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CRISPR/Cas9: a nebula of patents

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CRISPR-Cas9 technology ("Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR)-Associated Protein 9 (Cas9)") is already one of the most important scientific developments of this century. Its applications are wide and varied, and touch almost every aspect of biology. It has the ability to transform such important fields as e.g., agriculture and medicine. This technology is in particular poised to revolutionise medicine, with the potential to cure a range of genetic diseases, including neurodegenerative disease, blood disorders, cancer, and ocular disorders.

CRISPR-Cas9 is the most potent gene-editing tools to date. Sections of nucleic acids are edited in cells by insertion, deletion, or replacement at a specific target sequence. It is precise, fast, easy to implement, cheap, and uses components readily accessible.

The original CRISPR is a bacterial defence mechanism against phages. The CRISPR-Cas9 technology, as developed in the labs of Jennifer Doudna and Emmanuelle Charpentier, is a simple two-component system wherein an endonuclease (Cas9) is guided by a single guide RNA to the target sequence. This technology was then "used" as a programmable tool to cleave any nucleic acid sequence. It has made numerous achievements in the field of correcting pathogenic mutations, searching for essential genes for cancer immunotherapy, and solving key problems in organ xenotransplantation.

Improvements of the technology have been numerous and varied, including dead-Cas9, other endonucleases such as Cpf1, base editing systems, Cas9 variants, RNA editing, prime editing, etc., making CRISPR-Cas9 a sort of Swiss army knife for biologists. Indeed, its applications are seemingly limitless. In particular, this technology is widely used for the amelioration of plants and crops, whilst the recent announcement of successful treatment of transthyretin amyloidosis in clinical trials suggests that CRISPR–Cas9 gene editing can be deployed directly into the body to treat disease.

It is important for any party wishing to commercialise a technology to identify the relevant patent rights in order to assess their freedom to operate. For CRISPR-Cas9, this is complicated by the sheer number of patent applications filed. If the original CRISPR-Cas9 system was already the subject of

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of half a dozen competing applications, this number has exploded with the development of the applications of the technology as well as its various improvements. Finding their way in this nebula of patents is thus crucial for all interested parties.

The present article will not examine the intellectual property issues associated with every aspect of every development of CRISPR-Cas9. Rather, the present article aims at exposing the situation and the issues associated with the patent protection of the basic CRISPR-Cas9 technology. As described below, the situation is murky, as several parties hold competing rights over the technology. These parties, including notable academic institutions, are engaged in a string of judicial disputes. Moreover, each of these parties has used distinct licensing strategies.

All of this results in growing incertitude for anyone willing to develop commercial applications of the CRISPR-Cas9 technology.

1. CHRONOLOGY OF PATENTS FILING

As is the case most often than not, breakthrough discoveries do not happen in a vacuum. They are usually preceded and/or accompanied by a string of incremental improvements of earlier technologies. In addition, several groups may arrive at the same crucial results within moments of each other.

Two teams have received the most attention: the University of California (UC) team led by Jennifer Doudna at Berkeley and her colleague Emmanuelle Charpentier; and the team led by Feng Zhang at the Broad Institute (Broad). The Doudna and Charpentier labs showed that CRISPR and Cas9 could be programmed to cut a specific DNA molecule[1]. A few months later, the use of the technology in eucaryotic cells was described by the Zhang lab[2]. Both teams have filed various patent applications covering the very basics of the CRISPR-Cas9 technology.

Although the groups at UC and Broad have received the most attention, other actors should not be ignored. Notably, the lab of Virginijus Šikšnys at the University of Vilnius, demonstrated that the CRISPR-Cas9 system can be programmed to cut DNA at specific sites[3]. Scientists at Toolgen, a South Korean company, and Harvard University showed that the system could be used in human cells[4,5]. Researchers at Sigma-Aldrich, later acquired by the pharmaceutical company Merck KGaA, also deployed CRISPR on human cells.

These "secondary" actors have all filed various patent applications covering several aspects of the core CRISPR-Cas9 technology, thereby creating an interlacing of potential patent rights and clouding even more the situation for other parties.

Patents are granted for inventions which are new, inventive (i.e., non obvious), susceptible of industrial applicability (i.e., useful), and sufficiently disclosed (i.e., enabled). Hence prior disclosures will have serious impact on the patentability of each player's invention.

