College Try

Columbia's Pursuit Of Patent Riches Angers Companies

As University Seeks to Extend A $600 Million Bonanza, Biotechs Refuse to Pay Up

Debate Over Academic Values

By Bernard Wysocki Jr.

NEW YORK—In the fall of 2000, Columbia University faced a problem familiar to many drug companies: A group of lucrative patents was about to expire.

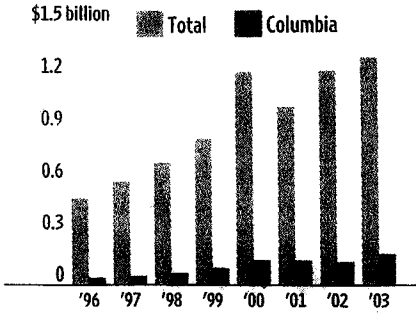
The patents were based on the work of three Columbia professors who laid the groundwork for a powerful new way to manufacture biotechnology drugs. Columbia had licensed these methods to more than 30 biotech companies and was bringing in nearly $100 million annually in royalties when, after 17 years, the patents ran out.

"In the near future, our revenues are likely to drop sharply," warned Jonathan Cole, then Columbia's provost, in an October 2000 internal document.

What Columbia did to replace those revenues might have been lifted from the playbook of an aggressive U.S. corporation. Through legal maneuvering, Columbia won a new patent in 2002 with similar claims as the old ones. Soon, Columbia demanded more royalties—until 2019—from various companies. Many balked.

Valuable Property

Net licensing income to U.S. academic institutions from intellectual property, with portion from Columbia University:



Note: Years ended June 30

Sources: Association of University Technology Managers; Columbia University

sity. He says critics are "applying a double standard" to Columbia—one that allows corporations to be tough but demands that universities be wimps.

Columbia says royalty rates are too small—typically 1% or 2%—to make a serious dent in the public's pocketbook. The university's outside litigation attorney, David Gindler of Los Angeles-based Irell & Manella, says a 1980 law requires universities to defend intellectual property that they have developed with the federal government's money. And Columbia notes that it plows much of the money it makes back into research that could produce more medical advances.

Some recent cases suggest that universities' aggressiveness has limits. Last month, the U.S. Supreme Court refused to hear an appeal by the University of Rochester in a fiercely fought patent case against Pfizer Inc. The university spent millions of dollars in a fruitless effort to extract millions of dollars in patent royalties from sales of anti-inflammatory drugs such as the blockbuster Celebrex, which is now running into safety concerns. And Columbia's attempt to exploit its new patent ran into criticism from a judge this year. The university has backed off trying to collect most royalties on its 2002 biotech patent, at least for now.

More disputes are likely since the number of patents controlled by universities has risen rapidly. Before 1980, universities typically won about 250 patents a year. In 2003, 195 universities and other research institutions received 3,933 U.S. patents, up 12% from the previous year, and generated $1.3 billion in licensing income from patents, according to the Association of University Technology Managers.

Seeking money from patents is still a hit-or-miss proposition, but universities have been captivated by the chance for home runs. Seminal discoveries by Stanford University's Stanley Cohen and the University of California's Herbert Boyer in how to combine pieces of DNA brought the two universities more than $200 million in royalties in the 1980s and 1990s as biotech companies flocked to use them. The Cohen-Boyer patents expired in 1997. Patents connected with the cancer drug Taxol have enriched Florida State University.

Much of the rise in patenting can be traced to the 1980 law, called the Bayh-Dole Act, which allowed universities to retain the rights to intellectual property developed on federal research grants. Obtaining such rights had been rare and difficult before. The purpose of Bayh-Dole was to give universities an incentive to transfer their discoveries to industry.

One concern is that the patent system rewards secrecy on the part of professor-inventors until patent papers are filed. Professors are coached to avoid disclosure by university lawyers and staffers from the burgeoning numbers of "technology transfer" offices on U.S. campuses. To many academics, secrecy is in itself a bad thing on campus. Others fear that scientific progress will be impeded if researchers can't debate ideas openly among themselves.

"This process of profit-seeking...can easily get out of hand and erode essential values of the university," said Derek Bok, the former president of Harvard University, in an interview last year in National CrossTalk, published by the National Center for Public Policy and Higher Education. Mr. Bok is the author of a book that criticizes excessive commercialization of academia.

By some measures, Columbia's technology-transfer office, Science & Technology Ventures, is in a league of its own. It boasts 27 staffers, many with industry experience. They scour the campus looking for discoveries, help professors draw up their patent papers, and then handle the business side of licensing deals. Columbia also has a powerhouse in-house legal team to defend its intellectual property.

In the year ended June 2003, Columbia ranked No. 1 among universities in licensing revenue, pulling in $178.4 million. That figure fell to $116.2 million in the year ended June 2004 as Columbia lost biotech royalties. The university shares 20% of the royalty income with the inventor and another 20% with his or her lab. Most of the rest goes to academic programs.

Spearheading Columbia's effort is Michael Cleare, who was hired in 2000 to help Columbia replace the lost revenue of expiring patents. Dr. Cleare spent 30 years at the chemical company Johnson Matthey PLC, where he headed the pharmaceutical materials and electronics materials groups.

