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Cox-2 confusion

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Debate over the University of Rochester's (UR) claim for royalties from arthritis blockbuster Celebrex continues as UR appeals an early defeat for its patent on cox-2 inhibitors. Though the district court ruling this month against UR sent a chill through academic labs that rely on basic-science patents, attorneys disagree on how relevant the Rochester case will really be for other academic researchers.

On March 5, US District Judge David Larimer invalidated the UR patent, ruling that it did not name a specific compound, such as Celebrex, or spell out how to create one.

Anti-inflammatories that operate by manipulating the cox-2 enzyme are big money makers. Had Larimer's ruling gone the other way, UR was ready to lay claim not only to a share of the billions of dollars in annual sales of Celebrex, but also to a cut of profits on other cox-2 inhibitors, such as Merck's Vioxx.

While some think Larimer's ruling strips academic scientists of the ability to patent basic science discoveries that fall short of identifying a particular compound, others say the impact is limited and tied to specific failings in the Rochester patent, which leave Searle and its successors Pharmacia Corp. and Pfizer room to claim Celebrex owes nothing to the UR researchers.

Princeton, NJ patent litigator Lawrence Ebert is one who believes Rochester came up with significant science, but was a step short of a patentable invention. Method of treatment patents are not the issue, he said. Rochester's error was in attempting to "reach through" from basic science to a particular commercial drug.

Celebrex defender Robert Baechtold of New York told *The Scientist* that universities have little to fear from the cox-2 ruling. "Method of treatment patents are fine patents. We have had them for decades and they work well, so long as you provide a method of treatment and not the beginning of a research plan," Baechtold said.

"There are many situations where the university has identified a target and drug companies take that identified target and run it through their compound library in an automated way," said David Parker, a biotech attorney with Fulbright Jaworski in Texas who has six major patent matters on his desk right now involving similar issues.

University of California (UC), which leads the nation's universities in obtaining patents, is weighing a possible switch away from patent strategy based on broadly defined methodologies and back in the direction of defined chemical species.

"In part because of the push to protect developing intellectual property that will benefit the public, universities have been encouraging early and broad protection," said Lynne Chronister, associate vice chancellor for research at UC Davis. "This ruling, if it stands, could change our approach to protection of inventions."

"If this decision stands, universities are out of the game," said Gerald Dodson, who pressed the claim for UR. "This will force universities to partner with pharmaceutical companies in a kind of bargain that

leaves them no rights." He has appealed Judge Larimer's decision to the US Court of Appeals for the Federal Circuit.

According to Dodson, the policy issues are so profound that even a defeat in the courts will not put an end to the argument. "Congress will not want multinational pharmaceutical companies controlling American university research," the Palo Alto, Calif. lawyer said.

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