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?

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)

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<th>Access rights granted by a beneficiary to another:</th>
<th>On Background</th>
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<td><strong>Beneficiaries for completion of the action:</strong></td>
<td>Royalty-free</td>
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<td><strong>Beneficiaries and affiliates for Research Use:</strong></td>
<td>Usually Fair &amp; Reasonable</td>
<td>Usually Royalty-free (depends usually on result cat. or field)</td>
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<tr>
<td><strong>Third Parties for Research Use after the action:</strong></td>
<td>Appropriate (tbn) conditions</td>
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<td><strong>Other Beneficiaries, affiliates or Third Parties for Direct Exploitation:</strong></td>
<td>To be negotiated later, may be refused</td>
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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.
- Bringing together the best scientists from industry and academia through the Innovative Medicines Initiative to accelerate the development of new diagnostics and treatments.
- Establishing a direct link between manufacturers and EMA or 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.
- Continuously monitoring our supply chains and working to ensure the supply of medicines to the patients that need them.
- 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.

WE WONT REST IN THE FIGHT AGAINST COVID-19

- 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.
- Expanding our manufacturing capabilities and sharing available capacity to ramp up production once a successful medicine or vaccine is developed.
- 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.
- Working with governments and health systems to ensure that when new treatments and vaccines are approved they are available and affordable.
- Protecting our workforce and the communities where we live and work, having employees working from home whenever possible.
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.
Thank You / Q&A