IMPAC3T

WP2 Scenario definition and process mapping

D 2.1 Report on scenarios and intervention points

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Deliverable Information Sheet

Version	2.2
Grant Agreement Number	101135832
Project Acronym	IMPAC3T-IP
Project Title	Improving outcoMes and imPact from scenArio based licensing: Classical_Crisis and Co-creaTed IP
Project Call	HORIZON-CL4-2023-HUMAN-01
Project Duration	36 months
Work Package	2 Scenario definition and process mapping
Lead Partner	PP3 UCD
Deliverable Number	2.1
Deliverable Title	Report on scenarios and intervention points
Deliverable Type	R
Deliverable Dissemination Level	PU
Authors	Natalia Zhuravleva, Ed Maughfling, Ana De Leon, Girish Somawarpet, László Bacsa, Tommi Järvinen and Lisa Cowey
Contributing Partners	UCD, e-Lucid, UA, Demola, META,
Reviewers	Lisa Cowey, Elizabeth Nolan
Official Due Date	M12
Delivery Date	M12

History of Changes

Version	Date	Description	Author(s)
1.0	01.08.2024	Draft	Lisa Cowey
2.0	15.10.2024	Combined draft	Lisa Cowey, Natalia Zhuravleva, Laszlo Bacsa, Tommi Järvinen, Janne Eskola, Ed Maughfling, Jose Fernandez, Ana De Leon, Girish Somawarpet
2.1	22.10.2024	Revised draft	Lisa Cowey, Natalia Zhuravleva
2.2	04.11.2024	Final draft	Elizabeth Nolan

List of Acronyms

AAP	Affordable Access Plan
AE CSIC	Agencia Estatal Consejo Superior de Investigaciones Científicas
AHSS	Arts, Humanities and Social Sciences
AUTM	Association of University Technology Managers
CC	Creating Commons
CL	Compulsory licensing
COA	Clinical Outcome Assessments
CPAP	Positive airway pressure
C-TAP	COVID-19 Technology Access Pool
EBQ	Eating Behaviour Questionnaires
EU	European Commission
FDA	Food and Drug Administration
FNU	Netherlands Federation of University Medical Centres
FOC	Free of Charge
GGC	Guiding Good Choices®
HEI	Higher Education Institution
HIC	High Income countries
HIPO	Hungarian Intellectual Property Office
HPP	High Performance Powertrains
HTAP	Health Technology Access Pool
IA	Intangible Assets
IGI	Innovative Genomics Institute
LMIC	Lower and Middle Income Countries
MC	Medical Center
MPP	Medicines Patent Pool
MS	Member States

NCD	Non-Communicable Diseases
ND	Natural disasters
NFP	Non-For Profit
NL	Netherlands
NOW	Dutch Research Council
PC	Preventable Crisis
PRO	Public Research Organisation
PROs	Public Research Organisations
SCD	Swiss Agency for Development and Cooperation
SRL	Socially Responsible Licensing
STEM	(Science, Technology Engineering Maths
T&C	Terms and Conditions
TRIPS	Trade-Related Aspects of Intellectual Property Rights
TTO	Technology Transfer Offices
UC	Unforeseen Crisis
UC	University of Columbia
UCB	University of California Berkeley
UCB IPIRA	University of California Berkeley Intellectual Property & Industry Research Alliances
UCL	University College London
UCLA TDG	University of Californian Los Angeles Technology Development Group
UCLH	University College London Hospital
UN	United Nations
VL	Voluntary licensing
WHO	World Health Organisation
WIPO	World Intellectual Property Organisation
WTO	World Trade Organisations
YES	Youth Empowerment Solutions

Keywords List

- Intellectual Property
- IPR management
- Licensing
- ToolBox
- Tool-kit
- Patent
- Classical+ licensing
- Crisis licensing
- Co-creation licensing
- Equitable Access
- Responsible Access
- Lower and Middle Income Countries (LMIC)

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1. Introduction to the Deliverable

This document is Deliverable 2.1 of the IMPAC3T-IP project.

IMPAC3T-IP is an ambitious Coordination and Support Action that aims to develop, pilot and support the sustainable adoption of a scenario based licensing ToolBox through a certified user and trainer programme, for efficient IP licensing for market uptake and societal value creation. IMPAC3T-IP explores three main licensing scenarios:

- Classical Plus – licensing that encompasses newer types of IP assets e.g. assets that are not patent based and are therefore different to the assets that have formed the main part of the traditional for-profit licensing approach.
- Crisis – licensing that takes place in repose to or to prevent crisis situations such as emerging or preventable medical emergencies.
- Co-creation – licensing that takes place as a result of interactions involving multiple different stakeholders and that goes beyond classical collaborations and contract research.

This document is an output of Work Package 2: Scenario definition and process mapping.

1.1. Aims and objectives of WP2

Work Package (WP2) had five main tasks:

Task 2.1 Establish special interest groups (3S and 3P)

Three small special interest groups (SIGs) were set up with representatives from public and private licensing communities and policy makers, to support the exploration and analysis of each of the 3 main scenarios outlined above.

Task 2.2 Definition of Scenarios

The 3 main scenarios were explored through situational analysis, key players, types of IPR, and desired outcome e.g. purpose of the licensing (economic, impact, social, crisis or to realise co-creation) as well as boundary conditions and legal aspects.

Task 2.3 Mapping of processes and intervention points

Each defined scenario was mapped though a series of analysed examples to identify 'intervention points' where a tool could facilitate progress towards the desired outcome.

Task 2.4 Study of drivers

Work was undertaken to understand the drivers for enterprises in engaging in licensing beyond pure economic gain.

Task 2.5 Collection of Case studies

Case studies were identified and analysed to further illustrate the different scenarios and to capture the best practice aspects that make the example transferable for others.

1.2. Outcomes

The outcomes of the WP2 activity were multifaceted, resulting in:

- **Defined Scenarios with Intervention Points:** A comprehensive set of licensing scenarios, each broken down into distinct stages and boundary conditions. These scenarios highlighted key

intervention points—specific stages in the licensing process where targeted tools could be applied to improve efficiency, reduce barriers, or better align with stakeholder objectives.

- **Analysed Examples**: A set of thoroughly analysed examples that allowed for a detailed examination of each sub-scenario and a better understanding of public and private sector licensing drivers. These examples helped refine the understanding of each scenario and provided insights that could be used to adjust findings as necessary in future phases of the project.
- **Preliminary Set of Tools:** A preliminary list of potential tools and methodologies applicable to each scenario. These tools were identified as promising means to support intervention at key points in the licensing process, ensuring that the developed toolbox would be practical and tailored to the needs of different licensing environments.

This document presents the results of the definitions of the scenarios (T2.2) and the mapping and intervention points, presented to and discussed with the SIGs (T2.1). It lists the preliminary set of tools that will be developed in Year 2 of the project.

The study of enterprises drivers is contained in D2.2 while the extended case studies can be found in D2.3.

2. Methodology

The following key steps were undertaken to meet the project objectives:

1. Establishment of Special Interest Groups
2. Collection of Examples and Illustrative Materials
3. Mapping of Processes and Intervention Points

1. Establishment of Special Interest Groups

The establishment of Special Interest Groups (SIGs) was a cornerstone activity of Task 2.1, designed to facilitate targeted exploration and analysis of three distinct licensing scenarios: Classical, Crisis, and Co-Creation.

Participants for the SIGs were identified by a partner-led call for nominations and direct referrals from the consortium's extensive network. Additionally, the existing ASTP 'Impact' SIG was notified to broaden the pool of potential candidates with specialised knowledge in impact-driven licensing.

In total, about a hundred potential candidates were considered and 35 candidates were invited to participate in SIGs.

The composition of the SIGs was aligned with the project's goals to include perspectives from academia, industry, and different committees and associations, ensuring that the insights gathered would be applicable across different sectors. Each SIG was designed to include up to 15 members, chosen to reflect a balance across various stages of the innovation process, technology specializations, the different drivers influencing licensing decisions, as well as gender diversity, representation from all segments of the quadruple helix, a broad spectrum of experiences, and geographic distribution. This diversity was crucial for capturing insights to inform the development and testing of the ToolBox.

Each SIG was responsible for supporting the identification and mapping of processes and intervention points relevant to their assigned scenario. Group and one to one meetings were held to gather information and solicit feedback on project direction.

Recognising the significant contribution of SIG members, an honorarium was offered as a token of appreciation for their time and expertise. This not only helped secure well-known experts but also underscored the importance of their role in shaping the project’s outcomes.

2. Collection of Examples and Illustrative Materials

Examples and illustrative materials were collected and organised to provide a definition for each of the 3 primary scenarios: Classical, Crisis, and Co-Creation. The definition of each scenario can be found at the beginning of the relevant sub-section.

The collection process involved a thorough situational analysis of existing licensing cases across diverse sectors and jurisdictions. The primary aim was to gather a representative set of examples that could illustrate the key elements of each scenario, including the main players involved, the types of intellectual property rights (IPR) and assets at play, and the desired outcomes of the licensing agreements.

The source of potential examples included the SIG members’ work experience, the consortium members’ experience, as well as internet searches of publicly available online information.

The collected examples were deconstructed using a purposely designed canvas. All important factors were separated into specific fields. The canvases were systematically organised into Excel tables to create a comprehensive database that could be used to define and refine the scenarios.

These materials served as the basis for identifying key intervention points in the licensing process, which would later inform the development of tools and methodologies under WP4.

By grounding the scenarios in real-world examples, the project ensures that the tools and frameworks developed are both practical and adaptable, capable of addressing the diverse challenges encountered in different licensing contexts.

3. Mapping of Processes and Intervention Points

The goal was to pinpoint the most important steps where specific tools could effectively intervene to facilitate better outcomes. The examples were analysed with the support in the licensing of their 'owners' – SIG members or companies and organisations involved in licensing process.

An important aspect of this task was defining the boundary conditions for each scenario. These were identified for each example to ensure that the scenarios could be accurately contextualised and that the tools developed would be applicable across different licensing situations.

The mapping process began with a comprehensive analysis of the innovation-to-licensing pathway within each scenario. This involved breaking down the entire process into distinct stages - from the initial development of IP to the final execution of a licensing agreement and identifying where an intervention could enhance results.

For each stage identified as important, the key activities were highlighted, and the main questions relevant to the stage were identified.

Identification of Intervention Points: A key objective of this task was to identify intervention points - specific moments within the licensing process where a tool could significantly enhance efficiency, resolve potential conflicts, or better align outcomes with stakeholder goals.

Evidence-Based Approach: All the research was based on real examples, and in the process of the scenario map development, every example of non-classical licensing was decomposed into all the stages outlined on the map. All challenges were matched with potential intervention points, and the intervention points relevant to the examples collected were reflected on the map along with the tools that could improve the licensing process in each case.

The outcome of the mapping process was a series of process maps for each scenario, visually representing the key stages, intervention points, and potential tools. These maps serve as foundational tools for the project, guiding the development of specific tools and methodologies designed to improve licensing outcomes.

- **Tool Development Guidance**: The process maps were instrumental in informing the development of tools and the structure of the ToolBox. By clearly outlining where interventions are most needed, the maps ensure that the tools created are relevant and effective in addressing the identified challenges.
- **Customisation for Scenarios**: Each scenario map was tailored to reflect its unique characteristics and challenges, ensuring that the tools developed are scenario-specific and capable of addressing the particular needs of Classical, Crisis, and Co-Creation licensing environments. When interconnections between scenarios were identified, the elements of the example relevant for each scenario were reflected on the corresponding map.

In summary, the mapping of processes and intervention points provided a structured and systematic approach to understanding the licensing pathways within each scenario. By identifying where and how tools can best intervene, this task has laid the groundwork for developing practical solutions that can enhance the efficiency and effectiveness of licensing across various contexts.

All the analysed examples can be found in Annex 1 and Case Studies can be found in Deliverable 2.3.

3. Classical Plus Scenario

3.1. Introduction to and definition of the Classical Plus Scenario

Licensing of technology has classically been undertaken for economic gain and with an emphasis on patent rights. There has also been a focus on exclusive licenses to create a premium on royalties and investing strongly in resources to negotiate and secure a deal for research results from STEM disciplines (Science, Technology, Engineering, Maths) with the highest economic value.

In recent years many EU MS (Member States) have started to emphasis the wider 'impact' that can come from technology transfer e.g. benefit for society and the environment. This has been reflected in new metrics used to assess and award funding to PROs (Public Research Organisations) and other not-for profit (NFP) organisations (museums, charities, health-care providers). As a result, more NFP organisations have started to address impact in their Mission. Research funding organisations, including the EC, have also started to emphasise the importance of creating impact from their funded projects. This has resulted in a wider range of research results entering the knowledge transfer pipeline and a broader base of IP 'assets' coming to the attention of Technology Transfer Offices (TTOs), in particular, more results from the Arts, Humanities and Social Sciences (AHSS) which are covered by copyrights and of interest to a large number of users. This is creating a market for 'low value, high volume' licensing activities or 'long tail' licensing when one very low value asset is licensed at a low level but over a significant time-frame.

Replacement of economic gain with wider impact has called for new business models for licensing to make them viable and sustainable. For example, a classical approach based on seeking an exclusive license for a patent protected drug candidate will not work for the copyright associated with the **Errore. L'argomento parametro è sconosciuto.** that are frequently a by-product of the associated research project e.g. a canine questionnaire designed to help dog owners and vets to interpret the behaviour of thousands of dogs or dietary behaviours associated with understanding and treating eating disorders.

Modern **Errore. L'argomento parametro è sconosciuto.**, incorporating multi-media content, will be covered by copyrights and can also use low price CC (Creative Commons) licenses when end benefit and impact are of higher priority than revenue generation and the underlying business model will struggle to identify a clear source for commercial funding. For example, when helping to build capacity in home carers, reduce risky behaviour towards drug taking in the teen years, improve English Grammar in school work and reduce bullying in schools. However, to simply cover the costs of the associated marketing and licensing activity, freemium models may have to be used and/ or a very large number of low value users will have to be secured and their eligibility checked and approved and their activities monitored. This calls for more automation in licensing but may require a research team to be more involved in making informed choices when approving a license application. Registration and downloads can also raise issues of IT security for a PRO.

Classical commercial copyright licensing of the sort used for software is also not readily applicable to many **Errore. L'argomento parametro è sconosciuto.** including **Digital Heritage Libraries** where copyright of an original photograph has expired but ownership of a collection of images is held by a Library or Museum who is interested sharing the collection widely under a creative commons (CC) license provided there is attribution (BY) with some rights retained for commercial use (CY) to help them recover the costs of digitisation and curation. A similar but slightly different approach needs to be taken with **new databases** where materials are still under copyright e.g. mapping information useful for navigation or plant and animal identification using AI. In this case, a CC license may still be used but extensive due diligence and 'rights clearance' will be needed before they can be offered for wider use. Access to other databases e.g. those with very large numbers and sizes of data-sets designed to help

support medical research may also need to reflect both academic and commercial users in the licensing terms and conditions.

In short, 'Classical Plus' licensing – licensing that goes beyond traditional or 'Classical' norms - is becoming increasingly important to PROs, charities and other NFP organisations, their funders and policy makers. Surveys and questionnaires from AHSS that are covered by copyright and have a value to both individual users and commercial companies are an increasing output of research projects; digitisation of objectives is creating a new type of assets with high potential for extensive 'sharing'; multi-media is forming the basis for training and teaching materials that can be distributed online and there has been an explosion in the amount of data that can be used for medical research.