Figure 1 shows the dates of filing of priority applications, dates of filing of international applications (framed) and publication numbers of said international applications, of the six "earliest" parties in the game. Relevant scientific publications disclosing the technology are also indicated.

As illustrated in Fig. 1, each of the teams respected the rules - each patent application was filed before the publication of the corresponding article. Fig. 1 also illustrates the importance of validly claiming priority when the invention is disclosed (e.g., through the publication of an article in a scientific journal) between the priority date and filing date of the application: if the priority of the international application is found to be not valid, the scientific publication becomes part of the prior art and can destroy the novelty and inventive step of claims. Examples of such issues are described below in relation to the patent wars between all these parties

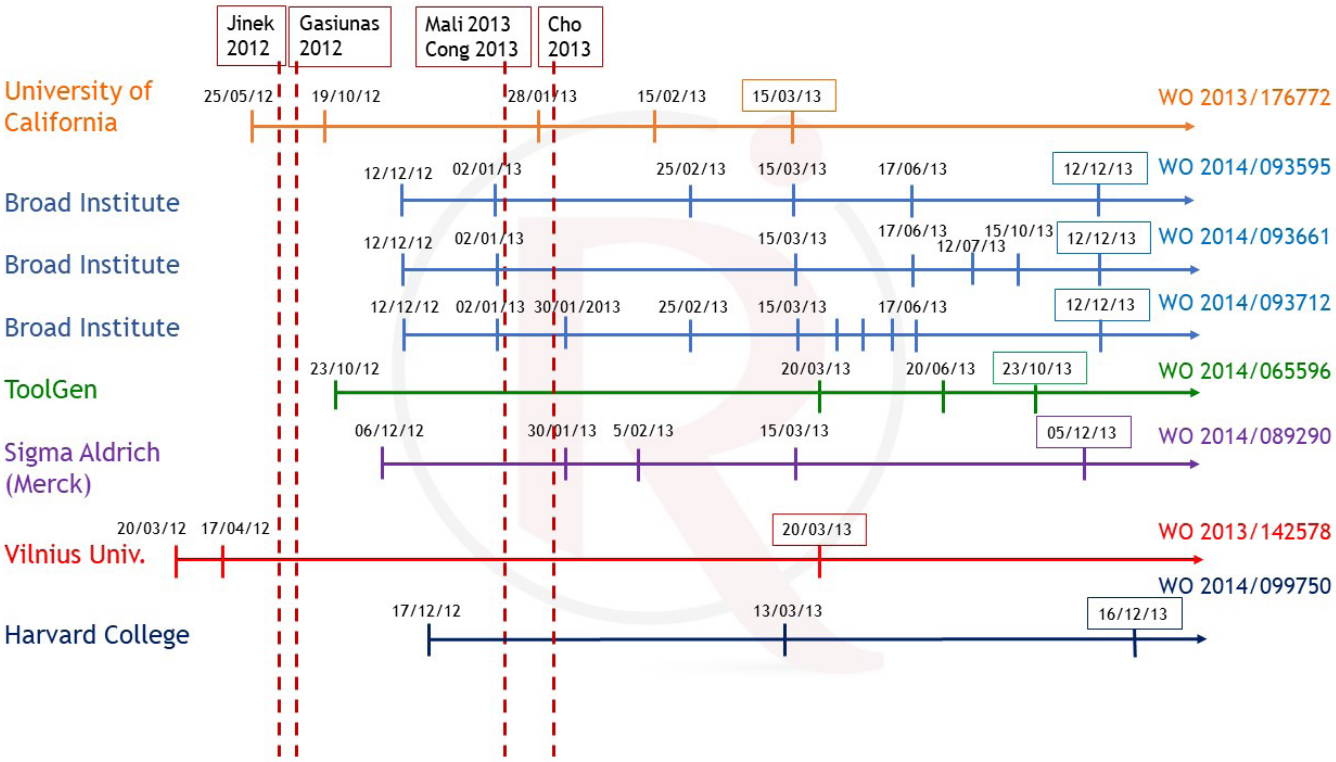

Figure 1: Timeline of patent applications filing and scientific publications

2. THE MAJOR PLAYERS

2.1 University of California (UC) with the University of Vienna and Dr Charpentier

The first player is UC, home of the Doudna lab. UC holds with the University of Vienna, where Emmanuelle Charpentier was based, a number of patents and applications relating to the CRISPR-Cas9 gene modification system in general. Claims relate to a synthetic DNA-targeting RNA and uses thereof to modify genomic DNA. Notably, the claims are not restricted to a specific cell type (i.e., procaryotic vs. eucaryotic). Indeed, the examples presented in the application concern both procaryotic and eucaryotic cells. However, these examples do not explicitly demonstrate that the technology is functional in eucaryotic cells.

Importantly, the first priority application had to be filed before the publication of the Jinek article in order to maintain novelty. UC could therefore only rely on the results obtained up to May 2012 in this priority application. Hence this priority application only contains examples relating to the use of CRISPR-Cas9 in procaryotes. Whether this priority application nonetheless taught how to use CRISPR-Cas9 in all types of cells, eucaryotes included, has become a crucial question in the patent battles which ensued. Different answers were given in the U.S. and in Europe.

2.2 Broad Institute (Broad) with the Massachusetts Institute of Technology (MIT), Harvard College and Rockefeller University

Shortly after the UC's earliest priority application was filed, Broad, the MIT, Harvard College, and Rockefeller University filed a patent application, directed specifically to eucaryotic applications of CRISPR-Cas9.

This application was based on data obtained in the Zhang lab at the Broad Institute (Broad). The principal improvement of Zhang's methods over his predecessors was the use of a nuclear localisation signal and, separately, codon optimisation to natively express Cas9. This first priority application was the basis for numerous applications, notably in the U.S. and in Europe,

