

molecules, and the *S. pyogenes* Cas9 (CRISPR-associated protein 9) DNA nuclease, which cleaves DNA at sites that are complementary to mature crRNA molecules. Zhang's group also attached nuclear localization signals to these constructs, to ensure their compartmentalization in the nucleus (*Science* **339**, 819–823, 2013).

The resulting patent claims a priority date of December 12, 2012, the same date the paper was accepted for publication (it was published online on January 3, 2013). The actual patent application was not filed until October 15, 2013; the entire patent examination process took just six months. "They petitioned for accelerated examination, and they got it," says Loughran. "Why the Berkeley guys didn't take that course I have no idea."

The IP landscape surrounding CRISPR-Cas is, of course, much wider than that part of it controlled by CRISPR Therapeutics and Editas. Granahan and Loughran identified CRISPR-related IP from several sources that could potentially be cited as prior art in future opposition proceedings (*Life Sciences Law & Industry Report* (Bloomberg Bureau of National Affairs, March 2014)). This includes research performed at the Danish

food ingredients firm Danisco, which is now part of Wilmington, Delaware-based DuPont; at the University of Georgia; and at Northwestern University in Chicago. Several other research groups and biotech firms have filed patent applications on genome editing tools and applications that come after the Charpentier-Doudna filing although the list is not complete (**Table 1**). "There are probably quite a few patent applications out there that haven't yet entered the public domain," Tannock says.

Despite the excitement surrounding the technology in scientific circles, it hasn't entered the wider public consciousness as yet, although this is likely to change dramatically as the technology matures and ultimately when the first clinical trials begin. Some of the hype surrounding CRISPR has been "really over the top," says Paul Shanks of the Berkeley, California-based Center for Genetics and Society, a not-for-profit group that encourages responsible use of human genetic technologies. "During the embryonic stem cell wars of close to ten years ago now, several people were saying the most likely use [for the technology] was to model diseases in a dish," says Shanks. "That's probably going to be the first use of CRISPR in a way."

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## FDA launches two research centers with academia

The US Food and Drug Administration (FDA) in May announced it was establishing two new Centers of Excellence in Regulatory Science and Innovation (CERSIs). One of the centers, which is to focus on improving preclinical safety and efficacy tests as well as clinical trials and evaluations, and on using information sciences to capture diverse data sets, will be set up jointly at the University of California, San Francisco (UCSF) and Stanford University. "The pharmaceutical and biotech industries are facing huge challenges, with the majority of drugs failing in clinical trials because they are not effective," says Kathy Giacomini of the UCSF School of Pharmacy, alluding to the new FDA-sponsored center in California. This partnership aims to develop new computer-based models and methods to predict drug metabolism, toxicity and effectiveness, and

help move these technologies out of academia and into practice, Giacomini adds. The second of the new CERSIs, which will be established at Johns Hopkins University in Baltimore, will focus on clinical evaluations, social and behavioral science, and food safety. This brings the number of CERSIs to four, with the two others established in 2011 at the University of Maryland medical campus in Baltimore and at Georgetown University in Washington, DC. "We strongly support regulatory science at FDA and partnerships between government, academia and the private sector to develop new tools and methodologies for evaluating the safety and effectiveness of drugs and biologics," says Cartier Esham, executive vice president, Emerging Companies Section for the Biotechnology Industry Organization (BIO) in Washington, DC.

**Jeffrey L. Fox**

### Corrections

The news brief "Microbes unite Novozymes and Monsanto" (**32**, 211, 2014) incorrectly states that BioAg Alliance's work involves microbial enzymes. The alliance will discover, develop and commercialize microbial solutions for agriculture. The error has been corrected in the HTML and PDF versions of the article.

In the news analysis "Master Protocol for squamous cell lung cancer readies for launch" (**32**, 116–118, 2014), Genentech's compound taselisib was incorrectly labeled as pitiilisib in Table 1. The error has been corrected in the HTML and PDF versions of the article.

In the news analysis "Engineered tracheas, corneas and arteries enter clinical testing" (**32**, 303–304, 2014), the article incorrectly stated there was one case of rejection in a phase 1 trial of corneal implants, when there were none. There was one case of rejection in the control group that received donor corneas. The error has been corrected in the HTML and PDF versions of the article.