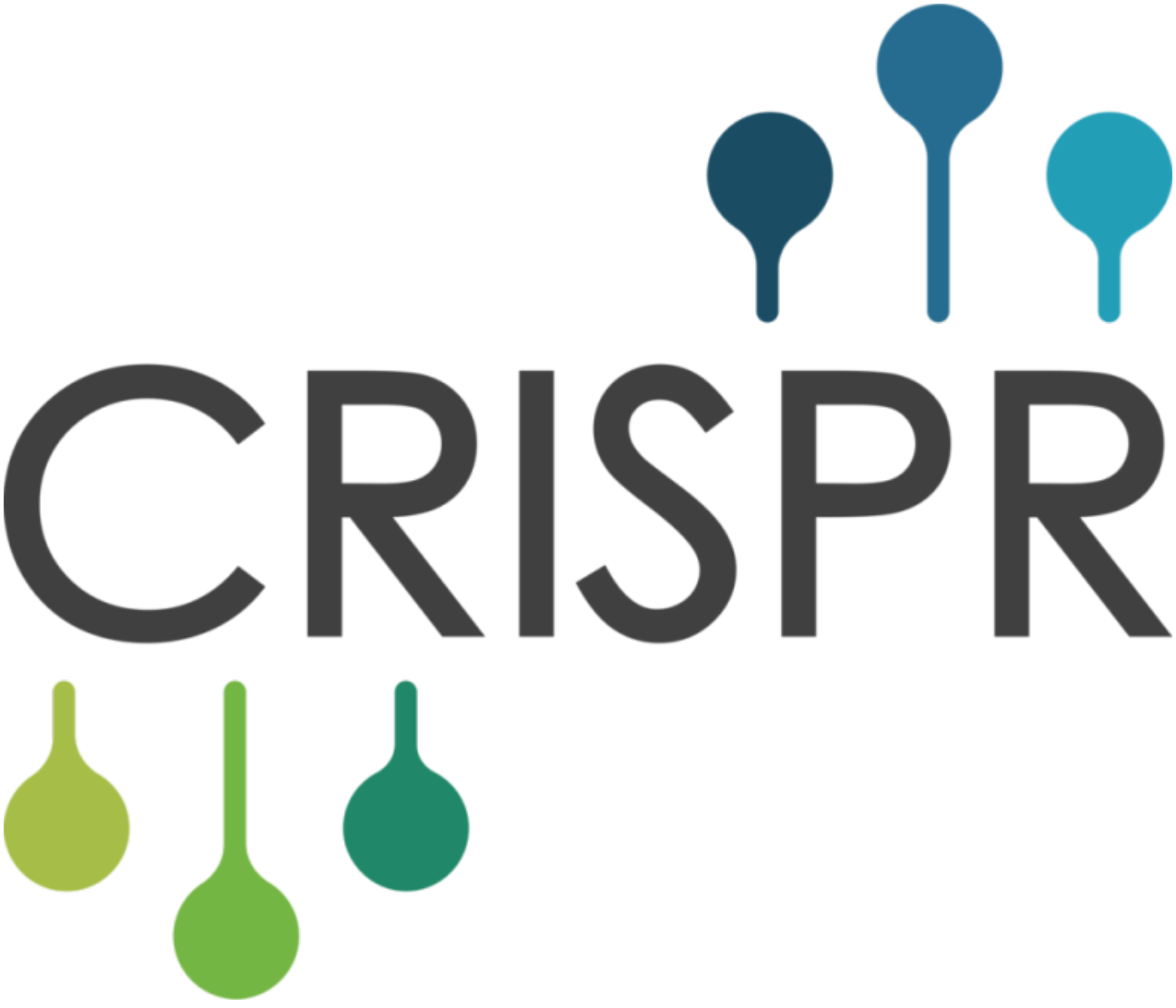
Veille citoyenne d'information sur les OGM et les semences

Crispr/Cas9 : from patent disputes to the widespread use of GMOs

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A dispute over patent rights to Crispr/Cas9 has been ongoing for several years between its main discoverers, universities and research institutes. To date, the outcome of this dispute and its impact on the Crispr/Cas9 economy remain unpredictable. Added to this is an ongoing dispute over Crispr applications between the parties to the main dispute and companies. Despite this, the widespread use of this tool for modifying living organisms, and the associated health, environmental and socio-economic consequences, seem inevitable.