all of which were directed to uses of the CRISPR-Cas9 technology in eucaryotic cells.

Whereas UC's applications had gone through prosecution without any particular haste, Broad's attorneys had sought to accelerate proceedings as much as possible, both in the U.S. and in Europe. As a result, they were issued patents whilst UC's applications were still being examined. This is important as there is a presumption of validity of granted patents.

However, the filing of the earliest priority applications has become crucial in the later disputes. Indeed, if the priority of these applications is not validly claimed, then the Cong paper becomes prior art and destroys the novelty of the claims. Once again different answers were given in the U.S. and in Europe.

2.3 ToolGen

Scientists at the South Korean company Toolgen published in March 2013 an article in Nature Biotechnology demonstrating the use of CRISPR-Cas9 technology in eucaryotes[4]. Before the publication of this paper, they had filed one priority application. However, data about the use of CRISPR in eucaryotic cells was not present in this earliest application.

Patents have been granted both in the U.S. and in Europe. They are directed to uses of the CRISPR-Cas9 system to effect site-specific modifications in eucaryotic cells, in particular human cells.

2.4 Sigma Aldrich, merged into Merck KGaA since 2014

Another major player – though often overlooked – is Sigma Aldrich. This company holds a significant patent portfolio relating to the applications of CRSPR-Cas9 in eucaryotic cells. Once again, claims relate to the use of the CRISPR technology in eucaryotic cells. Several priority applications were filed by Sigma Aldrich. The earliest was filed six days before Broad's earliest priority application. However, it is not before the latest priority applications that data supporting this use of CRISPR in eucaryotic cells was provided.

2.5 Vilnius University

Contrary to popular belief, the very first filed patent application regarding a method of site-specific modification of a target DNA molecule with the CRISPR-Cas9 technology is the US provisional application 61/613,373 filed on March 20, 2012 by Vilnius University (Lithuania).

In the U.S., a patent was granted as U.S. Patent No. 9,637,739 with claims directed to CRISPR-Cas9 complexes assembled in vitro and used for site-specific modification of target DNA sequences, in particular ex vivo. In Europe, a patent EP 2828386B1 has been granted with claims regarding in vitro methods only. A divisional patent application EP 3594341A1 is still pending, also related only to in vitro methods.

2.6 Harvard College

Harvard is one the co-applicants of Broad in three patent applications. On the other hand, it is also the sole proprietor of several patents and applications. All of them relate to the work of the lab of George Church, whose team demonstrated the use of CRISPR-Cas9 in human cells[5].

