

licensing arrangements. “The pending UC patent has no impact on our intellectual property covering the use of CRISPR–Cas9 in eukaryotic cells, including humans. Our current issued patents cover what it would take to make a medicine using either CRISPR–Cas9 or CRISPR–Cas12a,” wrote a company spokesperson in a statement to *Nature Biotechnology*.

Other companies who want to commercialize gene editing technology using CRISPR–Cas9 may try to avoid licensing agreements. “If the licensing situation becomes too complicated, people will invent around the current technology or apply the technology in new ways so as not to need a license,” says Rubino. This may be especially true as the CRISPR–Cas9 patent space gains more players. In May 2017, the USPTO issued a patent to Vilnius University in Lithuania. Unlike the University of California’s application, the Vilnius patent is directed towards an in vitro pre-assembled Cas9–RNA complex, and so the existence

of the Vilnius patent didn’t scupper the patentability of the ’859 invention.

Indeed, licensing fees for CRISPR–Cas9 played a “strong part” in the business model of Inscripta, says Kevin Ness, the company’s CEO. Inscripta makes the sequence of its proprietary CRISPR nuclease known as MAD7 (from the Cas12a family) available to users with no upfront licensing fee or royalties on products made using the technology. “Many companies, from small start-ups to large global players, can’t absorb the licensing fees and potential reach-through royalties for CRISPR–Cas9.” The company employs an alternative to Cas9. “Broad and the University of California can fight amongst themselves for Cas9, but there are many other nucleases out there that will be important for CRISPR-mediated gene editing,” says Ness.

The ’859 foundational patent will add to University of California’s small but growing CRISPR–Cas9 patent portfolio (*Nat. Biotechnol.* **36**, 673, 2018; *Nat. Biotechnol.* **37**, 6, 2019). But this

dispute over ownership of CRISPR–Cas9 for gene editing is likely to continue for some time. Information on the USPTO website related to further University of California patent applications indicates that so-called ‘interference’ proceedings are likely to occur. These procedures, held at the USPTO, determine which inventor is entitled to a patent when there is more than one application claiming substantially the same invention. “A decision is necessary regarding which research team first invented the use of CRISPR–Cas9 in eukaryotic cells and, thus, actually who should have the patents expressly claiming this specific use,” says José Rivera, general counsel at Intellia Therapeutics, a company that licenses University of California patents. □

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## PODCAST

# First Rounders: George Church

George Church is professor of genetics at Harvard University and professor of health sciences and technology at Harvard and the Massachusetts Institute of Technology. He is also cofounder of more than 20 biotech companies. His talk with *Nature Biotechnology* covers being held back in ninth grade, launching the Human Genome Project, and the necessity of surveilling synthetic biologists. <https://www.nature.com/nbt/podcast/index.html>



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