This is broadening the base of IP assets that need to be transferred for wider impact and calls for new tools and techniques to help those who create the assets and those who manage their dissemination to address new intervention points and find viable business models to enable sustainable licensing activity.

This situation is analysed in the real life examples that can be found in Annex 1. Some of these have been lightly or fully anonymised at the request of the contributing party.

3.2. Conclusions and emerging recommendations for Classical Plus tool-kit development

The analysed Classical Plus examples (See Annex 1 Section 1.1) suggest that there are three main interventions points where tools would be useful:

1. Early in the process: Identifying potentially licensable assets by raising awareness of valorisation potential.

Many researchers from the AHSS sector still not do consider valorisation of their research results. They view valorisation narrowly as Technology Transfer with the focus on commercialisation for high-value economic gain. This situation is exacerbated by many traditional TTOs that are focused on sale or licensing of high-value IPR. Raising early awareness helps ensure researchers recognise opportunities to protect and share their innovations effectively.

2. During the process of Opportunity Definition – Including when identifying sustainable business models e.g. those not driven by or dependent on the direct financial value of an individual asset

Many examples highlight not only the issue of a sustainable business model but also one that aligns with the mission of NFPs or PROs. In many instances, traditional business models were not well suited to commercialisation, which hampered the exploitation of valuable research outcomes. For example, home-care e-learning modules created under FH Campus Wien faced challenges in determining a sustainable payment model for users who were unlikely to bear the full cost themselves. As a result, licensing efforts often required external sponsorship. A "Freemium" model, where basic services are offered for free, with premium content available at a cost might be a powerful solution for such cases.

3. License execution – Automating the licensing and setting up any necessary approvals.

Automation of licensing, as seen in the case of the VRGS (Virtual Reality Geological Studio) software, can prove beneficial for low-value, high-volume assets. Automating licensing processes reduces administrative costs and validates market demand, supporting the development of spin-off companies without significant upfront investment. This model, however, requires clear auditing and assignment of IP rights, which were often problematic in multi-author scenarios.

The following tools are suggested for development by IMPAC3T-IP in Year 2.

Table 1 List of Potential Tools relevant to the Classical Plus scenario

Tool	Stage	TYPE	Purpose	Target user
Guidelines				
Guidelines on Copyright Ownership (context of Academic Publishing)	1	Questionnaires / Assessment tools		Tech Transfer Office, Individual Researchers
Guidelines on Creative Common Licensing	2	Copyrights		Tech Transfer Office, Individual Researchers, R&D and Liaison Departments
Guidelines on Rights Clearance and Ownership in Consortium Projects	1	All types of intangible assets (IA) and rights		Policy Makers and Civil Society, University Innovation departments, R&D and Liaison Departments
Guidelines on Transferring IP Copyrighted Assets to a Company	3	Copyrights	Clarify, access mechanism, costs and financing and derivative works.	Tech Transfer Office, Individual Researchers
Guidelines on Sustainable business models in Community Educative Projects	1	All types of IA and rights	To provide examples of sustainable community education projects	Tech Transfer Office, Individual Researchers, Policy Makers and Civil Society, University Innovation departments
Guidelines on Freemium Model	2			Tech Transfer Office, University Innovation departments, R&D and Liaison Departments.
Checklist/ guidelines for non-classical assets licensing	1-2	Research Outputs of Community Projects.	To assess commercial and non-commercial licensing possibilities.	Tech Transfer Office, Community Councils
Guidelines on Scaling, Marketing and Valorising Copyrighted IP Assets.	2	Biobanks, Other Databases		Tech Transfer Office, R&D Departments, Public Institutions
Guidelines on possible semi-commercial models	1-2	Biobanks, Other Databases, SSH assets and rights		Tech Transfer Office, R&D Departments, Public Institutions

Checklist for internal stakeholder consultation process	1	All types of IA and rights		Tech Transfer Office, R&D Departments, Public Institutions
Case Studies on Pricing Models for Database Access	1-2	Biobanks, Other Databases, SSH assets and rights		Tech Transfer Office, R&D Departments, Public Institutions
Repository of IMPACT Stories	1	All types of IA and rights		Public at large
Guideline for Consideration for AI licensing	1	Databases, software		Tech Transfer Office, Individual Researchers
Guidelines and considerations for Open Science (disclosure rules, open access rules)	1-2	All types of IA and rights	Understand limits of disclosure, IP protection and commercialising aspects.	Tech Transfer Office, Individual Researchers
Software				
License Template Generator (Copyright Clauses, Derivative Work Clauses, Warranties, Liability Clauses)	2-3	Databases, software, copyrights, questionaries, assessment tools		Tech Transfer Office, University Innovation departments, Parents, Teachers, Schools
Volume Licensing Tool	2-3	Databases, software, copyrights, questionaries, assessment tools		Tech Transfer Office, R&D Departments, Public Institutions, University Innovation departments
Smart Disclosure Forms	1-2	Databases, software, copyrights, questionaries, assessment tools		Tech Transfer Office, R&D Departments, Public Institutions, University Innovation departments

3.3. Classical Plus biography

Finland – most advanced ecosystem for healthcare innovations, Nora Kaarela, Invest in Finland, Business Finland 2019

4. Co-Creation Scenario

4.1. Introduction to and definition of the Co-Creation Scenario

4.1.1. Definition

Co-creation represents a significant shift in the approach to innovation, moving away from traditional top-down, organisation-centric models to more inclusive, participatory approaches. In this model, the lines between producers and consumers, creators and users, are blurred. Organisations collaborate with various stakeholders, such as users, customers, employees, partners, and communities, to create value collectively. Co-creation allows for the active involvement of stakeholders in the creation process, contrasting with traditional business models where value is created by companies and consumed by customers. By unlocking collective potential, co-creation fosters more innovative, valuable, and relevant results for all parties involved.

Co-creation encompasses a broad range of stakeholders, including not only end-users but also partners and employees. While not all co-creation efforts are guaranteed to succeed, they provide valuable opportunities for fresh perspectives and idea generation. Co-creation is now defined as the active involvement of various stakeholders throughout the production process, aiming to unlock collective potential for innovative, relevant, and valuable results for all participants.

4.1.2. Characteristics of co-creation today

Co-creation is driven by various motivations depending on the context and stakeholders involved, typically linked to innovation, engagement, and competitive advantage.

Companies use co-creation for customer-centric innovation by involving stakeholders directly in the design or development processes to ensure that products and services meet user needs. The personalization of experiences and products through stakeholder engagement allows companies to create more relevant offerings. Additionally, co-creation fosters innovation by inviting diverse perspectives from various stakeholders, including employees, customers, and partners. This collaboration can generate novel solutions that might not arise from internal efforts alone. Co-creation also helps organisations to crowdsource solutions for complex challenges, tapping into broader creative resources. Stakeholder involvement in co-creation strengthens engagement and loyalty. By creating emotional connections and building communities around their brand, organisations foster a sense of ownership among customers and stakeholders, leading to increased advocacy and loyalty. This connection often provides a competitive edge, allowing organisations to differentiate themselves in the market with products tailored to specific audiences.

Furthermore, co-creation can reduce development costs by integrating external resources and feedback early in the process, avoiding costly errors and accelerating time-to-market. Real-world feedback gained during co-creation ensures higher-quality outcomes, as potential issues can be addressed early on. Beyond product development, co-creation can address societal challenges. Organisations collaborate with stakeholders to co-create solutions that align with sustainability and corporate social responsibility (CSR) goals, addressing environmental, social, and ethical issues.

Internally, co-creation improves organizational culture and collaboration. Engaging employees in decision-making processes fosters a more dynamic and innovative environment, while cross-departmental collaboration helps break down silos, leading to greater innovation. Co-creation builds trust and transparency between organisations and their stakeholders by inviting them to contribute to decision-making processes. This openness enhances trust and accountability. Additionally, co-creation

helps organisations navigate market disruptions and adapt to rapid industry changes by leveraging external input to remain agile and innovative.

Co-creation today reflects modern trends in technology, business, and society. It emphasizes collaboration with a range of stakeholders, including customers, employees, and partners, and focuses on innovation, engagement, and shared value creation. Co-creation provides organisations with tools to enhance competitiveness, foster loyalty, and address both economic and societal challenges.

4.1.3. Licensing insights

This situation is illustrated by the real life mapped and analysed examples that can be found in Annex 1. Most of these have been lightly or fully anonymised at the request of the contributing party. The mapping and analysis include outcomes, an indication where possible of specific licensing terms, lessons learned and possible intervention points and 'tools' to support others in the future.

4.2. Conclusions and emerging recommendations for Co-creation tool-kit development

The various examples (See Annex 1 Section 1.2) demonstrate that addressing IP issues in co-creation requires proactive strategies and clear legal frameworks. Before entering co-creation projects, it is essential to draft comprehensive agreements that outline ownership, profit-sharing, confidentiality, and dispute resolution mechanisms. These agreements should be tailored to the specific nature of the collaboration and the jurisdictions involved. Licensing models should be implemented where contributors can license their IP to the company in exchange for royalties or other forms of compensation. This approach ensures that contributors are rewarded while the company retains the rights to commercialise the IP. Regular communication with all stakeholders about the importance of IP protection and the specifics of the agreements in place can help prevent misunderstandings and foster a collaborative atmosphere based on trust.

While corporations are the most visible entities involved in co-creation, they are not the only ones participating in or driving co-creation activities. Co-creation can and does occur across various sectors and organizational types, but corporations often dominate the conversation due to their resources, visibility, and access to large-scale platforms.

Corporations have the financial, technological, and operational capacity to implement co-created ideas on a large scale. They can invest in research and development (R&D), build platforms for customer engagement, and deploy co-created innovations in the market. Smaller organisations, non-profits, or individuals may not have the same level of resources to fund or scale co-creation initiatives.

Corporations have been able to establish well-defined co-creation processes and platforms, making it easier for external innovators, customers, and partners to participate. Smaller organisations may not have the resources to create and manage such large-scale co-creation platforms. Co-creation often involves complex intellectual property (IP) issues, including the transfer of ownership or licensing of ideas. Corporations have established legal teams and frameworks to manage these IP challenges, allowing them to negotiate and acquire IP from external partners, customers, or collaborators more efficiently. Smaller entities may not have the same level of expertise or resources to navigate these complexities, making co-creation harder to implement.

For a successful co-creation project, businesses need to build a strong relationship with their community. Customers need to trust that their contributions will be valued, and creators need to believe that their ideas will be handled fairly. Small businesses, especially newer ones, may face difficulties in building this trust and credibility in the early stages, as they don't have the established brand reputation that larger corporations do. Without a history of successful projects or widespread brand recognition, small businesses might struggle to convince participants that their ideas will be properly evaluated and potentially rewarded. Participants might be concerned that their ideas will be used without proper credit or compensation, making them hesitant to contribute to small businesses with less formalized processes or legal protections.

Managing intellectual property rights (IPR) is crucial in any co-creation project, as contributors may generate ideas that need to be protected. Deciding who owns the ideas or innovations generated during the co-creation process can be legally complex. Small businesses might not have the resources to handle these negotiations or to protect the IP. To avoid disputes, it’s important to have clear agreements in place with participants about how ideas will be used, who will own them, and how contributors will be compensated. Small businesses may lack the legal expertise to draft these contracts effectively.

4.2.1. The importance of engagement level

When evaluating the suitability of methods and tools that support co-creation, it is important to consider the requirements of different types of co-creation models for tools. One such model that characterises co-creation is to look at the engagement level of co-creators. Co-creation can be classified at one of three different levels:

1. **Low-level engagement**: Submitting an idea, feedback or other contribution without a refining process or two-way interaction. The co-creator may not even be aware that she/he is part of the co-creation process.

2. **Middle-level engagement**: Participation in a predefined co-creation session, which can be a workshop, group work or testing event.

3. **High-level engagement**: Active involvement in product or service design and development. The co-creator is involved in several interaction points and the work is iterative in nature. The contribution is clearly verifiable and measurable.

The higher the level of engagement, the more significant the role IP plays. In this case, the tools must also answer the more demanding IP questions in advance. When co-reactors are clearly aware that they are part of value creation and the creation of new IP, they are also more demanding in terms of IP policy and rights. High engagement level co-creation has a recognisable life cycle and stages, so it also contains more intervention points. Accordingly, low-engagement co-creation can consist of only one intervention point: Submitting feedback to a co-creation platform and accepting the terms.

4.2.2. Intervention points

A comprehensive review of intervention points based on the analysed examples and case studies reveals patterns that highlight critical phases and "moments of truth" where targeted interventions can significantly influence the success of co-creation activities. These intervention points cover the full lifecycle of co-creation, from preparation and engagement to post-project exploitation and long-term partnerships. This structured analysis aims to uncover common challenges and provide actionable insights to optimise co-creation efforts.

Co-creation projects typically follow a clear lifecycle that includes preparatory stages, active engagement, ongoing IP management, and post-project exploitation. Each phase has critical "moments of truth," such as setting IP agreements early, managing customer engagement, conducting regular IP audits, and negotiating licensing agreements. Addressing these intervention points effectively leads to smoother collaboration, greater innovation output, and more sustainable partnerships.

These intervention points can be grouped into distinct phases that reflect critical "moments of truth" where effective intervention is essential for successful outcomes. The five identified phases are:

1. Pre-co-creation phase (Preparation)

Defining the scope and focus of co-creation, setting clear IP rights, forming partnerships, and establishing agreements before co-creation begins. This phase is critical to avoid misunderstandings and conflicts later. Clear agreements on IP, licensing, and responsibilities form the foundation of the co-creation effort.

Intervention Points:

- "Defining IP Rights Early"
- "Contractual model before co-creation activities start"
- "Agreeing on access conditions for results at the beginning"
- "Licensing Decision (Before Project)"

2. Co-creation and engagement phase (Collaboration)

Launching the co-creation process, managing background material, managing submissions or inputs, and ensuring ongoing engagement and transparency among contributors. Phase focuses on active participation, engagement, and managing the co-creation process. Effective communication and transparent IP agreements during this phase are crucial for maintaining trust.

Intervention Points:

- "Launching the co-creation activities"
- "When the customer submits an idea or other contribution"
- "Co-creation focus and scope defining"
- "Co-creation engagement and facilitation"

3. IP and Knowledge Management During Co-Creation (IP management and Governance)

Ongoing IP audits, tracking contributions, and managing licensing issues throughout the project. Ensuring transparency in IP ownership and knowledge transfer during the co-creation process is essential for fostering collaboration and preventing future conflicts.

Intervention Points:

- "IP Auditing and Transparency (During Development)"
- "Regular Reviews of Design Evolution"
- "Tracking of emerging results and fair pricing"
- "Knowledge transform during and after co-creation"

4. Post-Co-Creation Evaluation and Exploitation Phase (Exploitation and commercialisation)

Evaluating co-created solutions, identifying IP to protect, negotiating licenses, and supporting the transition to commercialisation or further development. This phase involves decisions on how to exploit the results of the co-creation process, including IP protection, licensing, and investment in future development.