The first priority application in the portfolio was filed five days after the first priority dates of the Broad's applications.

As-filed claims relate to methods of modulating target gene expression comprising using guide RNAs and a nuclease-null Cas9 bearing effector domains, to multiplex activate or repress genes in vivo. Claims also relate to a method of altering a eucaryotic cell, as well as a method for altering human cells.

3. JUDICIAL DISPUTES

3.1 The "war" between the Broad Institute and the University of California

UC and Broad are the key players in the discovery and first uses of CRISPR-Cas9. The two are battling each other to determine which has the right to the claimed invention. The main issue is whether the initial UC's patent discloses the

use of this technology in eucaryotic cells, which would ensure that the University is entitled to this invention.

The main patent battlegrounds have been in the United States and in Europe, with slightly different questions asked in each jurisdiction, but receiving significantly different answers.

Because these patents claim priority earlier than 16 March 2013, the "old" system of first-to-invent applies in the US (it has now been replaced with a "first-to-file" system more akin to the rest of the world). Under this system, a patent applicant could use an interference proceeding to challenge whether another applicant should be granted a patent covering the same subject matter. For there to be no interference, it is only necessary to show that one party's claim would be considered novel and non-obvious (i.e., inventive) over the other party's claim. If this condition is not met, the proceedings would continue to determine which party was first to invent.

The present case pits 10 patent applications of UC against Broad's 13 patents and one patent application.

A first interference between the parties ended in 2018 after an appeal, which concluded that there was no interference. The Federal Circuit (i.e., the U.S. Federal Court of Appeal specialising in patents) found that Broad's invention, directed to CRISPR-Cas9 in eucaryotic cells, would not have been obvious in light of the University of California's invention, which claims the CRISPR-Cas9 generically.

Shortly after, UC filed new claims directed to CRISPR-Cas9 in eucaryotic cells. The scope of these new claims was tailored to be exactly identical to those of Broad which survived the first interference. Clearly UC was not satisfied with the outcome of the first interference. The USPTO examiner had no choice but to declare a new interference.

On 10 September 2020, the Patent and Trial Appeal Board (PTAB) decided key motions in this second interference. This decision addressed several important points for the rest of the proceedings. However, it is only an intermediary decision and the final word in this second interference will not be given until later in 2022 at least.

In their decision of September 2020, the PTAB decided notably that UC was only entitled to its third priority date of 28 January 2013 for this invention (CRISPR-Cas9 with a single guide RNA in eucaryotic cells), after Broad's priority date of 12 December 2012. However, the PTAB also decided that the dispute was only directed to a eucaryotic cell comprising CRISPR-Cas9 with a single guide RNA. This may be important when the Board decides on the interference because Broad's earliest proofs of invention are directed to the use of dual guide RNA.

This mix of outcomes – with Broad receiving an advantage on priority but with the University of California prevailing on the terms of priority contest – leaves both parties with considerable uncertainty. It cannot be excluded that the parties now feel an increasing pressure to settle. However, this looks unlikely, as they had plenty of opportunities to negotiate in all these years

Meanwhile, things have been going differently in Europe.

All of Broad's and UC' patents were individually opposed. Opposition is a mechanism which allows anyone to challenge a European patent in front of the European Patent Office (EPO) within of grant. Whereas in the US, interference aims at determining which Party has the right to the invention, opposition in Europe rather addresses the question of whether an invention is patentable at all. Hence an opposition ends either in the maintenance of the patent, as granted or as amended during the opposition, or in its revocation. A decision of an opposition division can be appealed in front of the EPO's Board of Appeals.

Since the Broad patents were the first granted, they were the first opposed. As is common for CRISPR patent challenges at the EPO, multiple opponents sought revocation of the patents on multiple grounds. In a landmark case[6], Broad's European patent No. EP2771468B1 was revoked for lack of novelty. In fact, the board of appeal concurred with the finding of the opposition division that the Broad patent did not validly

claim the earliest priorities because some of the applicants on these priority applications did not assign their rights to the invention to the Broad Institute and its co-applicants. As a result, the Cong paper - published on 3 January 2013 - became prior art and destroyed the novelty of the claims.

