



Rigorous empirical
research on
intellectual property

CRISPR Processes Patents in Green Biotechnology

INTELLECTUAL PROPERTY LICENSING PLATFORMS AND CLEARING HOUSES

Host: Axel Ferrazzini, Managing Director, 4iP Council

Presenter: Dr Agnès Ricroch, PhD, HDR



What do we do?



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Which types of intellectual property do you need?

Filter table columns

	Patents	Copyrights	Designs	Trademarks	Trade Secrets
What do they protect?	An invention, a new and inventive idea or thing, something or solving a technical problem.	A work of original intellectual creation.	A new and original visual appearance of a product.	Words, logos, symbols, computer icons, business graphical user interfaces, trade dress.	Confidential information.
Examples of what is protected	Medicine, machine, process, or software.	Books, music, films, paintings, software, designs, databases, websites, games, etc.	Product design, packaging, logos, symbols, computer icons, business graphical user interfaces, trade dress.	Words, logos, symbols, computer icons, business graphical user interfaces, trade dress.	Confidential information.
How are my rights protected?	Patents are conditional on being granted by the patent office.	Copyrights are automatic and do not require registration.	Designs are automatic and do not require registration.	Trademarks are automatic and do not require registration.	Trade secrets are automatic and do not require registration.
How long is my innovation protected?	Up to 20 years.	Up to 70 years after the author's death.	Up to 25 years for registered designs.	Up to 10 years for registered trademarks.	As long as the information remains confidential.
Do I have to register it?	Yes, filing an application to a patent office is required.	No, copyright protection arises automatically on the work.	No, design protection arises automatically on the work.	Yes, filing an application to a trademark office is required.	No, trade secret protection arises automatically on the work.

How do I use intellectual property to grow my business?

2 - NEGOTIATING
Explore how patents add value with our [Interactive guide](#).

3 - FUNDING
Explore the benefits of copyright with our [Interactive guide](#).

4 - STRATEGIC VALUE
Explore the benefits of trademarks with our [Interactive guide](#).

4 REASONS 4 TRADEMARKS

- 1 - DIFFERENTIATION
- 2 - PROTECTION
- 3 - REPUTATION
- 4 - REVENUE

4 REASONS 4 DESIGN RIGHTS

- 1 - EXCLUSIVITY
- 2 - COMMERCIALISATION
- 3 - REPUTATION
- 4 - VALUE

Case Law post CJEU ruling *Huawei v ZTE*

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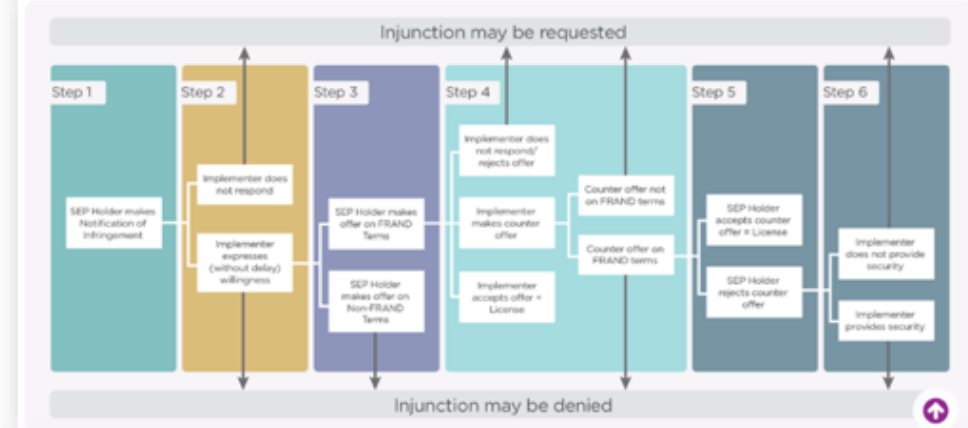
National Courts Guidance

Negotiating Licenses for Essential Patents in Europe

Increased clarity provided on the principles established by the Court of Justice of the European Union in *Huawei v ZTE*.

