IN brief

Kite and NCI partner on T cells

Kite Pharma and the National Cancer Institute (NCI) have partnered to develop and commercialize genetically engineered T cells as immunotherapies for advanced cancer. Under the leadership of Steven A. Rosenberg, the Surgery Branch of the NCI has pioneered the use of autologous T cells modified *ex vivo* to treat patients with multiple tumor types. The platform involves removing T cells from patients' peripheral blood, and genetically reprogramming them using recombinant retroviral vectors to contain chimeric antigen receptors (CARs). Most CARs consist of a single-chain antibody domain designed to recognize a tumor antigen, and a spliced-in co-stimulatory T-cell receptor to activate the modified T cells (*Nat. Biotechnol.* **29**, 853–855, 2011). Once re-injected into the patient, the engineered T cells traffic directly to the tumors and selectively eradicate them (*Blood*, **119**, 2709, 2012). Under a cooperative research and development agreement, the Los Angeles–based Kite will gain exclusive access to the NCI's current and future clinical product pipeline. Having raised $15 million of initial funding, Kite now plans to evaluate NCI's products and take them to phase 2 and 3 clinical trials. Although engineered T cells are remarkably potent, they can be coupled to serious and unexpected toxicities, says Martin Pule at University College London. Their bespoke nature is another constraint. "Currently a therapeutic product must be produced for each patient. This limits treatment to the few research medical centers...licensed to use integrating vectors," he adds. *Moheb Costandi*

Pan-African genomics

The US National Institutes of Health (NIH) and the London-based charity Wellcome Trust launched a new initiative designed to bolster Africa's genomics research capacity. The Human Heredity and Health in Africa (H3Africa) scheme announced on October 8 is a $38-million, five-year project aimed at studying diseases that affect the continent's people. "There is almost no cutting edge genomics in Africa. We can help correct that," says Jane Peterson, a senior NIH advisor based in Bethesda, Maryland. The first H3Africa projects aim to identify genetic risk factors in African populations for a number of diseases, including rheumatic heart disease, kidney disease, diabetes, African sleeping sickness and cardio-metabolic diseases. The project will fund two repositories for genetic samples—one in South Africa, the other in Nigeria. A pan-African bioinformatics network providing computational hardware and training for staff in genomics and population-based research are also included. The findings could have global importance, says Pat Goodwin, head of pathogens, immunology and population health at the Wellcome Trust. Africans are more genetically diverse than any other group on the planet, she says. This genetic variability could make it easier for scientists to identify genetic risk factors that would be hard to spot in a more genetically homogenous population. *Linda Nordling*

Threat to global GM soybean access as patent nears expiry

This October, five major seed companies came together to sign the first part of an agreement called the Generic Event Marketability and Access Agreement (GEMAA). Facilitated by the Biotechnology Industry Organization (BIO) of Washington, DC, and the American Seed Trade Association of Alexandria, Virginia, the accord is a legally binding contract that covers expirations of single-gene patents, and aims to ensure global access to genetically modified (GM) crops, even once they go off patent. "GEMAA is the most immediate concern," says Cathy Enright, executive vice president of BIO's food and agriculture section. "Farmers want to make sure that if they use a product that's under patent today they can continue to when it's off patent." Because regulatory agencies in some countries require reregistration of GM crops, the accord allays concerns that companies would fail to re-apply for registration of their products, once the patent expires.

The future global use of GM soybean is at stake as patent set to expire.

In 2014, the 20-year term for the gene patent on Monsanto's Roundup Ready soybean, which is used by >90% of US soybean farmers, will expire, and the looming deadline has raised fears among farmers that the expiration may disrupt trade. Their concern hinges on the disparity between how genetically modified organisms (GMOs) are regulated in the US and internationally. In the US, after a gene inserted into a crop is deregulated, the US Department of Agriculture (USDA) accepts its use in the crop indefinitely. But in the rest of the world, GM crops are approved for a specified time, which means that companies must periodically reapply with the regulatory agencies. In China, applications are submitted every three years, in Korea every five years, in Japan and Europe every ten.

Trade today moves smoothly because Monsanto maintains these approvals, but once the patent expires, Monsanto loses the financial incentive to continue filing. Nearly 60% of American-grown soy is exported abroad, mainly to China, Japan and Mexico, and almost all of it contains the Roundup Ready resistance gene. So in 2009, when Monsanto launched a second-generation GM soybean—Roundup Ready 2 Yield—farmers and other industry stakeholders realized that Monsanto had a *de facto* lock on the soybean trade. They feared that the seed giant would force them to adopt the next-generation trait by failing to file international approvals after expiration.

"There could be a terrible trade disruption if we had a product that was no longer registered in a foreign country. It could lock down ships. It could disrupt the entire trade system," says farmer Ray Gaesser, vice president and chairman of the regulatory committee of the American Soybean Association in St. Louis.

Monsanto acknowledges the problem and has pledged to continue filing until 2021. "There clearly were legitimate concerns from growers and grain handlers about what happens at the end of patent expiry. Quite honestly, we hadn't faced this situation ever before," says Jerry Steiner, executive vice president of sustainability and corporate affairs at Monsanto. "No one had prepared for that kind of thing."

Meanwhile, another wave of gene patents are scheduled to expire around 2020, including those owned by other companies. The industry had no strategy on how to maintain the regulatory approvals once off patent.

The accord requires signatories to announce their patent expiration three years ahead of time, after which patent