Far from being a technicality as Broad contends, the assignment of the priority applications from the original applicants to the applicants of the PCT application is an essential formal requirement of the European Patent Convention relating to priority. Since most, if not all, of the present Broad patents claim the same priorities, there is a strong chance that all these patents might be revoked for exactly the same reason.

Interestingly, following this earlier revocation of Broad's patent based on a successful priority challenge, UC's European patent No. EP 3241902 was revoked in opposition based on an invalid claim of priority. In this case, the claims were directed to a CRISPR-Cas9 system wherein the Cas9 protein has reduced nuclease activity. The opposition division considered that the earliest priority date of 25 May 2012 was not valid because it did not disclose credibly this invention. It followed that Jinek was prior art and that the claims were not new.

On the other hand, the parent patent EP 2800811, also held by UC, was found to be entitled to its earliest priority date of 25 May 2012. The opposition division considered that the claimed invention in that case (a CRISPR-Cas9 system in a procaryotic or a eucaryotic cell) was credibly enabled by the first priority application. Hence the opposition division of the EPO and the PTAB of the USPTO reached conclusions exactly opposite with regard to the teaching of the priority application of 25 May 2012, thus adding another layer of complexity to the case.

Needless to say, both decisions were appealed. The boards of appeal are not expected to decide on these cases before 2022.

3.2 The remaining parties

The conflict between Broad and UC has featured prominently in the media as the *ur*-CRISPR-patent battle, since it involves several universities and two Nobel prize winners, and has now dragged on for several years. However, this is an oversimplification, as new characters now enter the judicial scene.

3.2.1 Toolgen

For example, the South Korean company Toolgen is now facing two interference challenges of its application in the U.S., one against 14 patents and two patent applications of Broad, the other against 14 patent applications of UC. In Europe, Toolgen's corresponding patent has been opposed by multiple parties (as seems to be the case in all CRISPR-Cas9-related oppositions), resulting in revocation of the patent. Appeal is under way.

3.2.2 Sigma-Aldrich

Sigma-Aldrich petitioned the USPTO for having an interference declared between three of their U.S. applications and the same 10 UC's U.S. patent applications which were already involved in the interferences with Broad. Once again, what is at stake here is to determine the Party which was the first to invent the CRISPR-Cas9 technology. However, the PTAB has refused to consider Sigma-Aldrich's petition, dismissing it as "premature". This does not mean, though, that no interference will be filed later when Sigma-Aldrich patents issue.

In Europe, all six granted patents have been opposed by multiple parties. Two of them, EP 3138910B1 and EP 3138911B1, were revoked for lack of inventive step. It appears that the priority claims of these patents were considered valid, a welcome change from the earlier CRISPR-Cas9 decisions. This was not the case for EP 3138912B1 whose first auxiliary request was deemed not enjoy a valid priority and which was thus revoked. Note that the main request had been rejected on a very formal but very important basis, i.e., added subject-matter.

The decision against EP 3138910B1 was appealed by the proprietor. The two other decisions were rendered on 9 and 12 November

2021. An appeal can be formed against each of them within two months of the issuance of the written decision. In other words, Sigma-Aldrich has at least until 9 and 12 January 2022 to decide on this matter. However, it can reasonably be predicted that the other two decisions will also be appealed.

The remaining three patents are currently facing multiple oppositions.

3.2.3 Vilnius University

Surprisingly in view of all the CRISPR-related activity at the PTAB, the Vilnius US patent has not been involved in any interference. This may due to the fact that the claims are limited to CRISPR-Cas9 complexes assembled in vitro whereas the other relevant applications and patents claim CRISPR-Cas9 complexes for in vivo uses.

On the other hand, the European patent EP 2828386B1 was opposed by three opponents in April 2020. The proceedings are under way.

3.2.4 Harvard College

Applications and patents held by Harvard do not seem, to the best of our knowledge, to be involved in any interference proceedings. This may be explained by the fact that these patents appear to be directed to specific embodiments of CRISPR-Cas9 rather than to the most general technology.

In contrast, Harvard's European patent has been opposed by 4 opponents. Oral proceedings will be held on 22 & 23 March 2022.

4. THE CRISPR LICENSING LANDSCAPE

The grant of large number of CRISR-Cas9 patents with overlapping scopes has created a landscape that is difficult to navigate for would-be licensees.