For the past dozen years or so, patents relating to Crispr/Cas9 have been the subject of litigation between the main "*inventors*" of this genetic modification tool, which is widely used in public and private research. Crispr/Cas9 is the subject of several patent rights and is logically at the heart of a dispute with an uncertain outcome, both for the holders of these rights and for the licence holders. This article provides an overview of the litigation in the jurisdictions where it is most active: Europe and the United States. It is unlikely that all of these patent rights, some of which affect farmers and small/medium-sized seed producers, will disappear at the end of the proceedings. At a time of debate on the deregulation of GMOs in Europe and disagreement on the issue of patents, this example of litigation shows that, when it comes to patents, the biotech industry is opportunistically juggling a legal landscape that is still in flux.

The origins of the Crispr/Cas9 dispute

In 2012, five main players filed patent applications covering different aspects of Crispr/Cas 9 within a very short period of time: California-Vienna-Charpentier (University of California, University of Vienna and Emmanuelle Charpentier – CVC), the Broad Institute (MIT-Harvard, with certain rights held by Rockefeller University), the University of Vilnius, the South Korean company ToolGen and the multinational Sigma-Aldrich (Merck) (see table).

This proximity of patent applications is a major cause of Crispr/Cas9 litigation, particularly due to the complexity of assessing the conditions of patentability, namely novelty and inventive step. Some patent applications were filed before the results of "*competing*" laboratories' work were published and thus became enforceable against the patentability of these applications. While the granting of patents is relatively clear in Europe – it is the date of filing that counts – it is more complicated in the United States, which in 2012 still applied a system giving priority to the first inventor rather than the first applicant. This legal peculiarity is at the root of the so-called "*interference*" dispute between CVC and the Broad Institute in the United States.

The current situation in Europe and the United States

CVC and the Broad Institute are now considered to hold the fundamental patents on the Crispr/Cas9 tool. We will therefore focus on these two entities in particular.

In Europe

- *CVC*

Since 2012, CVC has filed various patent applications with the European Patent Office (EPO) relating to Crispr/Cas91. However, in September 2024, it unexpectedly withdrew two of its main patents on Crispr/Cas92, following a preliminary unfavourable opinion from the EPO Board of Appeal. In this preliminary opinion, the Board highlighted the insufficient disclosure of the invention concerning the PAM sequence3 and questioned the "*right of priority*" conferred by the corresponding US patent applications4. This strategic withdrawal from the European proceedings allowed CVC to avoid a negative final decision by the Board of Appeal, which could have affected the US proceedings. CVC thus appears to have chosen to prioritise the US market over the European market.

Another application by CVC was successful in January 2025, when the EPO granted it a patent with broad claims relating to guide RNAs, modified RNAs used to guide the Cas protein to the targeted DNA sequence. However, this patent is currently the subject of a major opposition

procedure[5]. In an attempt to have it revoked, the opponents have submitted hundreds of "*prior art*" documents, *i.e.* documents published before CVC filed its patent application. All this points to a lengthy procedure, adding to the uncertainty surrounding the ownership and therefore the effect in Europe of this key patent on the use of Crispr/Cas9. In November 2025, CVC saw another of its major patents, relating to the use of RNA to guide Cas9 to a target DNA, revoked in a similarly extensive opposition procedure[6] . CVC has appealed this decision.

- *Broad Institute*

In March 2024, the EPO Board of Appeal ruled that the Broad Institute was indeed entitled to claim, for its European patents, the priority of its fundamental US patent rights on the Crispr/Cas9 tool for eukaryotes, *i.e.* animals, including humans, plants and fungi (even though Crispr/Cas9 had been discovered in prokaryotes). This strengthened the Broad Institute's prospects of obtaining significant patent rights for Crispr/Cas9 in Europe. This dispute is still pending before the EPO at the opposition stage (first instance or appeal).

