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Montana State University Billings researchers Dr. David Butler, below right, and Dr. Kurt Toenjes, upper left, pose in a lab at MSU Billings recently. With the researchers are Dr. Tasneem Khaleel, below left, Toni Tease, a registered patent attorney in Billings. Tease has filed paperwork on behalf of Butler and Toenjes that would secure the first patent for MSU Billings.

SMALL-SCALE WORK IS HUGE STEP FOR MSU BILLINGS

Biological researchers, alumnus team up for university's first pending patent

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By Dan Carter
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Advances in science often trail gigantic events: The discovery of penicillin in 1928 or the launch of Sputnik 50 years ago this week or completing the map of the human genome in 1999.

In 2007 at Montana State University Billings, a major step in science is taking place in a small way. In fact, it's on a molecular level.

But it is a huge advancement for the university, which is now on its way to its first patent because of it.

It's a story that involves two researchers who also teach, a collaboration that could reach to Vermont and an MSU Billings alumnus whose legal expertise guided the university through the patent process.

MICRO-DETECTIVES

Research by Dr. David Butler and Dr. Kurt Toenjes, scientists and faculty members in the Department of Biological and Physical Sciences at MSU Billings, has found a possible new use of a synthetic compound that could help stem the spread of fungal diseases. Painstakingly done in crowded old research labs and around their teaching schedules, Butler, Toenjes and the university now have their names on patent papers filed with the U.S. government.

And as their research proceeds, any hospital, laboratory, specialist or patient who has had to deal with the dangerous spread of fungal or yeast infections will likely be paying close attention.

While reviews are taking place, novel use of the compound holds a "patent pending" status to protect the intellectual property. The legal work was done by Toni Tease, a Billings patent attorney who also happens to be a graduate of MSU Billings.

"This is very exciting," said Dr. Tasneem Khaleel, dean of the College of Arts and Sciences who also has her own considerable legacy of biological research. "Their work has also involved undergraduates and shows that when we hire faculty in arts and sciences at MSU Billings it's an investment in our students."

Both Butler and Toenjes said it has been gratifying to have students involved in the research work because of the value it has added to their education.

"We've essentially combined our labs," said Butler, who this fall began his 11th year with the university. "We have different programs and classes but are working in parallel."

In general terms, their parallel research over the past two years led to an inventive new use of a molecule that they believe can be used to controlling certain kinds of fungal infections.

Specifically, here's what the patent summary says:

"A METHOD FOR CONTROLLING THE YEAST-TO-FILAMENTOUS GROWTH TRANSITION IN FUNGI

The present invention is based on the discovery of novel anti-fungal properties of a small molecule that was previously shown to induce programmed cell death in mammalian cells. The invention provides a method for treating or controlling fungal infections, such as those caused by *C. albicans*, through inhibition of the yeast-to-filamentous growth transition. The yeast-to-filamentous growth transition is important for the pathogenicity of *C. albicans*. The invention also provides a method for controlling the yeast-to-filamentous growth transition in *in vitro* systems."

Think of it as providing the right direction over urban growth. Left unchecked when sprawl gets going, infrastructure damage can occur. The right kind of direction, however, leads to a balanced development.

INFECTION FIGHTER

In this case, the research by Butler and Toenjes, involves a small molecule (BH31-1) and its ability to block the growth transition of *Candida albicans* (or *C. albicans* as it is referred to in scientific journals.) The infection is usually confined to the skin (thrush is one example) and mucous membranes, but in premature babies, AIDS patients and those on immunosuppressive drugs, it can spread throughout the body.

C. albicans is the most common cause of human fungal infections and scientists say it is a major opportunistic pathogen of immunocompromised hosts, including those undergoing chemotherapy and tissue transplants. Studies indicate that up to 90 percent of AIDS patients suffer from infections tied to *C. albicans*. Approximately 10,000 people die each year from such infections, said Toenjes.

The scientific challenge lies in not going too far. If you try to stop *C. albicans* altogether, other valuable cells are destroyed in the process. In normal healthy humans, *C. albicans* exists in our bodies in a balanced state that

does us no harm. The pending patent involves a new way of using BH3I-1 to limit changes in *C. albicans* so it doesn't grow out of control.

C. albicans maintains a happy existence inside our bodies as long as adequate amounts of sugars and amino acids keep them happy in a "budded state." When that gets out of balance, the *C. albicans* will form tubes, spread out like unchecked urban sprawl and eventually become an infection. That budded-to-hyphal transition is the place where scientists know the fungi becomes more dangerous.

"Basically, the filamentous form is infectious and the budded form is not," Toenjes said.

Used as an inhibitor, Butler and Toenjes have noted that using BH3I-1 would keep the fungi in check without destroying any other healthy cells, which is a problem with many antifungal drugs.

"This is a paradigm-shifting idea," Toenjes said. "BH3I-1 is a novel compound; we found some interesting things."

INTELLECTUAL PROPERTY PROTECTION

What the two scientists also believed was that their work on the novel use of the compound was worth preserving. When they started talking about filing for a patent to protect their rights and the university's rights, they got help from Billings registered patent attorney Toni Tease.

Tease's connection to MSU Billings goes back several years, when she got valuable advice from Khaleel on what courses to take to meet patent office requirements for taking the patent exam.

"It meant a tremendous amount to me to work on this," said Tease, whose intellectual property work ranges from mechanical devices to antibiotics to software. "I am a patent attorney because of MSU Billings."

Tease studied economics at Harvard and received her law degree from the University of Connecticut. She practiced law in New York and Washington, DC before coming to Montana in 1995. Until 2001, she was a member of the law firm of Crowley, Haughey, Hanson, Toole & Dietrich. She practiced in-house with a software development company from 2001 to 2003 and opened her own firm in late 2003.

Before she could become a registered patent attorney, she needed to supplement the science courses she had taken as a pre-med student at Harvard. She paid a visit to Khaleel, who walked her step-by-step through the upper-level science courses she would need to round out her science credentials. Butler was one of her professors then, and it was Butler who called on her later for her legal expertise.

"To have the kind of top professors I had in David Butler and others was phenomenal," she said. "And to have them call me several years later to work on this patent application was fantastic."

Butler said he was very excited when he had a reason to retain Toni's legal services.

"She was a star student and I always looked forward to an opportunity to work with her again," he said.

The patent application process helps protect the rights of the researchers and the university, Tease said, so that Butler and Toenjes can proceed with their work in the lab without having to worry about legal issues. It could take four or five years for the patent to issue, she said.

In the meantime, the scientists are working on possible collaborations and moving ahead with their research. They have involved undergraduate students in their research in the past, and a graduate assistant has co-authored papers with his instructors.

They also continue their quest for research funding. MSU Billings is a partner in the Montana Idea Network of Biomedical Research Excellence (INBRE) at Montana State University in Bozeman (a program funded by the National Institutes of Health), and the faculty researchers here have received support and grants through the INBRE program. Butler and Toenjes are also part of a National Institutes of Health funding request being put forward by Dr. Douglas Johnson at the University of Vermont. If approved, that grant would provide about \$75,000 a year for five years to help keep the research going.

As far as the future, neither Butler nor Toenjes are speculating about things such as licensing or possible windfalls from this new pending patent. Both men say the research with BH3I-1 has possibilities for new pharmaceuticals or antifungal drugs, but it also has an equally promising future in laboratory experiments to further understanding how *C. albicans* works.

"There are a number of projects going on that this will help answer some questions," Butler said.

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