The Court of Justice of the European Union clarified, in *Huawei v ZTE* (Case No. C-170/13), European law relating to the availability of injunctive relief for infringements of FRAND-based standard essential patents. In doing so, the Court provided a legal framework focused on the good faith conduct to be expected of both parties. Since

Huawei v ZTE process



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CRISPR Processes Patents in Green Biotechnology: the Benefits of Patent Pools and Clearing Houses

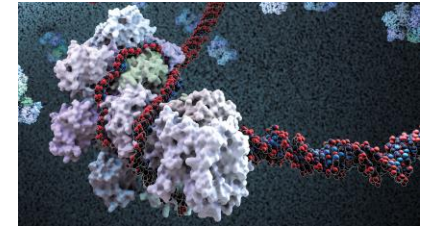


Dr Agnès Ricroch holds a PhD in plant science and obtained an HDR (ability to conduct researches) from Paris-Saclay University (Orsay, France) in genetic resources and plant breeding.

She is a senior lecturer at AgroParisTech (Paris, France) and Adjunct Professor at Pennsylvania State University, College of Agricultural Sciences (USA), she teaches biotechnology and bioethics since 2016.

New Genomic Techniques (NGTs) as Tools for Green Biotechnology Applications

- CRISPR-Cas-based technique: **revolutionary** and very **successful** with public and private researchers/breeders.
- **Not very expensive** and **quick to implement**. This is why there are so many patents.
- **Still evolving** (*e.g.* base editing).



Source: Science

CRISPR: Clustered Regularly Interspaced Short Palindromic Repeats

The CRISPR global patent landscape

A strong patent system is necessary **to enable innovation** by incentivising investments in R&D and **promoting the dissemination of knowledge**.

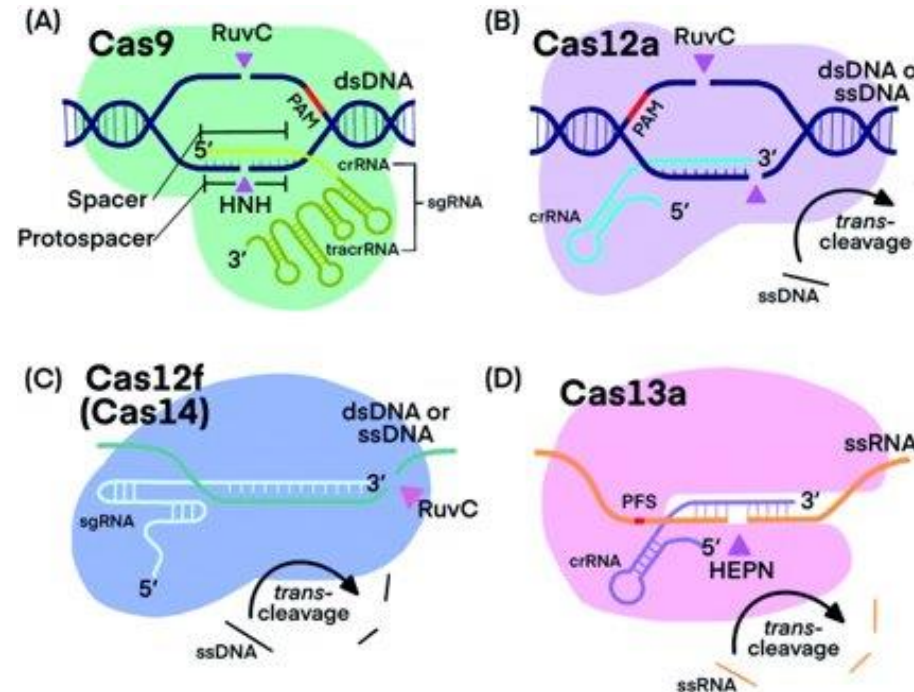


More than 11 000 CRISPR-related patent applications filed worldwide (USA and China)

- 1/3 of CRISPR patents hold by private companies.
 - Protracted legal battles surrounding two of the technology's inventors UC Berkeley's and the Broad Institute/MIT's CRISPR patents.
- > could be barriers to innovation.

- Companies now also have the option of avoiding these key patents (UC Berkeley, the Broad Institute) altogether by using different CRISPR systems

(Cas 9 alternative enzymes such as Cas12a, Cas13 or Cas14, and base editors).



Source: Royal Society of Chemistry, UK

Difficulties in patenting

- Patent profusion

- necessary **to facilitate freedom to operate** (FTO).
 - a FTO analysis clarifies if a product or its potential commercialization infringes on other existing intellectual property rights (IPRs).
 - **expensive** undertaking.