To date, only the Broad Institute has definitively granted patents (having passed the opposition stage or not having been opposed) at the EPO[7]. However, their scope is limited to methods of genetic modification of prokaryotic cells by introducing one or more mutations. They cover applications that are currently of less commercial significance than, for example, the genetic modification of eukaryotes.

In the United States

The United States is the scene of a particular dispute concerning the inventorship of the Crispr/Cas9 invention[8]. In March 2022, the CVC was confirmed by the United States Patent and Trademark Office (USPTO) as the first to have "*invented*" the Crispr/Cas9 system. However, this decision also affirmed that the Broad Institute *ultimately* holds the rights to the application of Crispr/Cas9 in eukaryotic cells.

However, in May 2025, following a complaint by CVC, the Federal Court of Appeal overturned and challenged[9] this decision by the USPTO, which had granted priority for the use of Crispr/Cas9 in eukaryotic cells to the Broad Institute. The Court found that the USPTO had confused the legal standards for the conception of the invention with its implementation and had not properly evaluated the evidence in the record. The Court reaffirmed that conception does not require certainty of success and asked the USPTO to re-examine the issue of conception in a manner consistent with the Court of Appeal's opinion. This decision also has repercussions as it further delays other parallel interference proceedings to determine the first inventor: on the one hand between CVC and, individually, ToolGen and Sigma-Aldrich; on the other hand between the Broad Institute and, individually, ToolGen and Sigma-Aldrich.

Impact of litigation on licences

This May 2025 decision by the US Federal Court of Appeal has prolonged the dispute between CVC and the Broad Institute over the use of Crispr/Cas9 in eukaryotic cells, which is believed to be the main source of financial revenue. The final decision of the USPTO will have significant repercussions on the licences granted by CVC and/or the Broad Institute.

While licence agreements have already been signed, entities holding such licences may have to review the contractual provisions, which may already be included in the contracts. Similarly, entities seeking a licence or wishing to invest in structures using Crispr/Cas9 will also need to anticipate

the various possible outcomes of the dispute and negotiate appropriate licence terms with the structures they hope will ultimately be recognised as the rights holders. Finally, once the dispute has been definitively resolved, which may still take several years, users of Crispr/Cas9 who do not yet have licences from the winning party in the dispute will have to obtain a licence for the latter's patent rights.

It is currently very difficult to determine the impact of the dispute on licences, not only because it is still ongoing, but also because of the complexity of the patent landscape. However, licences already granted by the current holders of the fundamental rights to Crispr/Cas9 remain in place. This is the case, for example, with the exclusive licence agreement for agricultural uses between CVC and Corteva, which in turn grants sub-licences, and the exclusive agreement between the Broad Institute and Editas Medicine[10] in the therapeutic sector. In practice, entities wishing to exploit Crispr/Cas9 generally need to obtain several licences – licences on ToolGen and Sigma-Aldrich (Merck) application patents may also be necessary – in order to ensure global coverage and limit the risk of litigation. If a user of Crispr/Cas9 does not obtain all the necessary licences, they only have insufficient exploitation rights, which is not, in fact, total freedom of exploitation.

The holders of the main patents could choose to agree to create a patent pool to reduce transaction costs, avoid cumulative royalties and provide security for licensees. However, the establishment of such a mechanism could encounter obstacles, particularly in terms of setting the amount of royalties[11] and their distribution. In the absence of a widely adopted pool, companies wishing to exploit Crispr/Cas9 must continue to deal with a variety of bilateral agreements, cross-licences[12] and an uncertain legal environment.