Intervention Points:

- "Protecting or Patenting Decision (Post-Project)"
- "Exclusive Licensing and Pricing (Post-Project)"
- "Investments on further development"
- "Post-Project Feedback (After Licensing)"

5. Long-Term Partnerships and co-development (strategic cooperation and joint value-creation)

Identifying joint ventures, supporting their establishment, and ensuring sustained collaboration after the co-creation project. Long-term collaboration opportunities (e.g., joint ventures) are key for sustaining and scaling the outcomes of co-creation projects. Early identification and support for joint ventures can ease the transition from project to commercialisation.

Intervention Points:

- “Joint Venture Anticipation"
- "Support for Establishment"

4.2.3. Identification of key issues and requirements to be addressed by tools

By examining multiple examples and case studies, we have identified the core requirements and issues that frequently arise in co-creation environments. These insights are crucial for developing tools that not only enhance efficiency and transparency but also ensure fairness and innovation.

The analysis identifies two sets of requirements: "must-have" tools, which are critical to ensuring the smooth running of a co-creation project, and "nice-to-have" tools, which add value but are not essential. Furthermore, the potential tools have been grouped according to the phases of the co-creation process: preparation, collaboration, governance, IP management, and commercialisation.

Across the case studies, a total of **16 key requirements** and **12 recurring issues** were identified. These highlight the critical needs for successful co-creation:

- **Must-have requirements**: These primarily focus on tools for transparent IP tracking, global collaboration platforms, and governance frameworks. For instance, open-source contribution tracking and IP licensing systems are essential to ensure fair distribution of rights and responsibilities.
- **Nice-to-have requirements**: These include tools like incentive and reward systems for contributors, and mentoring support for start-up commercialisation, which help enhance the overall effectiveness and fairness of the co-creation process.

The recurring issues mainly revolve around **IP ownership**, ensuring **fair recognition** of contributions, and **effective governance**. These challenges drive the need for tools that promote transparency, fairness, and efficiency.

4.2.4. Tool Development overview

This analysis compiles and reviews a set of **40 tool ideas** from the examination of multiple co-creation case studies. The tools have been categorized across **5 key phases** of co-creation

1. Co-creation knowledge and preparation
2. Collaboration
3. Governance
4. IP Management
5. Exploitation & Commercialisation

This categorization based on the phases of the co-creation process, allows for a more strategic approach to development and deployment. Tools for preparation and agreement, such as IP trackers and agreement models, are foundational, ensuring that clear guidelines are established from the outset. During the co-creation phase, collaboration platforms and governance tools become essential, enabling smooth coordination and quality management.

As the project progresses into the IP management and commercialisation stages, tools that support auditing, contribution tracking, and commercialisation route evaluation come into play. These tools ensure that IP is properly managed and that the most efficient and viable commercialisation paths are chosen. Additionally, tools that provide recognition and incentive systems help maintain motivation and fairness, especially for open-source contributors and external partners.

Table 2 Tool idea evaluation for the phase: Co-creation knowledge and preparation

Tool Idea	**Description**	**Main source (Example No.)**	**Justification for further development**	**Argument against further development**
Agreement Model Selection Tool	A tool to help co-creators choose the appropriate agreement model based on the nature of their project and expected contribution.	E1/E2	The models are still undeveloped and unestablished, and there are still no standard solutions.	
Agreement Templates	Ready-to-use contract templates tailored for co-creation projects.	E1	Enables wider utilisation of co-creation	
Guide for Co-Creation Participants	A comprehensive guide to help (new) participants understand the principles of co-creation, IP management, and negotiation strategies to ensure fair and transparent collaboration.	E1	The level of co-creation competence and management capabilities is low	

Phase: Collaboration

Tool Idea	Description	Main source	Justification for further development	Argument against further development
Contribution Tracking System	A system that tracks individual contributions, ensuring that all co-creators are properly credited for their ideas and efforts, especially when IP is involved.	E4	Bring a solution to one of co-creation's most significant problem	
Communication Tracker for IP:	A tool for clearly documenting the source of materials, ensuring that teams mark whether content is original, licensed, or borrowed from 3rd-party sources.	E5	Mixing background material and external IP with the IP being created is a risk	Could be solved using the Contribution tracking system
Trust-Building Workshop Tool:	A facilitation guide for conducting workshops aimed at enhancing trust and collaboration within project teams.	E6		There is no co-creation specific problem to solve
Mentoring and coaching Support System:	A structured feedback tool that connects co-creators with seasoned professionals to build their confidence and guide start-up paths.	E7		Is relevant, but not in the context of co-creation and IP
Community Engagement Dashboard:	Tracks customer involvement and engagement metrics to help optimize the platform's effectiveness.	E8		Could be solved using the Contribution tracking system
Customer Innovation Management System:	A platform for managing the submission, voting, and selection of customer-generated ideas.	E8		Too generic an idea in the context of co-creation

Collaborative Research Platform:	Facilitates communication, data sharing, and project management between external partners and the company.	E9	A relevant use case related to the contribution tracking system	Could be solved using the Contribution tracking system
IP Contribution Management Tool:	Helps track and manage the individual contributions of external collaborators in shared IP projects.	E9	A relevant use case related to the contribution tracking system	Could be solved using the Contribution tracking system
Global Collaboration Platform:	Facilitates real-time collaboration and knowledge sharing for open-source or public-sector co-creation initiatives.	E10	The need for solutions that enable the involvement of broad user groups (consumers, citizens, city residents, etc.) under the co-creation contract model.	It should be specifically limited to the context of co-creation, and there should be no overlap with crowdsourcing platforms.
Open-Source Contribution Tracker	Tracks individual contributions in open-source projects and ensures compliance with open-source licenses.	E10		Open-Source specific.

Table 3 Tool idea evaluation for the phase: Governance

Tool Idea	**Description**	**Main source**	**Justification for further development**	**Argument against further development**
Rights Management Database	A system to track and manage IP rights, ensuring clarity on ownership and licensing terms for all parties involved.	E1	Master data (a comprehensive record of who owns what) is needed for all applications.	

IP and Rights Tracking Database:	A platform that tracks IP ownership, created results, and licensing agreements. This ensures that all stakeholders can see and validate who contributed what and how IP is being used.	E2	Solves the life-cycle related problem in context of dynamic co-creation processes with multiple contributors	Extension of rights management database
Recruitment Impact Tracking Tool:	A tool designed to monitor how recruitment decisions are made in post-co-creation phase to prevent misuse of hiring to bypass IP negotiations, conditions or obligations.	E2		Can be resolved with a code of conduct or other agreements.
Confidentiality and Data Protection Dashboard	A tool for managing and enforcing NDAs within the consortium, ensuring that sensitive research data, and end-user feedback, are handled and protected throughout the co-creation process.	E3		Is relevant, but not in the context of co-creation and IP.
Feedback vs. Innovation Tracker	A system that categorizes end-user contributions, distinguishing between usability feedback and innovative ideas that may have IP implications. This helps in recognizing valuable inputs that may influence the product's design, features or functionality.	E3		Could be solved using the global platform or the contribution tracking system
IP Management Platform for Consortiums:	A tool designed for consortium-type projects, enabling partners to track contributions from academia, industry, and end-users. It would integrate confidential information sharing and	E3	A meaningful context (consortia), where the different backgrounds and positions of actors bring challenges to	Could be partly solved using the contribution tracking system

	track ideas as they develop into potential IP asset, like product features.		co-creation activities	
IP Rights and Obligations Tracker:	A system for maintaining ongoing records of IP rights, responsibilities, and agreements among project partners.	E6		Main problems could be solved using the contribution tracking system
Governance and Integrity Management Tool:	Helps maintain the integrity of open-source projects by ensuring quality control and community-driven governance	E10		Open source specific problems.

Table 4 Tool idea evaluation for the phase: IP Management

Tool Idea	**Description**	**Main source**	**Justification for further development**	**Argument against further development**
Competence and Outcome Evaluation Tool	A tool to assess the indirect benefits of the co-creation process, including competence development, risk mitigation, and technological test and validations.	E2		Main problems could be solved using the contribution tracking system
End-User Contribution Recognition Tool	This tool tracks transparently tracks contributions made by end-users and ensures fair compensation, if those contributions lead to innovation. It could integrate royalty agreements or other incentive mechanisms if innovations from end-	E3		Could be part of the global platform or contribution tracking system

	users become part of the final product.			
IP Mapping Tool	A tool to map the different aspects of project results, helping stakeholders to identify which parts can be patented and which parts should remain open for use by the other stakeholders.	E4	A very relevant problem in the context of co-creation	
Patent Decision Support Tool	A system that helps companies or stakeholders decide which parts of the solution to patent, and whether they need exclusive or non-exclusive rights.	E4		Patenting focused approach. The problem could be solved by IP mapping, and/or IP tracking tool.
IP Auditing Tool	A system that regularly checks the IP used throughout the project, highlighting any potential issues related to 3rd-party IP, content or ownership.	E5	A verified issue related to the use of background material. Violation prevention.	
IP Ownership and Risk Assessment Tool	A framework that guides teams through evaluating potential IP risks before project outcomes are commercialised.	E5		Could be partly solved using the IP auditing tool or IP and Rights Tracking Database
Licensing Decision Tool	A guide that assists teams and partners in navigating licensing agreements, ensuring clarity on rights and responsibilities for all parties involved.	E5		Can be solved by skill development
Results Evaluation and IP Mapping Tool:	A post-project tool to track the long-term usage of the co-creation outputs and ensure that IP issues	E5	A problem that prevents and limits the use of co-creation methods. Risk avoidance	Partly overlapping with IP and Rights Tracking Database

	are resolved during the implementation phase.		reduces the use of co-creation.	
IP Licensing and Ownership Tracker:	Tracks IP ownership, licensing agreements, and ensures proper usage rights.	E9	A significant problem that affects the life cycle of the IP	Partly overlapping with IP and Rights Tracking Database

Table 5 Tool idea evaluation for the phase: Exploitation & Commercialisation

Tool Idea	**Description**	**Main source**	**Justification for further development**	**Argument against further development**
Joint Venture Planning Toolkit:	A set of resources designed to guide teams through the process of establishing a joint venture, including templates and best practices.	E6		Relevant, but out of co-creation scope
Market Opportunity Evaluation Tool:	A tool that helps teams assess and prioritize potential commercial routes for their innovations based on market needs.	E6		A significant but overly generic problem. Not specifically a co-creation / IP problem
Technology Transfer Framework:	A structured approach that outlines the steps for effective technology transfer between industries, ensuring alignment and clarity.	E6		Traditional tech transfer issue, not co-creation specific
Agile Route Evaluation Tool:	A framework to evaluate different commercialisation routes (internal vs. start-up) and recommend the most efficient one based on project specifics.	E7	Competence related issue. Reformulated as: Exploitation & Commercialisation Planning tool	Too broad

Start-up Commercialisation Agreement Tool:	A tool to create and manage agreements that facilitate the transition of co-creation project results into start-ups while ensuring fair IP management.	E7	A significant problem that slows down the commercialisation of IP generated by co-creation	
IP Transfer and Compensation Tracker:	Monitors the transfer of IP and the corresponding royalties or compensations.	E8	Removes obstacles to using the co-creation method also in more critical product development activities.	

In the following, based on this evaluation, we suggest the three most significant tools for each co-creation phase. The proposed tools are shown in Table 6 below.

Table 6 List of Potential Tools relevant to the Co-creation scenario

Stage	**Possible tools**
Co-creation knowledge and preparation	Co-creation knowledge development: knowledge packages, courses and training Agreement Model Selection Tool Agreement templates
Collaboration	Global Collaboration Platform Contribution Tracking System Co-creator matchmaking tool
Governance	Agreement database IP and Rights Tracking Database Consortium management tools
IP Management	IP Licensing and Ownership Tracker IP Mapping Tool IP Auditing Tool
Exploitation & Commercialisation	Compensation and Royalty Tracker Commercialisation Agreement Tool Exploitation & Commercialisation Planning tool

4.3. Co-creation biography

"Testing the feasibility of a new industry-academia knowledge exchange concept focusing on companies' needs", European Commission, Directorate-General for Research and Innovation, Prosperity Directorate, Brussels, Final report, 2021.

5. Crisis Scenario

5.1. Introduction to and definition of the 'Crisis' Scenarios

Crisis scenarios involving licensing can be separated into 2 main classes: **unforeseen** (UC) and requiring **immediate action** and **foreseen** and **preventable** (PC) through **advanced planned action**. The global COVID-19 pandemic is an example of the first when there was an acute need for rapid licensing of new technologies including ventilation and continuous positive airway pressure (CPAP) devices such as the UCL and Mercedes Ventura breathing aid and the Isinnova Charlotte valve used in conjunction with diving masks, new vaccines, e.g. Vaxzevria from AstraZeneca/Oxford and Comirnaty from Pfizer/BioNTech and medicines to stop symptoms from getting worse such as Remdesivir. This need for rapid and wider access to technology led to temporary waivers of intellectual property rights and royalties, reflected in both voluntary and compulsory IPR licensing. UC is probably the 'scenario' that comes most readily and rapidly to mind in Western Europe and other High-Income countries (HIC) such as the USA when the term 'crisis' is used in relation to technology licensing.

Awareness of the steps being taken to support the second scenario of PC (Preventable Crisis) is lower in Europe amongst policy makers, researchers and civil society. This is primarily because preventable crises are largely prevalent in LMIC (Lower- and Middle-Income Countries) where nearly 2 billion people have no access to basic medicines[1] and receive far less attention in northern hemisphere and western HIC. An example is the AIDS 'crisis' which peaked in the west in the 1990s but which is now largely under control in HIC due to the availability and affordability of antiretroviral drugs. The same situation is not true for LMIC: in 2020 more than 80% of people living with HIV (PLHIV) lived in LMICs and it is estimated that only 47% of adults and 23% of children who are eligible are accessing treatment. The uneven global distribution of COVID vaccines between HIC and LMIC is also leading to preventable crises with the wealthiest nations having received more than 87% of the vaccines while LMICs just 0.2%[2].

PC is also seen in natural disasters (ND) such as a tsunami, flood, earthquake and similar catastrophes. In recent years, the focus for IP licensing for ND has been on risk reduction and impact mitigation by prediction and contingency planning using mature technology e.g. using remote sensing, radars, and satellite imaging for early detection. However, licensing for ND risk mitigation is seen to be a mature field that has not revealed any particular barriers that would merit a new licensing tool.

Both sub-scenarios, UC and PC have intervention points to support increased licensing of technology and these are outlined below. In some cases Lessons Learned under COVID 19 have been shown to be applicable to preventative crisis.

The PC in LMIC scenario has been identified as one where the IMPAC3T-IP project is most likely to be able to offer support leading to sustainable impact. Both sub-scenarios are outlined below with an indication of current status of activities and how IMPAC3T-IP could usefully contribute.

5.1.1. Unforeseen Crisis

Unforeseen crisis situations include medical emergencies such as a global pandemic or a natural disaster (ND) such as a tsunami, flood, earthquake and similar catastrophes. In such times there can be

[1] WHO 2017 Ten years in Public Health https://cdn.who.int/media/docs/default-source/essential-medicines/fair-price/chapter-medicines.pdf?sfvrsn=adcffc8f_4&download=true

[2] Peacocke EF, Heupink LF, Frønsdal K, et al Global access to COVID-19 vaccines: a scoping review of factors that may influence equitable access for low and middle-income countries BMJ Open 2021;11:e049505. doi: 10.1136/bmjopen-2021-049505

an acute and pressing need to make IP protected technology available very rapidly to alleviate the situation. This may be fully mature technology that is already being used or it may be technology that is developed in response to the situation. In both cases, the technology will need regulatory approval for use by an official organisation, e.g. the EMA in Europe, and be manufactured to stringent standards e.g. ISO9001 and associated ISO medical standards.