Working from cramped offices at Columbia's engineering school, the bearded, British-born Dr. Cleare has searched for breakthroughs right in his own building. To illustrate, he picks up a sample of a glass-and-concrete composite, a Columbia-patented building material that has just begun to deliver royalties. For another promising venture, Dr. Cleare and an engineering professor have traveled to Asia several times, where they have struck deals to license Columbia's patents in flat-panel liquid-crystal displays.

Last year, Columbia made 443 patent applications world-wide, up from 178 in 2000, and completed 44 new technology-licensing deals, double the number in 2000. Still, the university has yet to fully replace the huge stream of royalties from the so-called Axel patents, one of the greatest patent bonanzas of all time.

The original scientific work was carried out by Richard Axel and two Columbia colleagues. Their discoveries, at the dawn of the biotech age in the 1970s, involved methods of inserting genes into the DNA of a cell. The methods made it possi-

ble to turn cells into factories producing a specific protein. This was a boon to the fledgling biotech industry, which sought to use human proteins rather than chemicals as the basis of drugs.

Dr. Axel, awarded the Nobel Prize in medicine this year for different work, says he is proud that his earlier work helped in the development of important drugs but never imagined this outcome at the time. And although he has received millions of dollars as his share of Columbia's royalty stream, he says professors shouldn't do their work looking for a commercial payoff. "It would diminish the science," Dr. Axel says.

The university's administrators, however, did have a keen eye for both patent and payoff. They submitted a patent application on the Axel discoveries in 1980, which the U.S. government granted in 1983. Because the original patent application preceded the Bayh-Dole Act by a few months, Columbia negotiated its deal with the National Institutes of Health under earlier rules. Columbia asked the NIH for permission to license the patents exclusively. NIH said no, forcing Columbia to offer nonexclusive licenses. The NIH also got Columbia to promise it wouldn't charge "unreasonable" royalties. The Bayh-Dole Act doesn't set such explicit rules about royalties.

Michael Cleare

Several of the products using the Axel patents have become blockbusters totaling billions of dollars in sales. Among them are Avonex, a Biogen Idec treatment for multiple sclerosis; Genzyme Corp.'s Cerezyme for Gaucher's disease; and several products of Genentech Inc. Over the course of nearly two decades, biotech companies paid Columbia roughly $600 million, the university says.

Columbia's patents "were a seminal invention in helping companies to manufacture products," says Mr. Bucknum of Biogen Idec. "We paid them willingly, without question."

In the spring of 2000, just a few months before the Axel patents were set to expire, Columbia tried to get a 15-month patent extension from Congress, enlisting Sen. Judd Gregg, a Republican from New Hampshire and Columbia alumnus. It said the extension would make up for the delay in receiving royalties that Columbia experienced while the drugs that used its patents were under regulatory review. Columbia said the extension would give it another $70 million to $100 million. The money, it said, would augment research and benefit the public. But the proposal failed in Congress.

Columbia had another plan to save its patents. In 1995, the university had secretly filed a new patent application at the U.S. Patent and Trademark Office. It was similar to the old Axel patents but with some tiny differences. For example, the old patent referred to "proteinaceous material" while the new one used the more specific word "glycoprotein." Biotech companies say that's like patenting a "rodent trap" and then trying to get a new patent for the same device as a "mouse trap."

Under the law at the time, a patent application didn't have to be disclosed until the patent was issued. Columbia made its filing just one day before new rules took effect that would have limited its ability to collect royalties. The university then amended the application several times, delaying the decision date until after the old patent expired. In 2002, the patent office ruled in Columbia's favor, awarding it a new patent.

The 2002 patent permitted Columbia to demand royalties from its licensees for another 17 years—which it promptly did. The university succeeded in getting two of its opponents to settle out of court, but several of the biggest companies continued to fight.

When the first hearing was held in June 2004 in U.S. District Court in Boston, the Columbia side walked in with eight lawyers. They all introduced themselves, prompting Judge Mark Wolf to interrupt and say: "I thought Columbia was a nonprofit organization who couldn't afford this litigation."

Judge Wolf, under whom the various cases were consolidated, said in August that he found testimony against the novelty of Columbia's 2002 patent "compelling." He said the biotech companies were likely to prevail. Columbia then withdrew royalty demands on the new patent. On Nov. 5, Judge Wolf concluded that there wasn't a current dispute and dismissed most of the case.

The biotech companies considered that a victory, since Columbia withdrew demands for payments on the new patent and gave up "hundreds of millions of dollars in potential royalties over the life of the patent," says Donald Ware of Boston-based Foley Hoag LLP, whose clients include Biogen Idec. However, several drug companies are still squabbling with Columbia over details—among them Wyeth, which wants Columbia to refund some royalties already paid.

Columbia is fighting on a second front against a small New York nonprofit called the Public Patent Foundation, which has asked the U.S. patent office to revoke the 2002 patent altogether. The patent office accepted the foundation's request and is re-examining the patent.

For its part, Columbia is asking the patent office to "reissue" the 2002 patent with new broader claims, although the basic discoveries behind the new claims are still the ones Dr. Axel and colleagues made in the 1970s. Theoretically at least, if the patent office agrees to reissue the patent Columbia can press the companies for royalties. "I keep hoping this vampire has a stake in its heart," says Biogen Idec's Mr. Bucknum, "but I think it will be back."

—Antonio Regalado contributed to this article.