For researchers and interested parties, the situation detailed above creates thorny issues around where to obtain the rights to use the CRISPR-Cas9 technique. In order to commercialise new CRISPR-Cas9 technologies and applications, interested parties will need to obtain commercial licences to the basic CRISPR-Cas9 patents. Notably, users of CRISPR technology need to obtain patent licences from UC, Broad, and others as the price of admission for operating in the space.

However, the continuing conflict between UC and Broad affects the evaluation any interested user must do. As of today, UC seems to have won the first round in Europe. On the other hand, in the U.S., the situation is a lot murkier. UC has claims to the use of CRISPR-Cas9 without further specification, whereas Broad has claims covering CRISPR technology in eukaryotes. It is therefore unclear whose patents a license is needed. For example, CRISPR-Cas9 users must decide whether they want to obtain a licence for patents which may later be declared invalid in one or more of the most important commercial markets. On the other hand, waiting before making a decision may expose them to a steep price hike if the patent is maintained in the US or in Europe by the competent legal authorities.

One way to facilitate easier access to technology created by multiple groups is to create a patent pool from which multi-party licenses can be obtained. A patent pool forms when multiple patentees combine their patents and use a single entity to license all the combined patents to third-parties as a single, non-exclusive licensing package.

In 2017, MPEG LA attempted to create a patent pool for a worldwide CRISPR licensing standard. Such patent pool would create a one-stop shop for commercial users to license CRISPR patents, without needing to navigate a complex patent and licensing landscape. The Broad Institute expressed interest in working with MPEG LA and other CRISPR patent holders to streamline non-exclusive access to the genome editing technology (except for human therapeutics applications). More recently, in July of 2019, Broad announced a joint CRISPR licensing framework with MilliporeSigma to "encourage innovation." With the intention of streamlining access for scientists, this licensing agreement includes patent rights from multiple key parties including: Broad, Millipore Sigma

(under the Sigma-Aldrich portfolio), Harvard University, MIT, New York Genome Center, The Rockefeller Center, and more. It is unclear how this new licensing venture will affect Broad's participation in MPEG LA.

On the other hand, up to now, University of California has not given any sign that they would be up to join any of the initiatives. Furthermore, these patent pools specifically exclude the possibility to request IP rights for human therapeutic and diagnosis applications and for agricultural uses.

The task is complicated by the fact that licences must be obtained from different sources. The owners of the core patent applications have granted their rights exclusively to marketing companies, with the mandate to grant exclusive or non-exclusive licences to private companies willing to invest in developing applications using CRISPR-Cas9. For example, for the development of human therapies, rights must be obtained from CRISPR Therapeutics, Intellia Therapeutics and Editas Medicine. CRISPR Therapeutics obtained its exclusive rights from Emmanuelle Charpentier, Intellia Therapeutics from UC and the University of Vienna, and Editas Medicine from the Broad Institute. For all other areas, the companies holding the relevant rights are ERS Genomics, Caribou Biosciences and the Broad Institute. ERS Genomics obtained its exclusive rights from Emmanuelle Charpentier, Caribou Biosciences from UC and the University of Vienna, while the Broad Institute licenses CRISPR IP non-exclusively for commercial research or to companies wishing to sell tools and reagents for genome editing.

To this day, no entity has been granted licenses for all CRISPR-Cas9 IP rights, whether held by one research group or the other. While the academics doing fundamental research with CRISPR Cas9 might pass over these IP questions, since they are usually exempt from the patent infringement regime under national laws, any commercial entity willing to obtain rights for using the technology will have to wait the end of legal controversies, or the creation of a patent pool.

5. CONCLUSION

The uncertainty about the CRISPR-Cas9 patent landscape presents a barrier to innovation.

One notable aspect of the CRISPR patent dispute is that it involves several large academic institutions. It has been rare for universities to sue one another over patents. This may dampen any spirit of scientific collaboration or even interaction between these institutions. As long as the legal battle is on, interested parties will thus not know for sure which patent owner they should contact for obtaining IP rights, neither how many licenses they would need. Unfortunately, the battle shows no sign of abating, suggesting that it is about something more than money[7].

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