A number of barriers to access technology in times of unforeseen crisis have been previously identified[3] including lack of manufacturing capacity for vital medical supplies or equipment. However, this project and ToolBox focuses on barriers that can be addressed through licensing of IP assets and rights. Other barriers are beyond the scope of the project.

Several issues need to be considered when making technology available under license in times of unforeseen crisis. These are outlined below and then explained in more detail through specific examples.

IP Rights and assets

The type of asset/ right to be licensed is typically under patent protection. Know-how can also play an important role - see compulsory licensing below.

Policy and legislative framework

Policy on access to IP during times of UC has focused on two main aspects: Compulsory Licensing (CL) and Voluntary licensing (VL).

Compulsory Licensing

CL of patents allows a government to authorise the use of a patent by a third party, without the consent of the patent right holder, subject to conditions aimed at preserving the interests of the patent holder.

The associated international legal obligations are laid out in the TRIPS Agreement (Agreement on Trade-Related Aspects of Intellectual Property Rights). TRIPS explicitly allows compulsory licensing under certain licensing conditions; these include limited duration and the payment of 'adequate' remuneration. The first type of compulsory licensing scheme is for the domestic market, (Article 31 TRIPS), which applies to all types of products. The second scheme is compulsory licensing for export, (Article 31*bis* TRIPS), which only applies to pharmaceutical products. The EU implemented this second disposition through the adoption of Regulation (EC) No 816/2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health issues.

The use of the invention for which a compulsory licence has been granted should only be **authorised to a qualified person** able to make, use, market, sell or import the crisis-relevant product, in accordance with licensee obligations provided for in Article 10 (Articles 5(1)(c) and (d) and 10(1)(a) and (b)).

The COVID-19 pandemic led many international organisations including the World Health Organisation (WHO), the World Trade Organisations (WTO), the United Nations (UN), the World Intellectual Property Organisation (WIPO), the EU and national government to revisit their guidelines on compulsory licensing and to engage in consultation exercises[4]. Although this led to intense debate it does not seem to have led to significant change.

[3] See https://www.wipo.int/export/sites/www/about-wipo/en/dg_gurry/pdf/ip_innovation_and_access_24042020.pdf

[4] See for example the EC Impact Assessment Report on the Proposal for a Regulation of the European Parliament and of the Council on compulsory licensing for crisis management and amending Regulation (EC) 816/2006

Significant issues remain relating to the ambiguity of terms such as 'crisis' and 'complementary measures', the open-ended composition and workings of the proposed advisory body, the trigger for a compulsory licensing procedure, and the circumstances under which a rights-holder would be notified that a compulsory license was being issued.

Compulsory licensing remains a major point of contention and is rarely used. Notable pandemic examples include the Hungarian Remdesivir example below but, outside the pandemic, it is more used as a threat to reduce pricing e.g. the UK case of Vertex Pharmaceuticals Kaftrio for cystic fibrosis.

The inclusion of know-how/ trade secrets in compulsory licensing has also been one of the main debating points in recent years[5]. A number of compulsory licences issued at the beginning of the COVID-19 pandemic were in relation to small-molecule medicines such as Remdesivir and Lopinavir/Ritonavir. These are regarded as more easily to replicate based on the patent specification that vaccines where substantial know-how is required.

The pros and cons of compulsory licensing[6] are also not well understood by policy makers or civil society; there is a need for balanced information for both stakeholder groups. There is a need to balance an IP monopoly, without which medicine and drug companies would not invest in new treatments, with the need for more accessible and affordable access for all people. While patents work well in HIC they do not work well for LMIC and compulsory licensing can be a necessity when other approaches to ensuring equitable access have failed.

Voluntary, non-exclusive licensing

Voluntary non-exclusive licensing ensures that 'blue-prints' for technology are not simply distributed without restrictions that ensure that they are manufactured and used in compliance with regulations and that the technology provider is protected from any liabilities arising from their use. Support for voluntary, non-exclusive licensing has taken a number of forms including establishing technology pools, developing pledges and issuing guidelines on licensing conditions. Direct supporting tools have included rapid online non-exclusive licensing e.g. as used for the UCL and Mercedes Ventura breathing aid.

However, as noted by the MPP, voluntary licensing alone is not sufficient to ensure patient access to all medicines – healthcare system capability to diagnose patients and deliver treatments are critical, together with other key capabilities along the regulatory and supply chains, including raw materials sourcing, cold chains, tariffs, and export restrictions. Finally, political commitment and government funding to invest in health are key to enabling access to medicines.

Technology pools

In an effort to make it easier for both technology provider and technology adopter to find each other, technology pools have been sent up to address a particular crisis situation. These focus on technology offered under voluntary non-exclusive licenses for humanitarian/ equitable purposes and often under similar terms and conditions.

Examples include the **Health Technology Access Pool (HTAP)**. This is the successor of the 2020 **COVID-19 Technology Access Pool (C-TAP)**[7], initiated by the World Health organisation (WHO), the Government of Costa Rica and other partners. C-TAP was designed to facilitate 'faster equitable and affordable access to COVID-19 health products for people in all countries'. It comprised a single global

[5] See for example Gurgula, Olga and Hull, John, Compulsory Licensing of Trade Secrets: Ensuring Access to COVID-19 Vaccines via Involuntary Technology Transfer (June 23, 2021). Queen Mary Law Research Paper No. 363/2021, Journal of Intellectual Property Law & Practice, Volume 18, Issue 6, June 2023, Pages 418–431, Available at SSRN: https://ssrn.com/abstract=3872796

[6] See https://www.ijssh.org/papers/239-D00013.pdf

[7] https://www.who.int/initiatives/covid-19-technology-access-pool

platform for the developers of COVID-19 therapeutics, diagnostics, vaccines and other health products to share their intellectual property, knowledge, and data with quality-assured manufacturers through 'public health-driven, transparent, voluntary, non-exclusive and transparent licences'. It also provided support for technology transfer agreements. These were by definition public health-oriented, transparent, voluntary, and non-exclusive licences, which could be issued through the Medicines Patent Pool (MPP), a C-TAP partner.

C-TAP/ MPP licences aimed to provide the qualified manufacturers with:

- The legal rights to manufacture and sell the licensed products;
- The technology and know-how required to develop quality-assured products effectively and efficiently;
- Access to clinical data needed to obtain regulatory approval for their products.

Licensing terms typically included royalty-free for low- and middle-income countries and remaining valid until the date the last patent expires.

HTAP builds on the foundation laid by C-TAP while incorporating structural, process and other changes that will enable it to attract and support a diverse range of priority technologies more effectively.

Guidelines on 'Humanitarian' Licensing

Humanitarian licensing is designed to facilitate a rapid response to a crisis for licensees and to make the execution of associated transactions a top priority. Guidelines are useful when the technology is not being handled by a central platform such as HTAP or the MPP but by individual technology providers such as universities.

An example is the AUTM COVID-19 Licensing Guidelines[8]. These were developed during the COVID-19 pandemic by AUTM, (originally the Association of University Technology Managers), who then invited organisations to sign up to them. The guidelines proposed the following approach to licensing:

"a time-limited, non-exclusive royalty-free licenses, in exchange for the licensees' commitment to rapidly make and broadly distribute products and services to prevent, diagnose, treat and contain COVID-19 and protect healthcare workers during the pandemic (as defined by the World Health Organization)".

The AUTM licensing guidelines were primarily aimed at universities and research institutions. They are often mentioned in conjunction with the Open COVID pledge which was more widely aimed at private technology suppliers. Signatories included well-known top-patenting companies such as Facebook, Intel, Microsoft and Amazon who showed themselves willing to publicly commit to making their IP relevant to COVID-19 freely available to help address the pandemic.

UC transferable policy lessons for PC

While the Covid-19 pandemic arguably significantly altered the landscape for humanitarian licensing it has been noted by some authors that 'public and charitable funders can play a larger role in encouraging universities to adopt such practices by making access and transparency clauses a mandatory condition for receiving public funds for research'[9].

[8] https://autm.net/about-tech-transfer/covid19/covid-19-licensing-guidelines

[9] Keestra S, Rodgers F, Osborne R, Wimmer S. University patenting and licensing practices in the United Kingdom during the first year of the COVID-19 pandemic. Glob Public Health. 2022 May;17(5):641-651. doi: 10.1080/17441692.2022.2049842. Epub 2022 Mar 17. PMID: 35298347.

This proposed policy approach to 'equitable access' to help mitigate crises is in-line with that taken by the Welcome Trust. It will form part of the envisaged ToolBox to be developed by IMPAC3T-IP under WP4.

5.1.2. Preventable Crisis in LMIC

Licensing technology to make it more accessible and affordable to LMIC is known variously as 'Global access' (Gates Foundation) 'Equitable access' 'EA' (MPP and Welcome Trust). Other terms that can cover aspects of this approach include 'Ethical access' and 'Socially Responsible access' (WIPO) and Impact Licensing (Université Grenoble Alpes).

Some definitions strongly overlap e.g. Global and Equitable, but in some cases e.g. 'Ethical access', 'Socially Responsible' and 'Impact Licensing', distinct differences are seen in rationale and goal for policy change, the type of technology involved and culture of the country involved. In this document the term 'equitable access' has been used and the focus is on licensing to LMIC. Other PC actions that will be reflected in the ToolBox e.g. to encourage more Socially Responsible access have been highlighted.

IP Rights and assets

The type of asset/ right to be licensed typically involves 'hard' rights e.g. patent, copyright and trademark rights. Know-how can also play a strong role.

National policy

Despite the basic economic fact that equitable access to medicines has the potential to reduce international aid payments from EU MS to LMIC by treating the cause and not the symptoms, not many EU countries have taken policy action. This is despite the fact that EU MS are seen to have difficulties getting a better price when negotiating single-handedly with monopoly-holding pharmaceutical companies. (See note on compulsory licensing).

A notable exception is the Netherlands who have made 'Responsible access' part of their Global Health Strategy 2023-2030[10]. Other cascading actions in the Netherlands, including the work of the Netherlands Federation of University Medical Centres (NFU) and the Dutch Access to Medicine Foundation are outlined below.

Introduction of such a mandatory national or EU policy to encourage more equitable access has been cited by some PROs (Public Research Organisations) as a way of strengthening their 'EA' negotiating position with large drugs companies. PROs have indicated that they would welcome the introduction such a policy at national level of from the funding agencies and research sponsors. The struggles to negotiate with large pharmaceutical companies experienced by EU MS places the negotiating power of individual PROs in context.

Funding Organisation Policies

Equitable access to the results of sponsored research has been introduced by a number of funding organisations, most notably the Gates Foundation and Welcome Trust. However, it is still not a requirement of most government funding agencies and it is not visible in HORIZON EUROPE. This omission is highlighted in a number of recent publications[11].

[10] See https://www.government.nl/binaries/government/documenten/publications/2023/03/29/dutch-global-health-strategy/Dutch+Global+Health+Strategy+2023-2030.pdf

[11] See for example Charani E, Abimbola S, Pai M, Adeyi O, Mendelson M, Laxminarayan R, Rasheed MA. Funders: The missing link in equitable global health research? PLOS Glob Public Health. 2022 Jun 3;2(6):e0000583. doi: 10.1371/journal.pgph.0000583. PMID: 36962429; PMCID: PMC10021882.

The Welcome Trust addressees EA direct through policy and funding contract making it a requirement in the research that they support and part of the monitoring and evaluation metrics. The Gates foundation requires that a clear action plan is put in place to turn policy in to practice e.g. with a detailed plan to bring the technology to LMIC once regulatory approval has been obtained.

Public health organisations and International non funding organisations

The MPP (Medicines Patent Pool) works directly to facilitate increased access to and facilitate the development of life-saving medicines for LMIC. Like the Gates Foundation, EA is a core goal of their activities. One notable difference is that while the MPP does not fund research and have primarily worked to license technology to large companies who manufacture drugs, e.g. as a partner of C-TAP, they are currently working more strongly with early stage technology providers like universities, to get them to adopt an EA policy that will influence all relevant licensing deals emerging from the PRO. The introduction of specific EA clauses into institutional policy is discussed more below.

WIPO is leading a **socially responsible licensing initiative**[12] as well as **Ethical Licensing**. However, this latter initiate is not specifically aimed at EA and is perceived by some PROs as aiming to achieve wider 'impact' from research e.g. beyond economic, rather than equitable access to prevent crisis.

Institutional Policy

Policy at individual institutions to address EQ is still very sparse but there are notable exceptions in the Netherlands where Government policy and the 'Ten principles for Socially Responsible Licensing'[13] (NFU) has led to a clear shift in policy. Also influential is the MPP Policy action although this is more visible in the USA than the EU. Notable HEIs who have made changes based on the MPP initiative include Erasmus University (The Netherlands) and UCLA and Columbia Universities in the USA.

Institutional actions can be aimed both at overarching policy and also at the specific licensing agreement. The final negotiated agreement is seen as a way to give the overarching policy 'teeth' and ensure that it does not simply become a statement of good intent. The most common clauses and negotiations currently focus on the production of an action plan once a drug has been approved for use and an attempt to negotiate over the price to the medicine to ensure that drugs are not just accessible but affordable in designated countries and territories.

[12] See https://www.wipo.int/web/global-health/w/news/2023/news_0004
[13] https://www.nfu.nl/sites/default/files/2020-08/19.4511_Ten_principles_for_Socially_Responsible_Licensing_v19-12-2019.pdf

5.2. Conclusions and emerging recommendations for Crisis Scenario tool-kit development

The analysed examples (See Annex 1 Section 1.3) suggest that there are three main interventions points in Crisis where tools would be useful. These apply to both PC and UC.

1. At the policy stage when policy makers, funding organisations and research performing institutes can link EA to mission.

2. At the research implementation stage where funding is being sought, secured and used under specific terms and conditions designed to create more EA.

3. At the license planning and execution stage when EA can be reflected in licensing clauses.

The following tools are suggested for development in Year 2.

Table 7 List of Potential Tools relevant to the Crisis scenario

Tool	Stage	Purpose	Target user
EA Policy Guidelines for development and examples	1	To justify and explain stance and set clear expectation.	PROs and well as enterprises seeking a more ethical approach to access to assets
Guidelines on Compulsory Licensing	1	To raise awareness of Pros and Cons of intervention with some indication of the legislative framework and ongoing debate.	Policy Makers and Civil Society
Guidelines on Voluntary Licensing	1	To help explain the issues inherent in voluntary licensing to technology providers.	PROs and well as enterprises seeking a more ethical approach to access to assets
Voluntary royalty free licenses for rapid access to technology Issues to be addressed Example Clauses Template Case Study	3		
Guidelines for Funding Agencies	1/ 2	To ensure that R &D funding results in equitable access	Funding Agencies/ Parent Institutions

Guidelines for development of EA approach and examples of how to embed in processes.			
Licensing clauses Explanation of main issues to be addressed Good practice process and initiatives Example clauses	3	To ensure that the Policy can be implemented in a licensing deal	Licensees seeking to ensure more equitable access to their assets
Access Plans Explanation of main issues to be addressed Good practice process and initiatives Example clauses	3	To ensure that the Policy can be implemented in a licensing deal	Licensees seeking to ensure more equitable access to their assets

6. Annex 1 Mapped and analysed examples

Introduction to the Annex

This annex accompanies D2.1 of the IMPAC3T-IP project.

