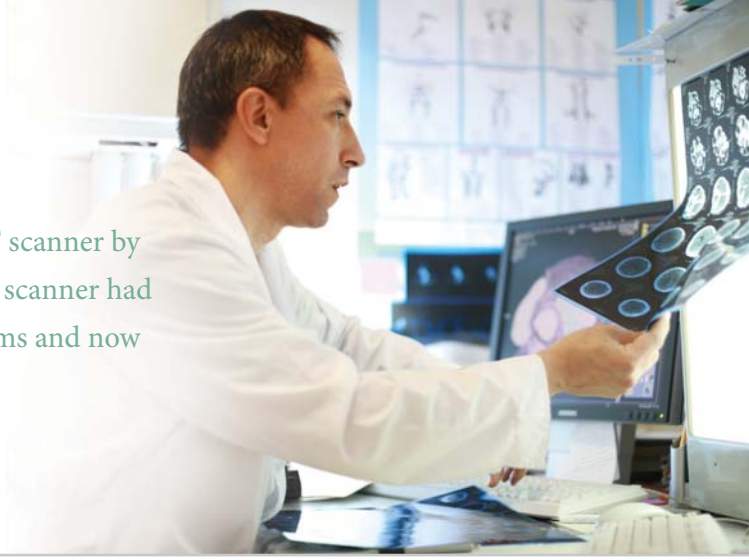
The case was initially filed in Pennsylvania, but defense attorneys easily won a request for a change of venue to the Federal District Court in Knoxville where the PET/CT prototype scanner had been developed and where CTI PET Systems was located.

At a glance, the victory in the lower court may seem to be sheer providence for Dr. Townsend, Dr. Nutt and CTI. They were awarded a summary judgment over the University of Pittsburgh on the basis of expired statute of limitations.

But a more in-depth look at the briefs, depositions and arguments presented by the University of Pittsburgh substantiates the merit of the inventors' defense, even if the statute of limitations had not forestalled the University.

The appeals court also sided with the inventors and affirmed the lower court's ruling against the University of Pittsburgh.





From 2001 through 2008, sales of the combined PET/CT scanner by all vendors exceeded 4,000 units. By 2006, the combined scanner had completely supplanted all sales of stand-alone PET systems and now accounts for the entire PET market.

Innovation And Patent Details

The combined scan is better than either the individual scans or the combined results of scans run separately. By diagnosing cancer in earlier stages, more lives can be saved and the patient's quality of life can be drastically improved. Depending on the type of cancer, a PET/CT scan has a 95-98% detection accuracy rate, particularly if the cancer has metastasized.

The CT (computerized axial tomography) scan is an x-ray based scan that provides information on the location, size and shape of cancerous and other growths in the body. CT images detect anatomical changes, even smaller ones that a PET scan could miss. Anatomical changes are physical changes in the structure of an organ or other body part. However, CT does not provide information on whether the growth (change) is cancerous or not.

The PET (positron emission tomography) scan measures photons emitted from the body after injection of a radioactive glucose analog solution. Tumors consume the glucose solution and then radioactive nuclei emit positrons as they decay, creating metabolic hot spots which are then displayed as an image by capturing the radiation emitted from the body. Tumors must be active for a PET scan to identify them. It is their growth that is the basis for discovery with this type of scan. However, once PET does detect a growth, it can often determine whether it is cancerous or benign, as well as establish staging of a cancerous tumor.

While PET alone is more helpful in diagnosing subtle metabolic changes in the body and staging cancer, its drawback is in less accurate localization information. CT, while adept at identifying more sizable growths, may not recognize smaller growths as tumors, but its advantage lies in pinpoint accuracy of the anatomical location of a growth.

In combination, the scans provide unparalleled diagnostic information that enables oncologists to detect cancer and other disorders in earlier stages and identify the specific region to be treated.

