IPR Regimes in Current Days of Crisis

Can the Traditional IPR Ownership and Control of IPR be Harnessed to Foster Faster Solutions?

14 May 2020, "Virtual" Topic Meeting

Agenda

- Welcoming note by Dr Achim Krebs, President LES Benelux, Partner at HGF
- Brief presentation and interview with Christophe Verbruggen, Director - Legal Affairs R&D EMEA at Janssen Pharmaceuticals (J&J), followed by a Q&A session
- Round table discussion with participants on subjects of particular interest for the next session of our new online topic event format.

IPR Regimes in Current Days of Crisis

- Covid-19 presents an unprecedented crisis for mankind – and this usually leads to step changes in technology developments.
- We are seeing many initiatives forming, involving private companies and many public institutions across the globe, making every effort to find a (preventive) treatment.
- How can these rights be harnessed by private individuals and companies to develop and supply essential new technologies?
  - Do we have the legal mechanisms that facilitate quantitatively and qualitatively sufficient, and financially acceptable, exploitation of IP rights?
  - How to handle the global tsunami of compulsory licensing developments spreading around the globe?
  - Are national IP Rights in the way of a borderless cooperation?

Do we need to change our practice?

- Does “Socially responsible licensing” form a suitable alternative?
  - Public and private sector organisations alike are rapidly signing up to the recently launched “Covid Pledge”, initiative driven by faculty members and researchers across the globe.
  - “Preset menu“ for royalty fee licence conditions for the use if IPR is relevant or required in the battle to fight Covid-19 as a pandemic.
  - Unprecedented co-operations between competitors – but how about competition laws?
- Increasing numbers of governments and public authorities have issued different iterations of “march-in rights” or “compulsory licensing rights”*:
  - Prevent IPR owner from exercising full control over commercial use of IP Rights, giving direct access, or even sublicence rights.
  - Called for in emergency situations, to manage short-term health care, infrastructure and other services critical to disaster recovery.
- Balanced impact on Investment and willingness to carry the risks involved?

* See for instance: https://www.wipo.int/edocs/mdocs/scp/en/scp_30/scp_30_3-main1.pdf

Roundtable Discussion

A few possible subjects for our next topic sessions

- The advent of compulsory licensing
- When, where and how is a crisis a “Force Majeure”?
- Milestones missed in agreed developments due to public restrictions – an “act of god”?
- Bankruptcy and licence position
- Use of Data
- E-signatures/validity of documents and electronic signatures in general

LES Virtual Discussion Forum

Licences on Investments
The Quid Pro Quo?

- Licences /Ownership Transfers

versus

- Own Investment of the collaborating parties
- Funding origin of a 1:1 Company/Academic Project :
  - Fully funded by Company
  - Partially funded by Company / Partially by Academic Centre
  - Partially funded by Company / By an external grantor (charity, fund, government, seed funding, venture capital) (e.g. PPP, IMI)
  - Fully funded by an external grantor (e.g. H2020)

  - The more a party invests from its own, the more rights it may expect…

Access Rights Conditions (potential terms)

Access rights granted by a beneficiary **to another:**	On Background	On Results
Beneficiaries for completion of the action:	**Royalty-free**	**Royalty-free**
Beneficiaries and affiliates for Research Use:	**Usually Fair & Reasonable**	**Usually Royalty-free (depends usually on result cat. or field)**
Third Parties for Research Use after the action:	**Appropriate (tbn) conditions**	**Appropriate (tbn) conditions**
Other Beneficiaries, affiliates or Third Parties for Direct Exploitation:	To be negotiated later, may be refused	To be negotiated later, may be refused

Typcial Modalities

- Pre-agreed
- Requested/Granted Upon signature of the agreement
- Difference of “Treatment” versus a “Research Tool”
- If extra costs, defined
- Collaborating partner should not be in a disadvantaged position versus a third party

- Pre-agreed licences even more so the case in public health threat projects, to avoid loss of negotiation time and ensure further use
- Less of issue as the fact most data and results will be published, so will be available freely

The European research-based pharmaceutical industry's commitment to tackling the coronavirus pandemic

EFPIA is the voice of the research-based pharmaceutical industry in Europe. As an industry #WeWontRest in fighting the COVID-19 pandemic.

Our first thoughts are with all those affected by the coronavirus pandemic. We are committed to working collaboratively across the research and healthcare communities, utilising our world-leading science, people and resources to tackle this outbreak.

Our aims in this time of public health crisis are to:

- Ensure the safe supply of medicines to the patients that need them
- Research and develop new vaccines, diagnostics and treatments for use in the fight against COVID-19
- Partner and support organisations on the ground to fight against COVID-19

WE ARE DOING THIS BY:

Rapidly screening our vast global libraries of medicines to **identify potential treatments** and have numerous clinical trials underway to test new and existing therapies.

Launching clinical development of potential vaccines against the coronavirus.

Sharing the learnings from clinical trials in real time with governments and other companies to advance the development of new therapies.

Bringing together the best scientists from industry and academia through the **Innovative Medicines Initiative** to accelerate the development of new diagnostics and treatments.

Expanding our manufacturing capabilities and sharing available capacity to **ramp up production** once a successful medicine or vaccine is developed.

Establishing a direct link between manufacturers and EMA & Heads of Medicines Agencies to provide constant information about stock, manufacturing capacity and market tensions in order to anticipate and pro-actively address any potential disruptions or shortages.

Coordinating with governments and diagnostic partners to **increase COVID-19 testing capability and capacity.**

Providing **financial support** and in-kind donations to organisations at the front line across Europe and beyond.

Continuously **monitoring our supply chains** and working to ensure the supply of medicines to the patients that need them.

Working with governments and health systems to ensure that when new treatments and vaccines are approved they are **available and affordable.**

Working with the European Institutions, Member States, public health partners, the research community, healthcare professionals and other partners to **fight the spread of COVID-19.**

Protecting our workforce and the communities where we live and work, having employees working from home whenever possible.

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Access & Affordability (example)

- Publication of Research in open access journals (no cost for accession research results)
- Access to Research Data (data are available/fast)
- Access to Terminated assets (anti-shelving)
- Availability & Affordability in L-LMIC of identified treatment
  - Use of unique regulatory pathways
  - Can never be obliged to make available at a loss

Public Health Threat Projects

- Speed is essence….
- How
  - Experienced Teams (all disciplines)
  - Dedication (freeing up time of staff from other projects)
  - Use of templates
  - Use of historical solutions to legal & IP problems, licensing solutions
  - Clear roles on who drives what
  - Direct lines of feedback to government, grant agencies and higher management
  - Entity must be prepared to work outside of regular “policies”
- Example: we don’t do electronic signature because our org does not allow it.

x

Thank You / Q&A