It details the examples that were collected and analysed in Year 1 Work Package 2 in order to identify opportunities for tools needed in 3 scenarios.

Most of these examples have been lightly or fully anonymised at the request of the contributing party. The mapping and analysis include outcomes, an indication where possible of specific licensing terms, lessons learned and possible intervention points and 'tools' to support others in the future.

For more information of the definition of each scenario and the methodology used for analysis please consult the main D2.1 report.

Mapped and analysed examples

6.1. Classical Plus Examples

6.1.1. Health and medical questionnaires

Research work related to the health and behaviour of both humans and animals frequently involves the use of surveys and questionnaires. Classically, the output has been a research paper drawing conclusions based on the statistically analysed data with the questionnaires appended as an Annex to the paper. However, once answers can be interpreted, the questionnaires become a valuable resource for others to use. Several examples have been mapped and are outlined below.

6.1.1.1. The Canine Behaviour Calculators

A good example of a questionnaire that is a valuable resource for others is the online **Canine Behaviour Calculators** developed by the Animal Behaviour, Cognition & Welfare Group at the University of Lincoln. This comprises a series of unique clinically validated scales designed to assess various behavioural traits in dogs that are now being used under license by individual dog owners and large and small vet practices across the world.

The starting point for the research was an awareness by the research team of a lack of reliable and validated tools to assess canine behaviour. The Canine Behaviour Calculators were an output of research undertaken and published that profiled behaviour in dogs to enable a clinically proven approach to the assessment of problem behaviour in animals.

Along with the academic paper, the research team wanted to disseminate the tools that had been generated to increase public awareness of their work and improve impact from the work. Supported by the University's Research and Enterprise team the goal was to disseminate the questionnaires to as many end users as possible with minimal administrative burden. The result was the Canine Behaviour Calculators.

All the IP assets were **copyright material** in the form of a series of 6 questionnaires that could be made available in pdf format. These had originally been an Annex to the journal paper but had been deliberately excluded from any copyright claim by the publishing house.

The team made the decision to host the license application point and questionnaire downloads on an external server to avoid perceived IT security risks for the university. A minimum amount of information was requested when applying to download the calculators to enable automatic approval. The information was designed to allow the team to track use at a later date if they so wished and to dissuade commercial downloads e.g. for onward sale and commercial use.

Outcomes

Easy access to these tools has enabled hundreds of dog owners and community vets to assess, monitor and manage problems relating to anxiety, sound sensitivity and impulsivity resulting in considerable societal benefit.

License

Licences were bespoke with non-negotiable terms drafted by the Research and Enterprise team. These included the clause:

"…you agree to provide to us, upon reasonable request, information relating to your use of the Product (to include effects, changes or benefits to the economy, society, public policy or services, health and the environment)."

This clause was used to help the team track 'impact' as part of the UK 'Research Assessment exercise' which is linked to funding for research.

Lessons Learned

Initial publishing of tools in journals may become an issue with regard to copyright ownership.

Hosting the licence applications and downloads on the university's servers was viewed as an IT security risk.

Intervention points and associated tools:

1. Before submission to a journal: Preventing assignment of all © in the questionnaires to the publishing journal.

Guiding tools:

Guidelines on © ownership and academic publishing.

2. When the on-line license is executed e.g. with or without eligibility checks and human approval.

Guiding tools:

Advice on the minimum amount of information to be requested to allow automatic registration and approval.

Advice on use restrictions / supporting statements to be included on copyright material itself.

6.1.1.2. Eating Behaviour Questionnaires (EBQ)

A research team from University College London (UCL) undertaking research into eating disorders developed a series of 11 Eating Behaviour Questionnaires (EBQs) and Clinical Outcome Assessments (COAs). These were in English as well as various translations. The resources have significant commercial potential in situations where pharma companies are sponsoring the clinical trial – EBQs can be used to measure the effect of drugs.

While the resources had been available for a while the team was struggling to disseminate them more broadly due to issues including rights clearance (legacy issues) and licensing of translations. They also needed to find a way to control commercial/ non-commercial use following incidents of bots 'raiding' the university web pages to download pdf copies of the questionnaire and scoring.

Once issues of rights clearance had been addressed, licensing terms were drawn up to address commercial/ non-commercial use and 'derivative works' e.g. translations.

The license and questionnaires were then hosted on the university 'e-lucid store-front'. They are licensed Free of Charge (FOC) for non-commercial research use. For other uses, prospective licensees can submit an online query.

Outcomes

The licenses were first made available in July 2024 and there have been approximately 10 licences concluded in the first 4 weeks.

Lessons learned

Academics from AHSS often do not know how to start the commercialisation process of their research outputs. Exploitation planning is often delayed, creating issues with rights clearance. Better linkages between a TTO and the university Library can strengthen the process as AHSS researchers will often consult Library staff on copyright related issues.

Translations (derivative works): Translation is a significant issue in questionnaires with global value. There may be a need to use quite specific language and words to reflect local (including national regional) language.

- In the case of a non commercial licences, UCL by default owns © of any unvalidated translations made and will in turn will only offer non-commercial licences for these.
- If UCLB Ltd (the technology transfer office and commercialisation company of University College London) decides to contract a translation (either of its own instigation or at request of licensee) that is then properly validated then UCLB takes ownership of the new version and is able to licence this version commercially.

Legacy issues: When resources have been developed/ evolved over a period of time and many people have been involved then it can be hard to ensure that all copyrights have been assigned to enable licensing of rights. This situation is even more complicated when a contributor has died. Early identification and transfer of rights in such a research project will facilitate licensing later.

Protections from 'Bots': Automated Software applications that are programmed to do certain tasks (Bots) can make it very hard to prevent download and use of valuable resources like EBQs if they are placed directly on to a traditional website. Use of a 'store-font' such as the one used by UCL where download must be approved can eliminate this issue.

Intervention points and associated tools:

1. Early intervention point: to advise who the team should contact for support in dissemination / licensing.

Guiding tools:

Guides for copyright considerations when publishing / translating clinical questionnaires

Decision-making tools to guide non-STEM academics along the right pathway.

6.1.2. Training and educational resources

6.1.2.1. 24h QuAality: E-learning modules for home-carers

Home-carers are not full health care professionals but a key part of the care community. They work in other people's homes, not in a hospital to care for people in the community. Most of these individuals are on short term contracts rather than being full time employees of a healthcare authority. Many of them have come from abroad so there is an added complexity over language. This target group would benefit from E-learning, including by being able to do it flexibly (between shifts) and at their own (2nd language) pace. They are unlikely to be willing to pay for it themselves due to their low hourly pay rates. There may be value for a healthcare authority, or a private agency, of offering E-learning it free / at cost to their contracted workers.

A university worked with other partners to create 24-E-learning modules for 'home careers' to meet the situation outlined above.

IP: The main form of IP was **copyright.** This was complex in terms of the multi-media nature of the resources e.g. distributed over different part of the asset (e.g. script, images, software....) and also ownership of the different parts as it was created by multiple authors. There was also significant commercially valuable **know-how** in terms of the content. Finally, there were **domain and design rights** in the platform. There were complexities in ownership of the different assets because they had been created by a consortium of organisations.

Outcomes

In 2021, IPR owned by the partners was transferred to a company who will now take the exploitation forward under a licensing agreement with the consortium partners. The learning models will be made available at certain price.

Lessons learned

Joint creation and multiple claims to ownership of IP rights proved to be a barrier to early commercialisation. This was resolved through clear assignment of rights and a joint license agreement between all partners and the company designated to exploit the IPR. However, auditing ideally needs to take place regularly during development to identify IP and also any possible claim to authorship/ownership; final transfer of rights and clear freedom to operate is then facilitated.

The T&C of the license between the project partners and the exploiting company took some time to negotiate. The final transfer included conditions for:

- upfront payment and possible bonus payment.
- revenue share until a certain threshold is reached after which unrestricted exploitation right for the educational videos is transferred to the exploitation company.
- fundamental revisions to the content of the E-learning courses, (any case when a learning video has to be newly created), when the university will receive a payment per course.
- retention by the university of all rights of use of its research results for the purpose of research and teaching. It is further clarified that the university will continue to fulfil its publication obligation according to the consortium agreement

Intervention points and associated tools:

1. Early identification of results, rights and claims to ownership

Guiding tools: Auditing tool and waiver/ transfer guidelines.

2. Identification of a viable business model that fits the organisational culture and mission as well as market conditions.

Guiding tools: examples of sustainable rather than fully commercial models.

3. Terms and conditions for transfer of rights to an exploitation entity.

Guiding tools: examples of clauses and comparator T&Cs from similar projects.

6.1.2.2. Guiding Good Choices® (USA)

Guiding Good Choices® (GGC) is a family skills-training program that aims to promote healthy development and reduce risky behaviour in the teen years e.g. leading to drug taking.

The GGC programme is the intellectual property of the University of Washington (UW). However, the original version, called "Preparing for Drug-Free Years", was created by J. David Hawkins and Richard F. Catalano and gifted to UW's Center for Communities That Care (CTC). The original motivation of developing the assets was to 'enhance positive parent-child interactions and help parents prevent their children's drug use and related behavioural problems'.

The course is delivered by training service agencies working with schools, social workers, preventionists, prevention coalitions and public health agencies. Final beneficiaries are parents, caregivers and their middle-school aged children in grades four through seven.

IP: The main form of IP is copyright in the training materials although the name Guiding Good Choices has been registered as a trademark. The copyright materials take the form of course materials (in PPT format), videos, guides and evaluation tools. There is also an optional printed GGC Workshop leader guide, available in English and Spanish.

After the materials were 'Gifted' to UW they took steps to try and find a sustainable distribution mechanism by conducting market research and reviewing similar evidence-based prevention program models and pricing.

Materials were produced in a format suitable for online distribution and made available via a 'click-through' + approvals needed' license execution. Approvals include export control review and payment (where applicable).

Outcomes

Since its publication on April 2021, GGC has been licenced from e-lucid based CoMotion's store 374 times generating a total revenue of $209,982 USD which is reinvested in product development.

Lessons Learned

Getting going: The University had been gifted the resources but needed to find finance to move them closer to valorisation.

Sustainable Business Model: The business model adopted to make the activity affordable to the target users and sustainable for the University (including addressing improvements) is

- 1-year membership subscription for $240 per user.
- or 3-year membership subscription for $500 per user
- Plus optional printed GGC Workshop Leader Guide (available in English or Spanish).

Efficient internal approval process: The internal approval process can take a long time unless it is limited to a small number of issues e.g. export control and payment. To limit the time taken to execute it is important to make sure that standard non-negotiable clauses are included; making amendments is problematic and requires too much work.

Supporting the resource: The University has set up a community of practice that holds monthly sessions. They also offer technical assistance to support uptake and use.

Intervention points and associated tools:

1. During the initial licence drafting with the academic teams

- Licence drafting tool

2. During the internal licence approvals process

- Check-list of critical points.

3. During the licence amendment process.
   - Licence amendments support through e-lucid or similar tool.
4. During licence execution
   - Feedback collection tool/process

6.1.2.3. YES: Youth Empowerment Solutions (USA)

Youth Empowerment Solutions (YES) is an evidence-based program that empowers youth to make positive changes in their communities and to work with adults to support their efforts. The resource was purposeful created by researchers at the University of Michigan School of Public Health and their community partners. The YES program was originally developed around 2010 and has been evolving since then, engaging in extended programming and reaching new communities. It is targeted at youth and adults in various communities across the U.S., with a focus on preventing youth violence and creating positive community changes.

IP: The resource contains a number of copyright materials:

- Youth Empowerment Solutions Curriculum, (Multicultural and African American version now available).
- Implementation guide
- Evaluation materials
- Supporting materials such as brochures, videos, research publications, music and multimedia.

Outcomes

Over 2,000 orders for the YES program have been fulfilled in the last 5 years and an equivalent list of outreach/ community connections have been generated.

Over time the program has evolved to include adaptations such as the creation of a multicultural and African American version and a subsequent module focused on healthy relationships.

Impact

The YES program has had a profound social impact by empowering youth, reducing violence, and fostering community change.

For more information see: https://yes.sph.umich.edu/research

Lessons learned

Finding a distribution mechanism: Building awareness for programs like this are always key to ensuring distribution. "*Supporting 'marketing' and general awareness building of the programs is always a challenge to ensure that the communities and people that can benefit from them are aware of them*."

Sustainable business model: The intention is and has always been to support open, broad no cost distribution of these materials. Licences for YES were distributed free of charge. This was made possible thanks to a very long history of funding from several Federal agencies including NIH-HHS, CDC as well as support from private groups such as The John Mohme Foundation and internal funds from the University of Michigan.

Intervention points and associated tools:

1. At the User registration and assets distribution point

Tool: Similar to the e-lucid platform for curriculum distribution and user registration.

2. At the stage of follow-up and outreach capabilities to support new users and maintain community engagement.

Tool: Potential tools for aggregating additional resources and gaining insights on user origins and engagement sources.

6.1.2.4. REACT (REducing bACTerial infections) Materials (UK)

REACT is a tool-kit for service providers to support people who inject drugs to care for their veins and make changes to help prevent bacterial infections and associated health complications. It was developed by researchers at the University of Bristol. It comprises education materials in digital format. The tool-kit was designed to address the issue that many people / services that come in contact with intravenous drug users don't have the confidence to deal with issues such as bacterial infections.
The research team wanted to make materials available free to suitable service providers, in the long term, with minimal barriers and with feedback collection enable to inform further research and impact studies

IP: The main form of IP was **copyright in the digital resources**.

Outcome

Since launch in March 2023 the material has been licensed nearly 200 times (mostly in 2023) under a non-exclusive licence for non-commercial use covering copyright of all materials. This has allowed for stakeholder engagement with licensees.

Lessoned learned

The research team had previously produced similar materials but they were distributed by a commercial co-creator which proved to be a barrier to dissemination. This included some NHS trusts not being able to download materials from behind their firewalls when materials were hosted by a commercial organisation.

Intervention points and associated tools:

1. Early in the research process so that academics are able to make informed decisions regarding any research outputs / IP assets.
Tool: Supporting early career / CPD training

2. Post-licensing to support qualitative feedback.
Tool: Check list of minimum useful registration/ approval information needed to maintain contact with end users.

6.1.2.5. Meals on Wheels infographics (UK)

Research work at the University of Bristol was undertaken into the 'Meals on Wheels' service. This is a way of delivering free meals to the home of someone who qualifies for the service. The service may be proved by an independent operator (charities of private contractors) but it is typically paid for from a health authority or council community budget. At the moment, around 30% of local UK authorities provide a Meals on Wheels service.

The researcher wanted to understand what did/ did not work well and to identify the major challenges to such a service. The research project involved interviewing Meals on Wheels Managers / Drivers as well as users about the service.

As a result of the research project a series of infographics was created to capture the results. The researcher wanted to use the infographics both to increase awareness of and create publicity for Meals on Wheels as a service and to generate feedback from consenting users of the resource.