INVENTION/INNOVATION NAME

The combined scanning technology is marketed as a PET/CT scanner. GE sells their imager under the brand name Discovery. Biograph and Biograph TruePoint are the products marketed by Siemens. The Philips product line is the Gemini. Additionally, there are a handful of other manufacturers, primarily in Japan, of the PET/CT scanner device.

INSTITUTION WHERE INVENTION/INNOVATION WAS DEVELOPED

University of Geneva, Switzerland (conceived)

CTI PET Systems, Knoxville, Tennessee (written plans developed, prototype developed, successful testing of prototype with phantoms conducted)

University of Pittsburgh (clinical trials with patients)

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Innovation And Patent Details Continued

NAMES OF INVENTORS/INNOVATORS – TITLE – ADVANCED DEGREES HELD

Dr. David Townsend, Ph.D.
Dr. Ronald Nutt, Ph.D.

REVENUE GENERATED

Imaging device revenues are often reported together on financial statements, so it is difficult to pinpoint revenues solely for the PET/CT device market. However, annual U.S. sales for all imaging products are well into the billions and PET/CT holds the lion's share of that market.

PATENT NUMBERS, DATES ISSUED, PATENT HOLDER'S NAME

PATENT 6,490,476: A combined PET and X-Ray CT for acquiring CT and PET images sequentially in a single device, overcoming alignment problems due to internal organ movement, variations in scanner bed profile, and positioning of the patient for the scan. In order to achieve a good signal-to-noise (SNR) for imaging any region of the body, an improvement to both the CT-based attenuation correction procedure and the uniformity of the noise structure in the PET emission scan is provided. The PET/CT scanner includes an X-ray CT and two arrays of PET detectors mounted on a single support within the same gantry, and rotate the support to acquire a full projection data set for both imaging modalities. The tomograph acquires functional and anatomical images which are accurately co-registered, without the use of external markers or internal landmarks.

Filed: October 10, 2000
Inventors: Dr. David W. Townsend, Dr. Ronald Nutt
Assignee: CTI PET Systems, Inc.
Commercial Name: N/A

PATENT 6,631,284: The abstract of both patents are identical. The difference between the two lies in the claims of the patent. The "476" patent's claims are for the method used to acquire the combined image, while the "284" patent's claims are to the mechanics of the device.

Filed: June 12, 2002
Inventors: Dr. Ronald Nutt, Dr. David W. Townsend
Assignee: CTI PET Systems, Inc.
Commercial Name: N/A

Dispute Details

The core legal issue for the University was the value of the patents, both perceived and actual. The University of Pittsburgh asked the court for ownership of the PET/CT patents so they could license an emerging technology and gain millions of dollars in royalty revenue.

The inventors, Townsend and Nutt, both technical and scientific experts in this field, understood that the patents' actual value was zero. This is further evidenced by the fact that though Siemens owns the first patent (the Townsend/Nutt patent), they have never litigated with GE or Philips over production of a similar device.

Who then, would pay to license a patent on a technology already in practice? No one.

This is a case that illustrates the difficulties encountered when a technology transfer office is dealing with a complex technology and does not engage the inventor in the patent and licensing process to facilitate understanding of the intricacies of marketplace opportunities.

If Pitt had reviewed Townsend's conflict of interest disclosures thoroughly and communicated any concerns from the outset, this costly lawsuit may have been avoided.

UNIVERSITY INVOLVEMENT

In 1992, Dr. Townsend was on faculty at the University of Geneva in Switzerland. He was already in collaboration with Dr. Nutt on various projects in the PET technology field when the University of Pittsburgh came knocking at his door.

Dr. Mark Mintun, Director of Pitt's PET facility, met with Townsend in London to lure him to the University of Pittsburgh. Dr. Townsend had a reputation as a leading PET physicist and Pitt wanted someone with his experience.

The University was well aware of Dr. Townsend's collaboration with Dr. Nutt and CTI. This was the differentiator that, to some extent, set him apart from others in his field.

