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Cloning patent claim rejected

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Infigen Inc. last week lost a bid to upset patents held by Advanced Cell Technology (ACT) for use of "proliferating somatic cells for the cloning of non-human animals." Infigen waited too long - more than a year - to press its claim against ACT, a three-judge panel of the Board of Patent Appeals and Interferences of the US Patent and Trademark Office ruled March 18, leaving the lives of researchers only slightly less complicated than before.

Working amid a welter of claims and cross-claims over cloning techniques, scientists are continuing to genetically engineer animals to produce biotherapeutics and organs for transplantto humans, as well as animals for research and food purposes. The dispute between Infigen of DeForest, Wis., and ACT, of Worcester, Mass., centered on pig cloning efforts.

"We keep moving forward, and we think we're protected," said Randall S. Prather, the University of Missouri-Columbia professor of reproductive biotechnology who led a research team that, in 2001, announced the first successful clone of a miniature swine genetically engineered for animal-to-human transplantation.

Prather produced the knock-out mini-swine in collaboration with Immerge BioTherapeutics, Inc., a joint venture of Novartis Pharma AG and BioTransplant Incorporated. Immerge holds licenses from both ACT and Infigen, the winner and loser, respectively, of the patent dispute decided last week.

"We are moving forward quite rapidly with work in early pig embryo development," Prather said. "I don't worry too much about the patent picture, but you have to keep it in the back of your mind."

ACT and Infigen are still involved in tugs-of-war over animal cloning patents with Geron Corp., the California biotech which bought rights to the technology that produced Dolly, the first cloned mammal.

At the end of the day, animal cloning technology will not be the exclusive province of any one company, predicted David J. Earp, Geron's vice president of intellectual property. "There is not going to be a single dominant patent. There are a number of claims on different aspects of the technology. Geron will have a portfolio of a number of patents, and I believe it will be the dominant one in the field."

Geron licenses the nuclear transfer technology it bought from the Roslin Institute in Scotland to Canadian researchers working on transgenic goats and to Australian scientists working to clone prize dairy bulls, among others. Geron also continues to fund work at Roslin, taking advantage of the cloning pioneers' expertise in gene targeting.

Both ACT and Infigen are working on clones to produce biopharmaceuticals, such as therapeuticprotein producing milk, and organs for transplant.

In the fall of 2000, the first pig clones designed as living transplant tissue factories were born as the result of the work Prather's team did with Immerge, which has a research collaboration with Infigen and licenses technology from ACT.

Last month, Infigen and Immerge announced they had produced a double knock-out mini-swine clone, which lacks both copies of a gene that causes humans to reject transplanted pig organs.

Immerge CEO Julia Greenstein said the company is trying to pick the winners in what are likely to be prolonged patent fights. "This whole field is filled with intellectual property claims and it's not really clear what's going to happen," she said. "The patent difficulties will evolve and the important thing is getting the work done."

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