The final set of infographics are aimed at general practitioners, hospital-based clinicians, and social and community carers and workers, as a resource to inform referral decisions to Meals on Wheels services. They can also be used by Meals on Wheels providers as a resource to raise awareness of their services on their websites and publicity materials. They are also useful for commissioners and policy makers as a resource to inform decisions about reviving or reintroducing a Meals on Wheels service.

IP: The main form of IP is copyright in the infographics.

Outcome

The materials have been made available via the University of Bristol's e-lucid storefront. The non-exclusive license copyright licence stipulates that they are free of charge for non-commercial purposes only (raising awareness of Meals on Wheels services, supporting referral decisions, informing decisions about funding, continuation and/or enhancement of services, and/or educational or research purposes).

The resources were licensed over 30 times in the first 6 months.

Lessoned learned

Invention Disclosure Forms (IDF) used by TTOs have largely been devised for STEM inventions.

The overall invention assessment and commercialisation processes used in TTOs are not a good fit for non-commercial 'impact' based opportunities.

Intervention points and associated tools:

1. Early in the evaluation process when the results are assessed to see if they are suitable for commercial or non-commercial licensing
Tool: Checklist/ guidelines for non-classical assets.

2. During the market exploration process when a business plan is being developed.
Tools: Tools and methods to help scale, market, and valorise non-classical copyright based result.

6.1.2.6. KiVa: A Finnish anti-bullying program (FL)

Background to the example

KiVa is an antibullying program targeted to schools for children aged between 6 and 16 years old. The goal of the KiVa program is to prevent bullying from happening via effective methods in order to minimize the negative effects of bullying. It includes three components: prevention, intervention and monitoring. Originally developed between 2006-2008 by the University of Turku, Finland, with funding from the Ministry of Education and Culture the program is evidence-based meaning that the effectiveness of KiVa has been proven scientifically.

Results: KiVa offers a wide range of concrete tools and materials for schools to tackle bullying. These are offered both nationally and via licensed partner organisations abroad.

IP

KiVa is protected by trademark owned solely by the University of Turku. The KiVa materials are covered by copyright and the University of Turku is the holder of the copyright. The University of Turku has exclusive rights to exploit all KiVa materials. There is significant know-how involved in delivering the program effectively which is imparted through training activities for schools in Finland and for partner organisations in other countries, themselves training and supporting KiVa schools. Materials for use outside of Finland are translated professionally and the University holds copyright and all other rights to all versions. IPR is licensed by the University to contracted partner organisations in countries outside of Finland for a commercial fee.

Outcomes and impact

In Finland, KiVa has been evaluated positively in a large randomised controlled trial including 117 intervention schools and 117 control schools. The first international studies show that KiVa is also effective outside of Finland.

Lessons learned

- To develop a program that would be effective and accepted for national use it was important to make this evidenced based and so to undertake rigorous scientific research and testing. The Ministry had the foresight to make a fully scientific approach part of the original requirements.
- Significant funding was needed to undertake the original research and the government commissioned the research to develop the school materials and study its efficacy for a national roll-out.
- It was clear from the beginning that funding would be needed by schools to be able to adopt and run the program in the long term and this was also made available by the government in the early years.
- Funding was needed to be able to continue to make the program available nationally and internationalising the program to generate revenue was an early part of the underlying business model.
- Creating a high quality trusted ‘brand’ for the program was important and selecting partners abroad who share values and can make a long-term commitment to the program is a strong focus for the KiVa team located at the University of Turku.
- KiVa partners with just one organisation in each country wishing to adopt the program to avoid compromising quality by multiple partners competing for a national market.
- There is a need for strong human resource support to create and maintain the different long term partnerships that are formalised through a commercial contract.

Intervention points and associated tools:

1. Early in the project to identify and work towards a sustainable access and delivery model.

Guiding tools: Comparator pricing information and a checklist of critical success factors including brand development.

2. At the end of the process to secure sustainability.

Guiding tools: Partnership and licensing agreements with both national and international partners.

6.1.2.7. Teaching English Grammar: Englicious

Englicious is an English grammar teaching resource, created by experts from the Survey of English Usage, a world-leading research unit at University College London. It offers hundreds of free resources which are mapped to the English National Curriculum from primary to sixth-form levels. The assets include lesson plans, exercises, videos, assessment materials, all covered by copyright.

Alongside the free online resources, the research team offer half-day intensive paid-for online CPD courses for teachers on Zoom:

- English Grammar for Teachers – FutureLearn
- Teaching English Grammar in Context – FutureLearn

Both course are also now available on the platform FutureLearn, allowing teachers to learn at their own pace.

The IP assets constituted **copyright materials** – both multi-media educational content and hard copy printed documents.

Use of the on-line teaching resources is free, but to access the resources is it first necessary to create an account by registering as a student, teacher or member of the public.

When registering it is made clear that all content is under copyright and is not to be used in any commercial product of whatever form without express agreement from Englicious.

Hard copy materials e.g. English Grammar Knowledge Organisers, a set of six laminated Grammar wall posters and a set of 28 double-sided grammar flashcards are available to buy. Other revenue is generated from the CPD activity. The revenues are used to maintain the website as a free resource.

Outcomes

The site currently has 15,000 registered users (teachers).

Lesson earned

Finding a sustainable Business Model: Initial funding from the UK Arts and Humanities Research Council (AHRC) was used to help develop the materials but revenues from printed materials and CPD courses have proved vital to support website maintenance and development of new resources.

The perceived value of 'free' vs. the demands of being fully professional: Resources offered 'free' are perceived as less valuable than commercial ones. However, if the site was fully commercial there would also be an expectation from users that it would be professionally supported and the research team do not have time to do this.

Paywalls, freemium models and the creation of a 2 tiered system: Making the online recourses more commercial e.g. by adding a Pay Wall, would create a 2 tiered system as some schools would not be able to afford to buy access as schools already operate under very tight budgets. It was important to the creators that it was available to everyone. A Freemium model has been considered to try and generate more revenue while still making some resources available to all.

Benefits of a 'click-through' license for hardcopy materials: An online 'click-through' license was used to minimise resources needed to manage hard-copy copyright materials.

Intervention points and associated tools:

1. Identifying the right business model for sustainability that fit the organizational culture.

Guiding tools:

- Guidelines on possible semi-commercial models and the internal stakeholder consultation process.

- Guidance note on CC BY CA and Freemium models.
- Comparator pricing examples and case studies.

3. Final Licensing T&D to support both commercial and non commercial use.

Guiding tools:

- Example licensing clauses.
- Possible automated licensing.
- Checklist for approvals.

6.1.3. Data Bases, Data Sets and Digital Libraries

6.1.3.1. FinnGen: Genome and health data from a Finnish biobank

The FinnGen study was initiated in Finland in 2017 as a pioneering initiative combining genomic information with digital healthcare data from national registries. It is one of the largest public-private partnerships in the field of genomics and personalised medicine and serves as a great example of how genomic and health data can be leveraged in a systematic, safe, and fair way for the benefit of all stakeholders in the healthcare ecosystem. The project aims to combine genomic data from over 500,000 Finnish biobank participants to explore the genetic basis of various diseases.

The FinnGen project is based on exceptionally wide and open cooperation involving universities, hospitals, biobanks, and pharmaceutical companies. The study is coordinated by the University of Helsinki (Institute for Molecular Medicine Finland, FIMM). Helsinki Biobank (the Hospital District of Helsinki and Uusimaa) coordinates the sample collection, while THL (Finnish Institute for Health and Welfare) coordinates the processing of register data.

The result of this collaboration is a unique world-class dataset integrating both genomic and health data, serving as a valuable resource for developing new medical treatments and preventive measures.

FinnGen provides a unique platform to explore the genetic basis of various diseases, offering the potential to address fundamental research questions and aid in the development and delivery of new medicines and therapies. The project is now expanding to explore the progression and biological mechanisms of diseases, ultimately benefiting healthcare systems and patients globally.

- **Intellectual Property (IP)**

Intellectual property considerations for FinnGen focused on ensuring that data access and privacy were handled ethically, complying with Finnish law on the secondary use of health data. The project implements a transparent framework for data sharing, allowing universities, hospitals, biobanks, and pharmaceutical companies to access anonymized data for research under regulated conditions, emphasizing compliance with ethical and data privacy laws.

The Fingenious® Service aims to advance biomedical research by speeding up the search and compilation of relevant data. The service is available to both academic and industry researchers.

- **Outcomes and Impact**
- FinnGen has revolutionized the understanding of genetic drivers behind various diseases, pinpointing potential therapeutic targets.
- The project has accelerated drug discovery and personalized medicine approaches, with significant international investment drawn to Finland.
- Long-term impact includes enhanced healthcare innovations benefiting both academia and the pharmaceutical industry.
- The project has positioned Finland as a leader in personalised medicine and strengthened its role in global health data research.

Some of the major outcomes of the project include the identification of genetic factors that increase the risk of certain types of leukaemia, especially among women. FinnGen continues to accelerate international collaboration and innovation in the field of genomics and personalised healthcare.

Lessons Learned

- Strong legal frameworks for health data sharing are critical to ensuring trust and compliance.

- Multistakeholder engagement solidified by proper agreements is critical for creating big databases and attracting investments.
- The data sources should be carefully examined and analysed before use, based on the preferred model of access.
- Clear guidelines for data access and sharing can promote both academic and commercial research.
- Proper infrastructure is essential for managing large-scale genomic datasets.
- Projects like FinnGen can place countries at the forefront of global biomedical research.

Intervention Points and Associated Tools

- Early-stage identification of potential delivery models – guideline.
- Early stage agreement of the data usage and data access rights – agreements templates, guideline on data licensing limitations based on the data source and type.
- Before the licensing – tools for ethical data management and privacy protection.

Guiding Tools:

- A checklist for ethical data sharing.
- A checklist for data sources usage limitations.
- Data privacy and security guidelines.
- A guide on potential licensing models for data access.

6.1.3.2. CHiME-5: distant-microphone dinner party speech dataset

CHiME-5 is a large dataset (consisting of audio files, transcripts and floor-plans) relating to conversational speech recordings collected from twenty real dinner parties that took place in real homes. They were gathered by the Speech and Hearing Research Group at the University of Sheffield, as part of research to advance distant microphone speech processing e.g. of the sort that would be recorded during large gatherings of people e.g. workshops and a challenge series. The research objective was to make improvements in word error rate and diarisation error rate for single-speaker voice commands in various environments and for multi-speaker conversations in homes.

The research team wanted to disseminate the audio-sets as tools to support further scientific advances in this research field. The target beneficiaries of licensing activity were mainly public research organisations but also included a small number commercial organisations.

IP: The main form of IP was **copyright** and the data was in the form of edited and transcribed audio files.

Outcomes

Copyright materials were offered for license via the University of Sheffield's 'e-lucid storefront'.

Lessons learned

Business Model: The team were able to use a dual-licensing strategy (free of charge licence to academic users, fee-bearing for commercial use) by creating 2 licences with different T&Cs and pricing. Whilst the majority of licences (c99%) were for non-commercial research, a small number of commercial licences generated revenue to support the team's research programmes. Price for commercial use was based on guess work rather than a clear classical evaluation of assets.

Licensing T&C: Licences were bespoke rather than CC with non-negotiable terms being drafted by the Commercialisation team.

6.1.3.3. Marine Regions database

Originator: Flanders Marine Institute/ Vlaams Instituut voor de Zee (VLIZ)

Background to the example

Geographic Information Systems (GIS) have become indispensable tools in managing and displaying marine data and information e.g. legal boundaries to territories as well as information on geophysical features such as sandbanks, seamounts, ridges, bays. This information is critical to those operating boats and other ocean going vessels to ensure that they operate safely and in conformance with national and international laws. It is also needed by those developing associated navigational software and associated services.

However, a unique georeferenced standard of marine place names and areas was not available; this hampered several marine geographic applications, for example the linking of these locations to databases to integrate data.

Aims and objectives

The aim of creating the Marine Regions database was to create a standard, relational list of geographic names, coupled with information and maps of the geographic location of these features. This was intended to improve access and clarity of the different geographic, marine names such as seas, sandbanks, ridges and bays and display univocally the boundaries of marine biogeographic or managerial marine areas.

Creators

The 'Marine Regions' database was developed by researchers from the Flanders Marine Institute/ Vlaams Instituut voor de Zee (VLIZ).

Results

The '**Marine Regions**' online resource is an integration of the VLIMAR Gazetteer and the VLIZ Maritime Boundaries Geodatabase. The VLIMAR Gazetteer is a database with geographic, mainly marine names such as seas, sandbanks, seamounts, ridges, bays or even standard sampling stations used in marine research. The geographic cover of the VLIMAR gazetteer is global but initially focused on the Belgian Continental Shelf and the Scheldt Estuary and the Southern Bight of the North Sea.

Gradually more regional and global geographic information have been added to VLIMAR and combining this information with the Maritime Boundaries database, representing the Exclusive Economic Zones (EEZ) of the world, led to the creation of marineregions.org.

Funding and sustainability

Marine Regions is managed by the Flanders Marine Institute. Funding for the creation of the VLIMAR gazetteer was provided initially through the EU Network of Excellence MarBEF, but also other European initiatives such as Lifewatch provide the necessary funding for the maintenance and management of Marine Regions. The database depends on ongoing data and knowledge sharing from global, European, regional and national data providers and relevant experts. This is done using Collaboration Agreements. By using collaboration agreements, data providers benefit from belonging to the Marine Regions partnership through increased visibility, access to a variety of data analysis services which benefit from integration of several distributed spatial datasets and gain benefit from the creation of stable unique identifiers.

Access Model

Marine Regions' products were originally licensed under a CC BY-NC-SA (Attribution-NonCommercial-ShareAlike) license[14]. This does not permit commercial use.

The Flanders Marine Institute was approached by commercial companies wanting to be able to legally use the data base inside their commercial products e.g. interpretation of GPS positioning on boats. They requested that the marine regions' maritime boundaries be made available under a CC BY license or under a fully commercial agreement linked to an associated pricing model.

The requests to offer fully commercial licenses created a number of difficulties for the Institute
1. Internal culture and commercial activity: Some researchers at the institute are unwilling to license the database under commercial terms. They feel it does not fit the mission and culture of the Institute which promotes open and FAIR data. Additionally, the developments and work of Marine Regions has been state funded either by project funding or direct institutional funding.
2. Information asymmetry and pricing: A pricing model has not been easy to construct as there are significant asymmetries in information between the institute and the commercials users regarding the 'value' of the data.
3. Commercial licensing agreement clause**s**: Commercial licensing templates would need to include commercial clauses e.g. disclaimers and waivers to protect the Institute. This would require licensing and legal experience which was not readily available.

Outcomes

From 2019 and version 11 the Institute took the decision to offer the database under a CC BY license[15]. This means that it can be used for commercial purposes but the Institute does not have to negotiate the terms of each individual license. At the moment, the database continues to be licensed under CC BY and commercial use is permitted. In a disclaimer the Institute requests users not to make the products available for download elsewhere and to refer to marineregions.org for the most up-to-date products and services. A Terms of use is also available on the website. Internal funding has been sought to maintain the resource.

Lessons Learned

- Finding a business model that caters to commercial use that is also acceptable to a not-for-profit organisation may be difficult.
- Freemium models or commercial licensing require a level of knowledge about the commercial value of the assets that may be difficult to obtain due to information asymmetries.

