CRISPR/CAS9 PORTFOLIO EVENTS

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Your connection to CRISPR/Cas9

17 January 2020: Revocation of Broad first EPO patent EP2771468

EP2771468 is viewed as the foundational Broad Institute's CRISPR/Cas9 patent in Europe. In January of 2018 the Opposition Division found that all claims of the Broad Institute's foundational CRISPR/Cas9 patent were invalid because the Broad Institute was not entitled to its two earliest priority dates and thus the claims lacked novelty in light of prior art.

The Broad Institute's appeal the Opposition Division's decision was finally rejected meaning all claims of the Broad Institute's patent remain fully revoked with no option left to overturn this decision. This was the beginning of a string of patent rejections for the Broad Institute in Europe.

Nine additional Broad EPO patents are subject to this same finding and are being either fully revoked or seriously limited to inconsequential claim sets.

10 February 2020: EPO Upholds CVC EP2800811 over opposition

The European Patent Office (EPO) rejected arguments filed in opposition to the CVC group's European patent No. EP2800811 and affirmed the patentability of the inventions described.

The claims of the patent are directed to the widely-used single-guide CRISPR/Cas9 gene editing system and cover uses in both cellular and non-cellular settings, including use in bacteria, plants, animals, and cells from vertebrate animals such as humans.

19 March 2021 Revocation of Sigma CRISPR patent EP 3138910 B1

The Opposition Division in Europe revoked EP3138910 B1, part of the Sigma-Aldrich patent portfolio, for lack of inventive step. The revocation is significant as it is the first time the EPO has substantially addressed the issue of inventive step in the wider dispute around CRISPR patents instead of ruling purely based on priority. (source **https://www.juve-patent.com/news-and-stories/cases/epo-revokes-first-sigma-aldrich-crispr-patent-for-lack-of-inventive-step/**).

13 April, 2021: Opposition of CVC EP 3241902, EU

CVC's EPO patent EP3241902 was revoked following oral proceedings. Multiple opponents sought revocation of the patent on multiple grounds. The written decision setting out the grounds for revocation by the EPO Opposition Division was published, the strict written description requirements of Europe were seen to be a determinative factor and a notice of appeal has been filed. This procedure is ongoing and the claims involved in the filing are expected to survive with modification.

1 June 2021: Japanese Patent Office Upholds Key CVC CRISPR Patent

The Japanese Patent Office (JPO) rejected arguments filed in opposition to the CVC's second Japanese patent (JP6692856) (the first was unchallenged). During the proceedings, opponents contested novelty and inventive step. In its opposition decision, the JPO re-affirmed the patentability of the inventions, further validating the fundamental value of these patents for use of the CRISPR/Cas9 technology.

For information on CRISPR/Cas9 Portfolio Events contact:

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Update on U.S. Patent Interferences

As background, U.S. patent interference proceedings occur when there is a perceived overlap in claims of different patents. The purpose of an interference is to sort out any overlaps that might exist between competing patents and determine which group should be awarded with certain patent rights. The initial proceedings generally take approximately two years and can be followed by an appeals process which may run another 2 or more years.

As some of you may recall, a patent interference was initiated in 2017 between a set of U.S. patents controlled by the Broad Institute and certain applications filed by the "CVC" (California/Vienna/Charpentier) group, with whom ERS is affiliated.

The expectation going into that interference was that the patent office would determine which group was the first to invent CRISPR as a gene editing tool. But unexpectedly the outcome was actually a finding that 'no interference in fact' existed and instead of determining who was first to invent, the patent office merely decided that use of CRISPR in eukaryotic cells was separately patentable from the very broad claims of use in any organism that were being pursued by the CVC group. In other words, both groups could have their claims stand and anyone using CRISPR would need a license from CVC (ERS) and only those using it in eukaryotes would also require a license to the Broad patents. The outcome was hardly satisfying for groups seeking to use CRISPR and looking for simplicity in licensing the technology.

Due to this perceived avoidance of the question of which group was first to invent (now isolated to use only in eukaryotes) the CVC group pursued new claims by filing 14 new U.S. applications in 2018. These pending applications are currently subject to three separate US patent office initiated interferences. The parties involved are 1) the Broad Institute; 2) Toolgen; and 3) Merck_Millipore_Sigma. Each party has claims to uses of the technology in eukaryotic cells.

Update on U.S. Patent Interferences

U.S. Interference No. 106,115 – CVC/Broad:
Was initiated in June 2019 and oral arguments are expected in September 2021. A decision might be expected by the end of 2021, subject to the right of any party to appeal the decision.

U.S. Interference No. 106,127 – CVC/Toolgen:
Was initiated in December 2020 and is still in the earliest 'motions' phase and would be expected to conclude sometime in 2023, subject to the right of any party to appeal the decision.

U.S. Interference No. 106,132 – CVC/Sigma:
Was initiated on June 21, 2021 and would be expected to conclude sometime in 2023, subject to the right of any party to appeal the decision.

Interference Outcomes:
Should CVC be recognised as the first to invent in eukaryotes; Broad (or Toolgen, or Sigma) patents involved in the respective interference should be revoked in their entirety.

Should Broad (or Toolgen, or Sigma] be recognised as the first to invent in eukaryotes; they will have patents covering use of CRISPR-Cas9 in eukaryotes, while CVC will still hold over 40 granted patents covering use of CRISPR 'in any environment' and 'in a cell'. This means that more than one license will be necessary to obtain full freedom to operate when editing eukaryotic cells with CRISPR/Cas9 in the U.S.

What's next? 2021 IP Outlook

The ERS CRISPR/Cas9 portfolio continues to expand and we are encouraged by the findings in Europe and Japan upholding our issued patents over opposition. We are the only CRISPR/Cas9 patent estate to survive opposition thus far. In the United States, we are optimistic about the ongoing interferences and want to remind our valued licensees that, win or lose, your license to the ERS portfolio will continue to provide access to essential and necessary intellectual property for practicing CRISPR/Cas9.

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