Difficulties in patenting

- Barriers to SMEs

- Some Member States in the EU and stakeholders expressed concerns about patenting or accessing patented NGTs for SMEs.
- The two causes of high transaction costs.
 - high costs of R&D (the outcome of which is uncertain) and the regulatory approval required for new products.
 - high licensing fees can occur in the biotechnology sector due to the overvaluation of IPR.

Solutions in terms of collaborative licensing models - patent pool

- **alternative licensing models** could overcome the difficulties.
- **identifying patents** in a profusion of patents :
 - avoid economic and welfare losses
 - accelerate technological progress

- **One-stop shop:**
 - allow for cross-licensing and facilitate **FTO**.
 - with a single licensing package, **any potential licensee** could use the technology platform.
 - **a patent pool** could be a useful model to
 - facilitate access
 - reduce potential litigation risk

- For licensees, a community such as a **pool can reduce the number of negotiations.**



- a **pool can reduce this cost** of FTO analyses because its directors must perform these analyses to determine the specific nature of the included patents.
- A successful transaction can reduce costs for all parties involved on a scale of **hundreds of millions of dollars-euros.**

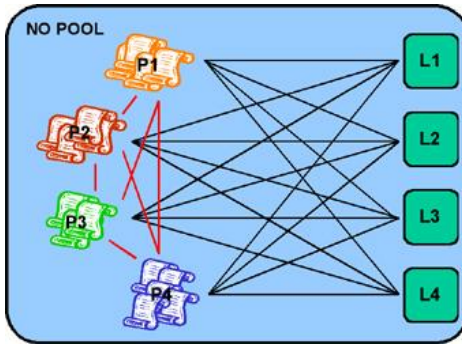
- **Non exclusive licensing:**

- the package of IPRs licensed on a non-exclusive basis, allowing licensees to benefit from affordability and freedom to operate, with **adequate royalties**.

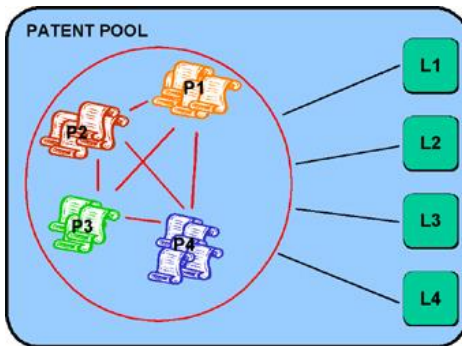
- allow many companies to enter the market.

- A **patent pool must be open to all IPR holders**, but each patent must be analysed individually to determine if it is needed
- Patent pool administrators (such as MPEG LA), use **independent experts** who analyse both the patent landscape and the patents.





- **In the absence of a patent pool**, users (licensees) have to enter into negotiations with all relevant patent holders, which is a time consuming and expensive process.

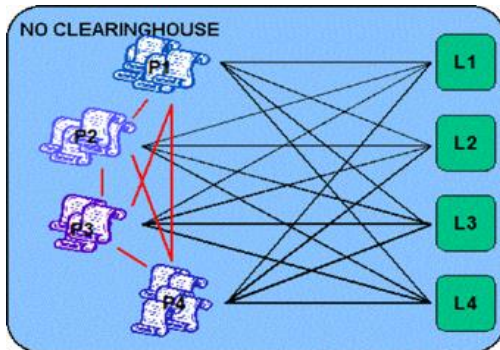


- **In the presence of a patent pool**, licensees turn to the patent pool for the rights as one package, which results in simplification and a significant reduction of transaction costs.

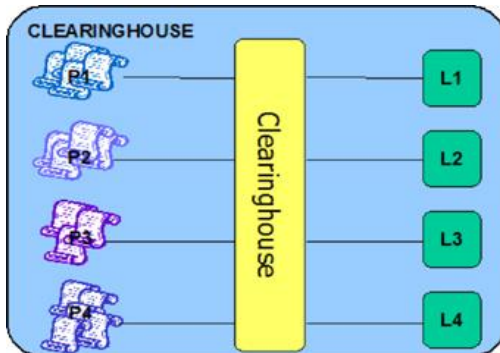
Source: Van Overwalle *et al.*

Solutions in terms of collaborative licensing models - clearing house CH

- The platform may
 - provide **information** on patented technologies,
 - bring together **licensors** and **licensees** of patented technologies,
 - and provide **additional services**, negotiating licensing conditions, and collecting and distributing royalties.