For more information visit: www.marineregions.org

[14] See https://creativecommons.org/licenses/by-nc-sa/4.0/
[15] See https://creativecommons.org/licenses/by/4.0/

6.1.3.4. VRGS: Virtual Reality Geological Studio

Type of IP 'asset': Software
Type of associated 'Rights' (if applicable): Copyright
Key Words: Software; geology; licensing; market validation; oil & gas; mining

Background to the asset
VRGS (Virtual Reality Geological Studio) is an integrated software solution to visualise, interpret and analyse 3D geological datasets of virtual outcrops. Initially developed as a research & teaching tool, it was designed to be accessible and usable by users beyond the creator – i.e. of commercial quality so that it could be used in industry (mainly oil and gas companies). The software can also be used in academic geology research.

Background to the licensing situation
The software had been in development for a number of years and was initially shared informally with (not licenced to) a small number of external users (academia and industry) with positive feedback.
A serendipitous introduction to the TTO of the University of Manchester lead to trial licences with a number of companies in the oil & gas sector.
The creator of the software wanted to be able to reach a wider audience and new markets but the commercial assessment by business managers determined (partly due to unfavourable market conditions in the oil and gas industry) that there was insufficient evidence to support spinning out the technology.

Challenges encountered in transferring the assets
Without a commercial vehicle with seed funding (spin out) it was very difficult to justify the expense of (i) marketing the software and (ii) negotiating and administering multiple licences of relatively low value. A sustainable means of managing non-exclusive licences within the University was required.

Tools utilised
In approximately 2015 UCLB made its e-lucid online licensing platform available to other institutions. VRGS was one of the first digital assets published on the University of Manchester store.

Outcomes
In 4-5 years on the store, VRGS was licensed approximately 50 times & realised c£20K of revenue per year. Other, higher value licences, were negotiated and concluded in the traditional way.

Lessons learned
- Market-ready IP assets of low value (but capable of high volume sales) are not the traditional technology type encountered by university TTOs.
- By automating much of the licensing process, admin costs are dramatically reduced to the point where there can be a ROI. Revenues may be sufficient to support a sustainable business model long term.
- An additional benefit is that the platform facilitates the market validation of digital products – user feedback, organic sales growth – globally and with minimal costs. Over time, sales data can support the development of a business plan for spinning-out.
- In this case the combined revenues allowed a spin-out to be created without needing to raise finance.

6.1.3.5. Digital Heritage project ARMA: the Art of Reading in the Middle Ages

The ARMA project was collaboration between 8 institutions: 6 libraries a Museum and the Europeana Foundation. The libraries and the museum came together to create a collection of over 23,000 digitised reproductions of medieval manuscripts, early printed books and artifacts from their own collections, covering the period from 500 to 1,550. The goal of digitising, pooling and placing online was to increase their visibility.

Because of the age of the materials, copyright of the creators was not longer an issue and the digitisation process does not typically create a new copyright unless it has involve an aspect of creativity; this was not the case. However, the digital images are 'owned' by the organisations who have the right to control how they are used and other new, multi-media materials, (e.g. videos and educational materials aimed at schoolchildren and students), linked to the collections are under copyright.

The IP assets constituted **ownership of a digital image but without copyright**. Other new **copyright material** existed in the form of multi-media educational commentary.

All metadata published by Europeana are available free of restriction under the **Creative Commons CC0 1.0 Universal Public Domain Dedication**. However, Europeana requests that any use is actively acknowledged and attribution given to all metadata sources, such as the data providers (being a specific cultural heritage institution) and any data aggregators, including Europeana.

The **CC0 1.0 Universal Public Domain Dedication** means that:

- The person who associated a work with this deed has 'dedicated' the work to the public domain by waiving all of his or her rights to the work worldwide under copyright law, including all related and neighbouring rights, to the extent allowed by law.
- A user can copy, modify, distribute and perform the work, even for commercial purposes, without asking permission. See Other Information below.

New copyrighted materials cannot be licensed commercially through Europeana. However, organizations using Europeana who want to retain and use some commercial copyrights can make the materials available elsewhere e.g. on their own websites and through commercial licenses.

To balance free public and royalty bearing commercial use an owner might use a freemium model e.g. allow a low resolution digital image to be freely downloaded, possibly also bearing a watermark and copyright marking; high resolution images would require an application, approval and a signed licensing agreement making clear the terms of use before they were released.

Outcomes

The ARMA collection is currently online under the **CC0 1.0 Universal Public Domain Dedication.** There is no indication of parallel commercial activity e.g. through a CC BY CA license linked to any one of the individual partners.

For more information see:

https://www.europeana.eu/en

https://www.medieval-reads.eu/home

Lessons Learned

A Freemium business model might suit museums and universities who want to be able to cover the costs of digitization and curation and/or to invest royalties back into research and educational activities.

Intervention points and associated tools:

1. Early rights clearance when creating/ identifying new copyrights.

Guiding tools: Rights clearance check list

2. Identifying the right business model for sustainability that fit the organizational culture.

Guiding tools:

- Guidelines on possible semi-commercial models and the internal stakeholder consultation process.
- Guidance note on CC BY CA and Freemium models.
- Comparator pricing examples and case studies.

3. Final Licensing T&D to support both commercial and non commercial use.

Guiding tools:

- Example licensing clauses.
- Possible automated licensing.
- Checklist for approvals.

6.1.3.6. Using an AI Model to predict crop yield

Background to the example

University College Dublin (UCD) developed and trained an AI model around weather and soil data to assist in prediction of crop yield. The project was supported by Science Foundation Ireland (SFI) and aimed to provide valuable insights for agricultural productivity. The outputs of the project were required to be transferred to the licensee as part of a collaboration agreement funded by the licensee and SFI. Various sources of historical statistical data were used to train the AI model, including from private data brokers under tailed made data supply contracts. This was a critical issue as the data needed to be free of any ongoing copyright or other ownership encumbrances so that the derived data and outputs of the work could be used for commercial purposes. The University Technology Transfer Office was aware that this was a critical aspect for the project and worked to ensure that the data contracts were customised and rigorous to ensure that the results could be freely used for the planned purposes. This included training of an AI model but also the need to allow PhD programmes to be completed and for researchers to publish, while keeping some critical aspects of the technology confidential. The issue of confidentiality was strongly managed as Universities typically find it a challenge to meet the legal requirements for keeping information confidential required under laws on 'trade secrets' e.g. in terms of the technical and procedural processes. This is important to the company as confidential aspects of AI models e.g. weights, epochs, and biases and the optimised hyperparameters are critical for competitive advantage and are not strongly protected by a patent. Special attention was therefore paid over the duration of the licensing agreement to consider what key features should be kept confidential. The Technology Transfer Office also investigated the issue of thesis embargo e.g. how long all or part of thesis could be kept off the open shelves.

Results

The work generated algorithms and parameters of an AI model as well as the associated training and test datasets developed to predict crop yield based on soil and weather data. The architecture, methods and algorithms were embodied in software that was maintained as confidential. The weights, epochs, and biases and the optimised hyperparameters of the AI model remain as confidential knowledge, as does the training datasets and the test datasets and the methodology around combining weather data and soil data for the purposes of the AI model.

IP assets and rights

Although the technology appeared patentable, a decision was made not to patent it due to the licensee's preference for confidentiality. The focus was on transferring the technology as know-how, (algorithms, parameters, datasets), ensuring some aspects remained confidential while allowing researchers to publish certain details.

Outcomes

- Successful transfer of know-how to the licensee under an exclusive licence in a specifically designed template licence that allowed access to know how as confidential information.
- As the licensee contributed much to the development, it was decided that royalties would only be payable above a certain threshold. The technology is currently being integrated into the licensee's platform.
- Embargoes and technical procedures ensured proprietary information remained confidential while allowing some academic publications.

Lessons Learned

- Various sources of data were used to train the AI model, including from private data brokers. Therefore, bespoke agreements had to be drafted and agreed such that any derived data from the data source was owned by the university and could be used to train any AI model for both academic and commercial use. It was also important to ensure that any Creative Commons (CC) licenses for public data that were accessed allowed for commercial use and for the data to be derived.
- Balancing commercial value and possibility to publish results of the academic research required involvement of Technology Transfer Officer as well as drafting some agreements in the initial stage of the project to maintain confidentiality while allowing necessary publications. In general, the Trade Secrets Directive is problematic for universities as they typically find it a challenge to meet the legal requirements required under laws on 'trade secrets' for keeping information confidential e.g. in terms of the technical and procedural processes confidentiality. PROs may be advised to refer to 'confidential information' rather than 'trade-secrets'.
- When using AI models a checklist outlining what key features can be kept confidential is useful.
- Because a PhD student had been involved it was important to understand the issues around a PhD publication embargo. Each university is likely to have different procedures around embargoing a thesis. It is important that the term of the licence does not exceed the length of period for which a thesis can be embargoed. Employed researchers should be made aware of their obligations using a Researcher Undertaking.
- Any relevant provisions around existing and emerging legislation e.g. the EU AI Act or counterpart US legislation need to be carefully considered.

Tools utilised:

- Custom agreements with data brokers
- Checklists to withdraw commercially valuable information from open publications.
- Confidentiality agreements and Researcher Undertakings.

6.1.3.7. Detection of Green-washing through AI-based Analysis

Background to the example

A team of experts in financial regulation, 'green washing' and analytics received funding from Enterprise Ireland to develop and commercialise a climate change mitigation greenwashing detection tool. This analyses the 'green' claims of companies worldwide and contrasts them with their actual emission performance.

Much of the data to develop such a model typically needs to be 'scraped' from the web.[1] This has implications because if copyright is attached to the scraped data then it may restrict use of both the data itself and derived data. The situation is changing rapidly with the development of legislation regulating AI. However, legislation also varies significantly between different territories including the EU, UK and USA. The US legal environment is currently more permissive than the UK and Europe regarding the use of copyrighted data due to the transformative fair use doctrine. But legislation in most other countries puts tighter restrictions on commercial use and this effects research that is then 'transferred' (commercialised).

The University Technology Transfer Office was aware that this was a potentially difficult legislative situation and were fortunately enough to have very specialised knowledge within the office.

Results

The technology developed thus far consists of a machine learning algorithm, with a claims analysis matched against greenhouse gases emission changes.

IP assets and rights

- Know-how, software, confidential information
- Copyright (in the software)) and potentially some patentable aspects.

Outcomes

- It is anticipated that the future beneficiary of the technology will be a spin out company that will sell insights to the financial sector around greenwashing.
- The business model is not yet, confirmed bur it is likely it will be one of AI as a Service (AIaaS) or Generative AI as a Service (GAIaaS).
- The project has developed a well-adapted AI management strategy .

Lessons learned

- While the project combined scientific research and plans for further commercialisation the first issue the project faced was how to protect commercial valuable information while allowing publication of findings. The balance was found in consultation with the University TTO.
- US and EU and UK law varies significantly with regard to the use of 'scraped' data. The transformative fair use doctrine in the US allows users, under certain circumstances, to use copyrighted data without the consent or renumeration of copyright holders. Transformative fair use has been particularly important for the training of certain types of AI models with data. In Europe the situation is more complex. Article 3 of the Directive on Copyright in the Digital Single Market (CDSM) allows for universities and cultural heritage entities to perform Text and Data Mining (TDM) and scrape data, regardless of the rights of copyright owners, for the public good and for "research" purposes. In contrast Article 4 of the CDSM allows any entity to also perform TDM, however, they are not permitted to do so if the copyright holder reserves its rights. This may

restrict transfer and use of any model from a publicly funded research team to a commercial company when it has been developed based on such data.

- In addition, Article 4 of the CDSM is the lynchpin for copyrights in the EU AI Act. This makes it complicated to commercialise research data and research teams need to be very aware of the implication of Articles 3 and 4 of the CDSM. Attention should be paid to how any data was scraped and whether copyrights holders' rights were maintained so that they will affect further use.
- There are provisions in the EU AI Act around how AI models deployed on the market are categorised from a rick perspective. and whether the AI model is "open source". Examples of applications classified as high risk would include, for example, medical devices utilising AI, along with critical infrastructure systems such as energy and water systems. High risk AI systems will need to adhere to significant compliance obligations. These include establishing a risk management system, providing accuracy, robustness and cybersecurity systems, ensuring data and data governance systems are in place, providing human oversight, ensuring transparency and the provision of information to users, and maintaining record keeping and technical documentation. A conformity assessment will be required before any high risk AI system can be put on the EU market. Special obligations also apply around General Purpose AI (GPAI) models Taking into account the rapid development of AI legislation, teams basing their products on AI should be aware of these regulations and their changes through all the process of the project development, revising the IP strategy as they go forward as necessary. I
- The ESG (Environment Social Governance) sector is becoming heavily regulated. All new documents should be considered. This may require the involvement of professional lawyers.

Tools utilized:

- Internal guideline to see if the idea was suitable for commercial or non-commercial licensing.
- Tools and methods employed to scale, market, and valorise the result.
  Technology-adapted Invention Disclosure Forms (IDF).
- Confidential Information agreements.
- Internal database of all the legislation acts corresponding to digital products and AI usage (including Directive on Copyright in the Digital Single Market, EU AI Act, etc.).

[1] Web scraping, also known as web data extraction or web harvesting, is the process of automatically collecting data from websites and storing it in files or spreadsheets.

6.2. Co-Creation Examples

6.2.1. Transparent Transportation

Company A offers transportation services to customers who have a legal right to use more tailored services than, e.g., public transportation. Thus, their customer segments vary, for instance, from young to old with different disabilities, such as physical, or mental health problems. Approximately 50 % of trips are made by customers over the age of 65.

The Company organises around 500.000 trips per year and most of these trips are ordered by calling its customer service advisors. When everything goes smoothly, one phone call is enough to get customers from A to B in carpool-style. This is known as a 'routine call'. When, however, the car is late or the driver cannot find customers from the agreed spot, things get more difficult, and more phone calls need to be made.

When the number of routine calls is combined with the additional calls, the average number of calls the customer service receives in one year rises to 400.000. This has a major impact on call queue time and negatively affects the customer experience.

Co-creation challenge

Company A wanted to explore how they could optimise the call process and improve the customer experience. Specifically, to demonstrate what a next generation ride-hailing, accessible service would look like. They wanted to see how they could offer their customers a service experience that is smooth and efficient for all. and how can they help their customers in the exceptional cases when, e.g., a car is late due to traffic. They also wanted to know what kind of digital solutions are out there already or in the future that could help them reduce the calls in general but still help the diverse needs of their customers.

Co-creation Process

Sponsor: Company A (mobility services)

Facilitator: The co-creation action was facilitated by experts from organisation Demola in Finland.

Team: The team included 6 students from different fields of study ranging from software development to usability and social sciences.

Motivation: Participants, mostly university students choose projects that fell into the area of their interests, so they are applying for interesting and collaborative projects where they can work with real organisations. Personal attitude makes a huge difference in the quality of the project outcomes and project workflow. The participants are selected based on the balance between their experience and motivation: the stronger the desire to learn, contribute and test multiple ideas, the easier it is for the participants to advance their knowledge and skills. This has a direct influence on the quality of the results and participants' confidence in pitching their solution to different stakeholders.

