

CRISPR-Cas9: Editing the Entangled Patent Dispute

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CRISPR-Cas9, the revolutionary genome editing technology, is undoubtedly one of the most versatile, efficient and precise genome editing tool. CRISPR-Cas9 stands for Clustered Regularly Interspaced Short Palindromic Repeats and CRISPR-associated protein 9. The CRISPR-Cas9 system was discovered in *Escherichia coli* iap gene in 1987, but biological significance of CRISPR as defense system was elucidated only 20 years later, in 2007. CRISPR-Cas 9 is the naturally occurring acquired immunity system of prokaryotes (bacteria and archaea). CRISPR sequences are an array of DNA sequences derived from the virus that infects the bacteria, which are used to recognise the viral DNA when the same or related virus attacks again, by producing RNA segments from the CRISPR arrays, and thus act as molecular memory or imprints of virus attack. The guide RNA (gRNA) from CRISPR array binds to the Cas9 endonuclease which cuts viral DNA by creating double-strands breaks (DSBs), thus disabling the virus. The prokaryotic immunity system is adapted to edit the genome of living organisms by using a long (nearly 20 bases) synthetic guide RNA along with Cas9, to create not only targeted genome editing but also to make transcriptome and epigenetic modifications.

CRISPR-Cas 9 technology has wide applications in basic research to understand structure and functions of genes, gene regulation, plant and animal breeding, drug development and human gene therapy. Immense are the opportunities and applications of the novel method, so are the challenges. There is an explosion of genome editing tools based on CRISPR-Cas9 and class II CRISPR-Cas systems. Improvements and refinements of the technology has been carried out to remove undesirable effects and drawbacks, for better efficiency and specificity. Patents on technologies and products based on CRISPR-Cas9 have already been granted. However, the unprecedented legal or patent wars on the novel and promising CRISPR-Cas technology, had a retarding effect on its progress and diverse use. A patent is a negative intellectual property right, to exclude others from using an invention, without the consent of the patent holder and is valid from the date of issue of the patent by the patent office, till 20 years from the date of filing the application. Patents like any real property can be mortgaged, licensed or sold.

One of the patent litigations on CRISPR-Cas was between researchers of University of California (UCB) and Broad Institute of MIT and Harvard in Cambridge, Massachusetts (MA). During 2012, UCB claimed of making the fundamental invention of adapting CRISPR from bacterial defence or immunity mechanism, to a lab-based genome editing tool. During 2013, researchers of Broad institute described the use of the technology in mammalian cells. In 2014, Broad institute received patent for the mammalian use of CRISPR (US patent No.8,697,359 dated April 15, 2014, titled CRISPR-Cas systems and methods for altering expression of gene products), which was contested and questioned by UCB, for issues with interpretation of non-obviousness, one of the essential criteria, required by an invention to qualify for a patent. UCB challenged the patent and claimed it was obvious to test the CRISPR-Cas system in mammalian cells and therefore the invention lacked non-obviousness. The controversy was over the issue of who has used the technology in mammalian cells. However, the Patent Trial and Appeal Board (PTAB) had supported the patent, stating that there was no guarantee on the success of CRISPR-Cas in eukaryotic systems like mammalian cells, even if it worked. The fierce patent war between two educational institutions came to an end in September 2018, when the US appeals court issued a decisive ruling, awarding the IP (patent) rights on CRISPR-Cas9 gene editing to the Broad Institute, upholding a previous decision by the US Patent and Trademark Office. However, even after the end of the epic patent fight, the question remains on how to define the limits of the versatile CRISPR-Cas technology for patents [1,2].

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