Holders	**Claimed scope** (overview)	**Comments**
Fundamental rights/discovery of Crispr/Cas9		
CVC	Discovery of Crispr/Cas9, targeted DNA modifications, sgRNA, general applications	Holder of founding patents, in litigation (interference) with the Broad Institute for eukaryotic applications
Broad Institute	Crispr/Cas9 in eukaryotic cells, general applications	Holders of founding patents, major player in the European and US portfolio; success reinforced by EPO decisions on priority
Vilnius University	PAM site, Cas nickase	First to file patent applications on the use of Crispr/Cas9 but without describing or claiming the guide RNA subsequently discovered by CVC
Application patents / specific techniques		
ToolGen	Ribonucleoprotein (RNP) technology, PAM site	Significant portfolio for industrial and therapeutic applications, strategic licences
Sigma-Aldrich (Merck)	Optimised Cas9, reduction of *off-target* effects	Extensive portfolio for industrial and therapeutic applications, strategic licences

Table: Historical holders of Crispr/Cas9 patent rights

Behind the legal debate, a trivialisation of GMOs

GMOs are a major health, environmental and socio-economic concern for many civil society organisations. Faced with the power of multinationals, which also want to impose their patents, civil society's capacity for action is limited.

The current legal conflict surrounding new genomic techniques should not obscure a fundamental reality: the modifications obtained by Crispr/Cas9 do indeed produce GMOs. They cause changes to the genome whose health and environmental effects are neither insignificant nor fully understood. Presenting these techniques as simple "*improvement*" tools – as multinationals in particular do – amounts to trivialising their use, a trivialisation that only increases the potential risks.

From a legal standpoint, the complexity of the issue makes the practical use of genetic modification techniques such as Crispr/Cas9 particularly uncertain. The holders of the fundamental patents have not yet been clearly established, and each party is seeking to defend its interests, at the risk of nullifying the effect of certain major patents relating to Crispr/Cas9.

It is in this climate of legal uncertainty that the current evolution of the European regulatory framework on GMOs is taking place. The draft regulation aimed at deregulating GMOs derived from new genetic modification techniques (NGTs), including Crispr/Cas9, confirms a worrying step backwards. By removing the traceability and labelling requirements that curb patent abuse, it strengthens the control of large multinationals over living organisms, increases the legal uncertainty of small seed producers and farmers in relation to patents and, potentially, puts upward pressure on seed prices. Ultimately, it is seed, agricultural and then food sovereignty that could be called into question.

- + ERS Genomics, "Intellectual Property".
- + European patents EP2800811 and EP3401400.
- + PAM for Protospacer Adjacent Motif.
- + Principle of "*priority right*": following the filing of a patent application in one country, the applicant has a period of 12 months from the date of that first application to extend their protection to another country, while retaining the date of the first filing.
- + European patent EP4289948. At present, only their representatives are known: an agent representing the Broad Institute in several other European patent cases, a "*straw man"* agent (Strawman Limited) for an anonymous third party – which is permitted by the EPO (decision G3/97) – and a third European agent, whose client is not mentioned.
  EPO, "EP4289948 – METHODS AND COMPOSITIONS FOR RNA-DIRECTED TARGET DNA MODIFICATION AND FOR RNA-DIRECTED MODULATION OF TRANSCRIPTION", under "Oppositions".
- + EPO, "EP3597749 – METHODS AND COMPOSITIONS FOR RNA-DIRECTED TARGET DNA MODIFICATION AND FOR RNA-DIRECTED MODULATION OF TRANSCRIPTION", under "Oppositions".
- + European patents EP2840140 and EP2848690.
- + Denis Meshaka, "OGM – Crispr/Cas9 : la bataille sur les brevets continue" , *Inf'OGM*, 10 March 2022.
- + United States Court of Appeals for the Federal Circuit, "The regents of the University of California, University of Vienna, Emmanuelle Charpentier, vs. The Broad Institute, Inc., Massachusetts Institute of Technology, President and Fellows of Harvard College," 12 May 2025.
- + Broad Communications, "Broad Institute, Harvard, and MIT license CRISPR-Cas9 technology to Editas Medicine for therapeutic applications," 30 November 2014.
- + Patrick Wingrove, "CRISPR patent pool unlikely, say therapeutics businesses,"*Managing IP*, 19 February 2019.
- + In a cross-licence, two (or more) patent holders grant each other licences covering their respective assets.

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