- **In the absence of a clearing house,** licensees must enter into negotiations with all patent holders.



- **In the presence of a clearing house,** licensees turn to the patent pool for acquisition of required rights.

Source: Van Overwalle *et al.*

Example: ACLP

Agricultural Crop Licensing Platform



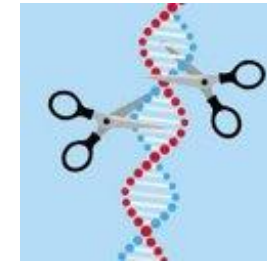
- This clearing house as a solution for products produced by the CRISPR technology in Europe.

Success and acceptability

- Specify **who** and **what** IPRs are contained in the pool.
- Need to include all **key** patents and **specific** patents.
- Increase patent **quality**:
 - the end product (trait) should be precisely defined for the definition of a key or a specific patent.
- **Alleviate litigation** concerns.
- A true **one-stop licensing point** allows cross-licensing and is easy to use.

Key patents versus specific patents?

- **Key patent:** the application is general (research tools)
 - make patented research tools as broadly available as possible
 - open licensing systems



- **Specific patent:** the application is specific
 - for a given trait
 - for a given species



- **Need to define a model**
- The platform pool could require broad “**target-agnostic**” patents that do not require a specific genome for better access to plant genetic resources.



Need to define a model: the Reference Model



- Because the platform could change due to advancements in technology, MPEG LA created the Reference Model.
- The platform plans to include **key** and **specific** IPRs.
- the pool is built to contain only broad,
- **"target-agnostic" patents.**

- The Reference also preserves the biotech industry's need for exclusivity through "**target-specific**" **patents** that will not be included in the scope of the pool.

The developers could get a license on an independent basis for specific genes or applications.

The public sector



- From an economic perspective,
 - plays a role in fundamental research and is a **substantial source** of IP in green biotechnology.
 - **Fundamental CRISPR patents** (research tools): **licensed and disseminated as widely as possible** while addressing **ethical concerns** about particular applications.

The Nine Points: Point 5 states that universities should make patented research tools as broadly available as possible.

(Association of University Technology Managers, in the Public Interest: Nine Points to Consider in Licensing University Technology (Washington, DC, 2007))

Ethical licensing



Ethics concerns the following points.

- Non-exclusive licence agreement
- Prohibiting patents on native sequence
- No germination restriction
- Prohibiting patents on tobacco for human use

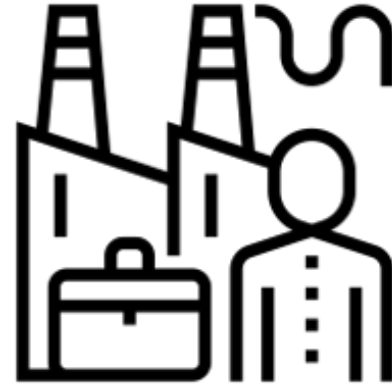
Minimum number of deposants

- support from several important and all **key players**,
- a **sufficient number** of IP owners to join the pool to ease licensing burdens and costs.
- A **major compagny** is needed.

The EU study acknowledged the benefits of patents and licensing in promoting innovation and the development of NGTs and their products.



- an EC roadmap in September 2021 to establish a new legal framework for plants obtained by NGTs and products based on the study in April 2021
- to contribute to the goals of
 - the *European Green Deal* and the *Farm-to-Fork Strategy*
 - biodiversity strategies and the UN' sustainable development



- Private companies and agribusiness SMEs see the benefits of **strong patent protection** for NGTs and NGT products as a prerequisite for innovation due to the high costs of research and development.

Conclusion

- With the existence of multiple patents, a **patent pool** could be a useful model to **facilitate access** and **reduce potential litigation risk**.
- The package of IPRs is licensed on a **non-exclusive** basis: affordability and freedom to operate, adequate royalties.
- The platform should be a **low-complexity platform**.

Thank You!

Q&A

Forthcoming Webinar:

Date	Title	Summary
19-Oct-2022 16h (CEST)	IP or Not IP during COVID times? Compulsory Licensing, IP Waivers & other initiatives	Analysis of the role of intellectual property rights (IPRs) and, more specifically, of patents during COVID times, with a focus on the pharmaceutical industry and COVID vaccines.



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