Prior to moving to Pitt, Dr. Townsend and Dr. Nutt had already conceived the combined PET/CT scanner. In fact, Dr. Mintun also met with Dr. Nutt to discuss the Townsend-Nutt-CTI collaboration prior to Pitt hiring Dr. Townsend.

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Townsend disclosed to Mintun and the University of Pittsburgh that he had previously executed a consulting agreement with CTI PET Systems related to his work with Dr. Nutt on the combined scanner and other PET-related projects. The University never asked for a copy of the agreement or for Dr. Townsend to disclose its terms.

Dispute Details Continued

Due diligence called for the TTO to review Townsend's consulting agreement with CPS as well as the annual conflict of interest documents he submitted each year, as required by the University.

Under that consulting agreement, Dr. Townsend received monthly payments from CTI PET Systems related to his work for them. He revealed this to Pitt and asked CTI to forward his payments to Pitt instead of him personally.

The payments were not recorded in the University's books as relating to Townsend's consultancy with CPS. Instead, they were booked each month as a "gift" to the University from CPS.

Although the documents and payments submitted to the University substantiated CTI's ownership of the innovation, Pitt claimed that they had been misled by Townsend, Nutt and CPS.

Despite these facts, Pitt contended in court that they were surprised to learn that CTI owned the technology and that Nutt and Townsend had somehow misled them about their joint research.

Of the decade's worth of disclosure documents that Dr. Townsend had executed at Pitt's request, only the last few years were produced for the court by the University. Acknowledging the existence of these files from his hire date and forward would contradict the premise that they had been deceived by Townsend and Nutt.

In July of 1999, Townsend completed the required Invention Disclosure Form, listing both himself and Dr. Nutt as co-inventors of the PET/CT scanner and that CPS was potentially interested in the device.

When CTI PET Systems' patent attorneys filed patent applications for the method and mechanics of the PET/CT scanner, Pitt was copied and the applications listed Townsend and Nutt as inventors and CTI as the assignee of the technology. The University of Pittsburgh was mentioned in the patent filing, but not as a beneficiary of the patent or intellectual property. The Office of Technology Management received all of these documents and issued no complaint.

In court Pitt alleged that they had been unaware of the development of the product and the patent application process and that the actions of the defendants was tantamount to conspiracy.

While Pitt asserted that the Townsend/Nutt collaboration had caused it financial harm, in fact, they had received equipment worth millions, consulting fees, prestige, publication and numerous other benefits courtesy of CTI and the inventors. And, in exchange for conducting the clinical trials of the prototype PET/CT scanner CTI built, Pitt was paid a fee of $350,000 by Nutt's company.

The upshot is, with other nearly identical devices in development, there was no potential for Pitt to license a patent for this technology, despite their allegations of lost revenues. Siemens, GE and Philips all produced and sold PET/CT scanners without a licensing agreement.

At every turn, Townsend, Nutt and CTI operated transparently and kept Pitt informed of the status of the research, development, testing and patent application status. It is understandable that when Dr. Townsend heard Pitt had filed the lawsuit, he was "shocked that they went ahead with this fabricated case."

By acting outside its own policies and guidelines and not exercising due diligence, Pitt's Office of Technology Management was careless. The lawsuit vindicated the inventors and failed to rewrite history in Pitt's favor.

LEGAL FILINGS/PROCEEDINGS

University of Pittsburgh v. David W. Townsend, Ronald Nutt, CTI Molecular Imaging, Inc and CTI PET Systems, Inc.

Plaintiff Assertions: The University of Pittsburgh filed suit against their former researcher, his collaborator and the company who financed the work alleging fraud, conspiracy and conversion.

Damages Sought: Ownership rights in the patents, actual damages (estimated at approximately $12 million) and punitive damages.

Filed: July 7, 2004 U.S. District Court, Western District Pennsylvania and April 19, 2005 U.S. District Court, Eastern District Tennessee

Defendants' Assertions: The inventors' defense was multi-fold; they maintained that the University's claims had no merit, could not be substantiated and that the statute of limitations for filing had expired.

