

THE EDIT

SEPTEMBER 2022

ers
GENOMICS



"Perhaps much in the same way that software has evolved to manipulate a computer and robotic hardware, so too will gene editing serve as a coding tool for exploring and exploiting the biological hardware of living systems."

Erid Rhodes
CEO ERS Genomics

WELCOME TO THE FALL ISSUE OF THE EDIT

Here is your update on ERS Genomics (part of the “CVC” group) and an overview of the CRISPR/Cas9 intellectual property landscape. There is a lot of misinformation circulating with regard to the CRISPR/Cas9 patent situation, particularly in the US. Here we try to address the most common misperceptions and reinforce that your decision to take a license to the CVC patent portfolio is still well advised.

MISPERCEPTION #1.

“The Broad Institute won the U.S. patent battle, so there is no need for a CVC license in the U.S.”

REALITY

Categorically false. While the most recent decision favored the Broad Institute, the reality is that nothing has changed in the US. The CVC group still has over 50 issued patents in the US claiming, among other things, use of CRISPR/Cas9 in ALL CELLS. This includes eukaryotic cells, which was the focus of the recent decision. The patent office ruling means that groups using CRISPR in eukaryotic cells in the US will need to take a license from both the Broad and the CVC group. This goes against the concept that an invention should only be covered by a single patent, but in this case the use in eukaryotes is considered a sub-category of ‘all cells’ and so both sets of patents apply. The situation is still not finally settled as the CVC group has appealed the most recent decision and hopes to reverse the decision to make it more in line with how the scientific community (and the rest of the world) see the situation.

MISPERCEPTION #2.

“I only need one license if I am using CRISPR/Cas9 technology because one license should cover any and all uses of CRISPR/Cas9.”

REALITY

Unfortunately, not true. Depending on your specific use of CRISPR, you may require additional licenses from 3rd parties. Virtually any use of CRISPR will require a license to the foundational CVC patents. But other uses, including specific improvements or applications of CRISPR may require additional licenses. As noted in #1 above, use of CRISPR in eukaryotes in the US currently requires at least a CVC and Broad license. This is not true elsewhere in the world.

MISPERCEPTION #3.

"I do not need a license to CRISPR/Cas9 because I am only doing research and am therefore covered by the 'research exemption.'"

REALITY

Incorrect. The research exemption in the US only allows for use of patented technology for the express purpose of obtaining data for regulatory purposes related to active pharmaceutical ingredients or medical devices. The exemption cannot be applied to discovery activities or other research uses. The situation is generally similar throughout most of Europe, although each country has its own specific rules. Having a license for all R&D uses is the best form of protection for the future.

WHO'S NEW?

New licensees: ERS Genomics continue to accelerate the use of our CRISPR/Cas9 technology and recently celebrated the signing of our 100th licensee.

New licensees include dynamic and progressive companies such as [Crown Bioscience](#), [Lepton Pharmaceutical](#) and [Cytosurge AG](#).

WHAT'S HAPPENING WITH ERS?

Global advancement continues as we recently announced our first patent in India. [Details here](#). The US portfolio continues to show robust growth with 5 new issuances in 2022. See our updated [patent list](#). Watch this space for more patent announcements in the near future. If you have any questions about patents and particular regions, send an [email](#) and we'll respond immediately.

Global advancement comes with global coverage. We now have team members in mainland Europe, the UK and Ireland, North American, China, Japan and India. Click [here](#) to find your closest point of contact.

UPDATE ON REGION-SPECIFIC LEGAL ACTIVITIES

U.S


Interference NO. 106,115 (CVC/Broad)

CVC filed its notice of appeal in the interference and will file its appeal brief to the federal circuit court in Q4 this year. Both the Broad and CVC CRISPR/Cas9 patents currently coexist in the US as they relate to use in eukaryotic cells.

US Interference No. 106,127 (CVC/Toolgen)

Oral argument in this interference was conducted on September 12, 2022. PTAB decision on priority and related motions is expected by Q4 2022.

US Interference No. 106,132 (CVC/Sigma)

Currently awaiting oral argument.

Commentary: We have had continued success in the European Opposition Division in the affirmation of the foundational CRISPR/Cas9 patents. The end of this year and early next year will be highly active in the EPO as opponents will continue to attack the affirmed patents and we will seek further broadening through auxiliary requests. The CVC portfolio continues to hold the dominant position in the EPO.

Europe



EP2800811: Although the EPO affirmed this patent upon opposition, the CVC group has decided to further appeal the affirmation to try to further expand the claims. Submissions to the EPO Opposition Division from multiple opponents continue; a consolidated response from CVC is being prepared. Oral argument and a final non-appealable decision is expected in Q2 2023.

EP3401400 ('EP400') affirmed: This patent withstood formal opposition at the European Patent Office ('EPO') with only minor modifications. The decision by the EPO Opposition Division ('OD') was published in May 2022 following lengthy hearings which concluded in February 2022. The patent claims fundamental use of CRISPR technology in eukaryotic cells and organisms, including humans, animals, and plants. Read more here in our press release.

EP3241902 continuations filed: This patent withstood formal opposition at the European Patent Office ('EPO') with only minor modifications. The decision by the EPO Opposition Division ('OD') was published in May 2022 following lengthy hearings which concluded in February 2022. The patent claims fundamental use of CRISPR technology in eukaryotic cells and organisms, including humans, animals, and plants. Read more here in our press release.

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Japan



JPO (Japan) 6692856 invalidation proceeding: Patent 6692856, which covers CRISPR/Cas9 compositions and methods for use in a variety of eukaryotic cells, previously affirmed by the JPO in 2021 (read more here) is now being challenged via a trial for patent Invalidation. The CVC rebuttal brief was filed this month and a determination is expected in 2023.

IN CONCLUSION...

The CVC portfolio of patents covering CRISPR/Cas9 gene editing remains the essential global intellectual property for the practise of this technology. Although multiple licenses may be required in some jurisdictions, your license from ERS continues to grow in value as our portfolio continues to expand. We look forward to seeing what you create with our technology.