AWARDS/LEGAL RULINGS

The first court the University of Pittsburgh applied to, the U.S. District Court for the Western District of Pennsylvania, declined to hear the case and allowed a change of venue to the U.S. District Court for the Eastern District of Tennessee.

The U.S. District Court in Tennessee awarded summary judgment to defendants Townsend, Nutt, CTI and CPS on August 3, 2007.

On September 9, 2008, the U.S. Sixth Circuit Court of Appeals affirmed the lower court decision in favor of the inventors, calling it a "well-reasoned opinion".

In its ruling, the Appeals Court found that summary judgment was warranted because "...there is no genuine issue as to any material fact." The Appeals Court also found that "the University contravened its own policy on patents..."

The University of Pittsburgh's claims against their faculty scientist had been rejected and their bid for a share of the PET/CT scanner sales had also failed.

Dr. Townsend and Dr. Nutt were vindicated; their life-saving technology thrived and Pitt was left with a huge legal bill and a blot on their reputation.

PERTINENT DOCUMENTS

Summary Judgment, U.S. District Court
Appeal Judgment, U.S. Circuit Court of Appeals
Invention Disclosure Form
Clinical Trial Agreement

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Analysis

"The lawsuit was just so much nonsense and innuendo. They just went ahead with this whole fabricated case. None of my colleagues in the field wanted to get involved and the Pitt lawyers never really talked to those people.

It was pretty absurd and everyone who reviewed it expressed rather similar feelings. Nevertheless it was a stressful period for several years."

- Dr. David Townsend, PhD

IMPLICATIONS OF CASE

There are several issues engendered by this case for academic inventor awareness.

First, the University of Pittsburgh operated under the assumption that they had rights in all intellectual property developed by its faculty. Best practices in university intellectual property policies spell out under what circumstances the university has a stake in an invention. In this instance, the University had no valid claim on the work.

The invention was conceived and recorded in writing prior to Dr. Townsend's employment at the University. It was NOT conceived at the University of Pittsburgh.

Second, the University violated its own policies by not keeping accurate records, ensuring it had complete documentation and managing the patent application process. And, Pitt then tried to hold Dr. Townsend accountable for their failure to comply with their own policies and lack of reasonable diligence.

Alarming but true, the last point is that academic inventors must educate themselves on university intellectual property policies and practices, as well as the provisions of the Bayh-Dole Act. In theory, a technology transfer office should manage the process from invention to licensing, operating in the mutual best interests of the university and their faculty, knowledgeably and with integrity.

However, there is a largely undisclosed darker aspect to university technology commercialization. The profitability of an invention may tempt university administrators to make questionable decisions or engage in amoral legal attacks on their faculty, disregarding the long term consequences of such actions upon the entire university's moral integrity and reputation. The greater the profit potential, the greater is the risk for unwarranted litigation.

FUTURE ACTIVITY ANTICIPATED

In 2009, Dr. Townsend will move from the University of Tennessee to serve as Director of PET Development at the National University of Singapore and work with A*STAR, Singapore's Agency for Science Technology and Research.

Dr. Ronald Nutt oversaw CTI and CTI PET Systems acquisition by Siemens, serving for a time as Chief Scientific Advisor for Siemens Molecular Imaging, a division of Siemens Medical Solutions.

Presently, Dr. Nutt serves on the board of Advanced Biomarker Technologies, a company he founded which specializes in improving molecular imaging by developing a small cyclotron design with associated radiochemistry production.

Dr. Nutt was unavailable for comment at the time of this writing.

Reed McManigle, formerly with the Office of Technology Management at Pitt, who provided deposition testimony in the case, said he was "not able to comment on ongoing litigation" and would not confirm whether Pitt was planning further appeal. McManigle now serves as the Manager of Business Development and Licensing at Carnegie Mellon University.

The University of Pittsburgh's Office of Technology Management replied "no comment" when asked if they planned to pursue the case further. However, the time for Pitt to seek a writ of certiorari from the U.S. Supreme Court has expired.