Goal: The goal of the co-creation project was to create demonstrations of value-adding future services and solutions to demonstrate how a next generation ride-hailing, accessible service could look like.

Stakeholders: The student team involved end-users in the development of the service e.g. people in need of more accessible mobility services. They participated in validation of the problems and solutions.

Duration: The project lasted around 10 weeks.

Contractual aspects: Company A signed a partner agreement with Demola. This laid out the non-exclusive terms under which they would be granted access to the results.

The students signed the Demola team agreement which agrees the basic foundations of IPR management and license conditions with the team, Demola and the partner organization. This included how any possible payments for exclusive access to results would be divided between team members.

Tools and approach: Demola offers university students the opportunity to do meaningful project studies as part of interdisciplinary team and international community. The co-creative design-thinking process was directly articulated with facilitation process.

IP: The main IP generated was the user interface design and the associated background material. The results were generated by the student team but where was crucial for the partner to develop the next generation of their service

Results

The main results were the compete re-design of the already existing ride-hailing solution. The team designed everything from ground up from accessibility in mind and thus transformed the way the service functions.

Access model

After the end of the project the partner was automatically granted a non-exclusive license to the results; this was the default situation set out in the up-front agreement. This meant that the student team could do whatever they wanted as the owners of the IP. However, Company A wanted to secure exclusive rights to the results and decided to offer a lump sum of money to the team. The team accepted and shared the money according to their team agreement between the team members (in this case equally).

Lessons learned

- Motivation plays a very strong role when engaging a team. It is crucial to shift the focus from the company brand or possible recruitment decisions to the actual work in the project.
- Setting a fair up-front price for the 'results' is challenging because is it hard to predict final value. It may be better to agree a fair acquisition fee for exclusive rights after the project ends so that there is a fair negotiation for both parties.

Intervention points and guiding tools

Key intervention points and actions for transfer of the Good Practice (GP)

Intervention points	Stakeholder(s) involved	Importance
The problem to be solved has been identified and defined	*Company*	*Co-creation activities are effective and projected.*
Contractual model before co-creation activities start	*Company, facilitator, co-creators*	*Clear agreements on IP, background material, and the scope of contributions ensure all parties understand their rights and obligations before co-creation begins.*
A decision according to the agreement	*Company, Co-creators*	*Negotiation point about the licensing of the solution, especially regarding exclusivity rights. Ensuring fair negotiation practices was crucial for a balanced agreement.*
Investments on further development	*All stakeholders with IP rights*	*A collective understanding of IP ownership, future investments, and freedom to operate is needed for further development and market deployment of the solution.*

Issues to address in tool development

- **Avoid dominance:** How can the resource, ability, competence and power differences of the parties participating in co-creation be equalized?
- **Valuation of IP at Early Stages**: How can the value of IP be estimated early in the co-creation process, and how might the final outcome influence IP valuation, especially when one party seeks exclusive rights?
- **Ensuring Fair Negotiations**: How can all parties, regardless of their position, resources, or bargaining power, engage in fair negotiations? This includes ensuring that weaker parties are not overshadowed during decision-making.
- **Monitoring Shared IP Utilization**: How can entities and individuals track the utilization and further development of shared IP to protect their interests?

List of possible tools to be developed based on this case:

- **Agreement Model Selection Tool**: A tool to help co-creators choose the appropriate agreement model based on the nature of their project and expected contribution.
- **Rights Management Database**: A system to track and manage IP rights, ensuring clarity on ownership and licensing terms for all parties involved.
- **Agreement Templates**: Ready-to-use contract templates tailored for co-creation projects.
- **Guide for Co-Creation Participants**: A comprehensive guide to help (new) participants understand the principles of co-creation, IP management, and negotiation strategies to ensure fair and transparent collaboration.

6.2.2. Maintenance and Augmented Reality (AR)

Background to the example

Company B works in the field of business automation and in particular VR (Virtual Reality)/ AR (Augmented Reality) solutions for factory automation and maintenance.

The connection and interaction of people, machines, and processes are transforming industry. The automatization of processes optimizes the entire value chain, improving quality, productivity, responsiveness, and reducing costs maximizing profitability.

This transformation requires a strong interaction between man and machine, which augmented reality (AR) supports. This technology allows the perception of physical and digital elements to overlap and interact and manipulate them in a real industrial environment.

This physical and virtual objects interaction is achieved using visualization devices, like smartphones, tablets, or special glasses (Smart glasses). Smart glasses allow an operator to follow augmented reality instructions and freely use their hands for practical operations.

Co-creation challenge

Company A wanted to explore different VR/AR solutions for factory automation and maintenance as applied to their main areas of work (product supply and maintenance):

Products supply: AR intends to give advanced instruction and real-time guidance in this area, with step-by-step visualization of a given procedure. Through a tablet, smartphone, or smart glasses, the operator can access virtual libraries, videos, 3D animations and follow all the steps.

Maintenance: AR allows partner collaborators to check preventive maintenance processes and to identify and correct equipment failure or malfunction.

Co-creation Process

Sponsor: Company B (Machine & factory automation)

Facilitator: The co-creation action was facilitated by experts from organisation Demola in Finland.

Team: The co-creation team consisted of 5 students from different fields of study ranging from automation tech to media and software development to social sciences.

Motivation: All those involved were primarily motivated by the topic.

Participants, mostly university students choose projects that fell into the area of their interests, so they are applying for interesting and collaborative projects where they can work with real organisations. Personal attitude makes a huge difference in the quality of the project outcomes and project workflow. The participants are selected based on the balance between their experience and motivation: the stronger the desire to learn, contribute and test multiple ideas, the easier it is for the participants to advance their knowledge and skills. This has a direct influence on the quality of the results and participants' confidence in pitching their solution to different stakeholders.

Goal: The goal of the co-creation project was to innovate different concepts and solutions for utilizing VR/AR technologies in a factory environment to support the work of maintenance experts.

Stakeholders: End-users, in this case factory maintenance experts participated in validation of the problems and solutions.

Duration: The project lasted around 10 weeks.

Contractual aspects:

Company A signed a partner agreement with Demola. This laid out the non-exclusive terms under which they would be granted access to the results.

The students signed the Demola team agreement which agrees the basic foundations of IPR management and license conditions with the team, Demola and the partner organization. This included how any possible payments for exclusive access to results would be divided between team members.

Tools and approach: The target was to create demonstrations of value-adding future services and solutions. the main challenge was to decide how much of the student team's time should be invested in understanding the partner's business and how much they should look at the problems with "fresh" eyes. The co-creative design-thinking process was directly articulated with facilitation process.

IP: The team created a number of small concepts and demonstrators that could have been turned into invention reports or patents. This route was not followed (see below – lessons learned).

Results

The team created several different demonstrations of how to use VR/AR tech in factory maintenance.

Outcomes

The partner did not find the specific solutions useful immediately but used the process to identify new talents from fields they have not previously recruited

Lessons learned

Motivation plays a very strong role when engaging a team. It is crucial to shift the focus from the company brand or possible recruitment decisions to the actual work in the project.

Co-creation offers a strong basis to explore and showcase an individual's skills and in particular soft skills.

When the licensing conditions are clear from the very beginning, then company representatives and team can focus on the work and skills rather than the legal framework.

Access model

Under the co-creation agreement, Company B got a license to utilize the results.

Intervention points and guiding tools

Key intervention points and actions for transfer of the Good Practice (GP)

Intervention point	Stakeholder(s) involved	Critical aspects
Agreeing on access conditions for results at the beginning	*All stakeholders*	Avoid misunderstandings, misinterpretations and surprises at the end of the co-creation and post-co-creation phases
Tracking of emerging results and fair pricing	*All stakeholders*	Brings transparency and trust for all stakeholders involved co-creation.
Recruitment process	*Company, Co-creators*	*A situation where instead of direct IP rights, the activities focus on the transfer of know-how and experts. Is recruitment used as a tool to bypass IP rights?*
Knowledge transform during and after co-creation	*All stakeholders*	*Interaction during the co-creation process, development of understanding, exchange of background information and communication between stakeholders.*

Issues to address in tool development

- **Soft Skills Exploration**: Co-creation offers a valuable environment for participants to showcase their soft skills (teamwork, communication, adaptability) or expert services (For example, acting as an independent consultant)
- **Avoiding IP Bypassing through Recruitment**: Tools need to take account for situations where recruitment or other bilateral assignments are used to bypass or ignore IP agreements or licensing frameworks. This could be a potential risk for all stakeholders.
- **Clear Licensing Conditions:** Starting with a simple, transparent licensing process ensures everyone can focus on innovation and skill development, without getting stuck in legal details later on.Tools should support this by highlighting individual contributions beyond the technical results.
- **Direct Knowledge Transfer and Communication**: Tools should facilitate smooth knowledge exchange between all stakeholders participating co-creation, ensuring the expertise shared during the process is retained and utilized.

List of possible tools to be developed based on this case:

- **Recruitment Impact Tracking Tool:** A tool designed to monitor how recruitment decisions are made in post-co-creation phase to prevent misuse of hiring to bypass IP negotiations, conditions or obligations.

- **Agreement Model Selection Tool**: This tool will help participants choose the right type of agreement based on the nature of the co-creation project and its objectives, ensuring a shared understanding of IP rights and access conditions from the beginning.
- **IP and Rights Tracking Database**: A platform that tracks IP ownership, created results, and licensing agreements. This ensures that all stakeholders can see and validate who contributed what and how IP is being used.
- **Competence and Outcome Evaluation Tool**: A tool to assess the indirect benefits of the co-creation process, including competence development, risk mitigation, and technological test and validations.

6.2.3. Improved drug delivery system

Background

Co-creation project was part of an EU-funded academy-industry research initiative aimed at improving drug delivery systems. Some medical molecules currently require injection, which is not always ideal for patients. Certain types of molecules used for medical purposes can currently only be administered via injection. This administration is suboptimal for many people who could benefit from these medicines. Biomaterials and novel medical devices that allow these drugs to be delivered via alternative routes, such as under the tongue, may represent a better alternative.

This project is a proof-of-concept project with six work packages (development; validation; manufacturing; health technology assessment; dissemination; and project management). It is all in the preclinical phase with a major focus on design of new ways to deliver these important types of drugs.

This Horizon Europe funded research project is ongoing.

Challenge

Co-creation was predominantly in design and design iteration phases to enable researchers/engineers to make device as user friendly/sensitive to user needs as possible.

The project has established both a scientific advisory board and an end-user advisory board (EUAB).

The EUAB consists of:

- Four people with lived experience (LE) of taking the injectable version of the drug (or similar).
- A specialist in public and patient involvement in research
- Communications advisor of the project
- Co-ordinator/lead of the project
- Project researchers (rotating)

The work to establish the EUAB started within the first six months of the project. The board was in place with agreements by approx. 18 months into the project. The collaboration and NDA agreement was iteratively developed to protect the information shared by the LE members in addition to the research information shared.

A process of coproduction was undertaken to align the interests and skills of the LE EUAB members with the project work packages. In addition to the EUAB meetings where LE members gave input and suggestions to the project work presented, they also carried out discrete tasks offline.

Design WP: Significant insight being given on the factors important to potential end users of the device. This includes a number of lifestyle factors that had not been considered by the researchers but could impact the suitability of materials used.

Health Technology Assessment (HTA): Reviewing and revising the patient preference questionnaire being designed to inform the HTA and health economics stream. These revisions were adopted by the project team and made the questionnaire easier to read and understand, thereby increasing the quality of data collected.

Communications and dissemination: Significantly improved the use of patient-preferred terms both in formal communication but also by the individual researchers. Helped the researchers to understand how to get the pitch of their public communications correct. In a multidisciplinary consortium this benefits the whole consortium in addition to the public.

The co-creation is ongoing. The researchers on this project are relatively new to co-creation and the involvement of people with lived experience. As they see the benefits, upskill themselves, and gain confidence in their collaborations with end users it is foreseen that the co-creation will deepen over time.

Outcomes

The co-creation project has successfully advanced the development of an improved drug delivery system while fostering collaborative partnerships and enhancing user engagement. The outcomes not only demonstrate technological innovation but also contribute to a more patient-centered approach in medical device development, laying the groundwork for successful future commercialization.

License

IP terms were set out in advance of consortium project as part of the collaboration agreement. No IP rights for end user members of the consortium.

Lessons Learned

Engaging end users from the outset helps ensure that their needs and preferences are prioritized in the design process. Establishing an End-User Advisory Board (EUAB) early in the project facilitated valuable input that significantly shaped the product design and functionality.

Clear communication and agreements regarding roles, responsibilities, and expectations among all partners are essential. Establishing clear collaboration and NDA agreements at the beginning of the project helped protect intellectual property and facilitated open dialogue among participants.

Recognizing and valuing the diverse contributions of all stakeholders, including patients, researchers, and industry partners, enhances collaboration and innovation. Motivation and specific features of all stakeholders should be considered. Contributions from individuals with lived experience provided critical insights that researchers had not considered, demonstrating the value of a multi-perspective approach.

Intervention points:

At the beginning of the project, it is essential to clearly define how IP rights will be managed, especially given the diverse set of contributors (academia, industry, SMEs, and end-users). Ambiguity at this stage can lead to disputes later.

As the design of the drug delivery device evolves, new IP (such as patents for design innovations or material uses) may emerge. Regular reviews help manage these evolving assets.

End-users (via the EUAB) provide valuable insights that can directly influence product design and other IP-generating elements, such as user-interface designs or process improvements.

Multiple academic, industry, and SME partners contribute to the project, potentially leading to shared IP. Clear structures for how shared IP will be managed and who gets the commercialization rights are necessary.

Associated tools:

Establish IP ownership, licensing terms, and revenue-sharing agreements that account for contributions from different parties.

Protect confidential information shared by both the lived experience members and researchers to avoid potential IP conflicts down the road.

Software or processes to track contributions and emerging IP throughout the project lifecycle.

For innovations identified during the design phase, provisional patents can secure early rights before full commercialization.

Establish clear rules around the ownership and use of contributions from end-users, ensuring that insights and feedback are respected as valuable contributions.

Consider royalty agreements where end-users (LE members) may receive royalties for innovations directly stemming from their input, especially if they significantly shape the final product.

Checklist/guidelines to see if the idea was suitable for co-creation.

Intervention points and guiding tools

Key intervention points and actions for transfer of the Good Practice

Intervention point	Stakeholder(s) involved	Critical aspects
Defining IP Rights Early	*All stakeholders*	*It's important to establish how IP will be managed from the start to avoid any confusion as the project progresses.*
Regular Reviews of Design Evolution	*All stakeholders*	*As the co-creation and solution design progresses, reviewing potential new IP opportunities, such as device patents, helps protect emerging innovations.*
Valuing End-User Input	*All stakeholders, end-user participants*	*Insights from the End-User Advisory Board contributed directly to product improvements and could generate IP opportunities.*

Issues to address in tool development

- **Consortium Management Tools:** Given the complexity of a multi-partner consortium, tools should support transparent tracking of contributions, roles, and evolving IP. Regular progress updates and input tracking are essential to ensure alignment between academia, industry, and end-users.
- **Distinction Between Feedback and Innovation**: Tools should help clarify when end-user feedback crosses into the category of innovation. Feedback may improve usability, while innovation (such as suggesting new functionalities or materials) could influence the product's IP landscape. The system should document these issues to handle IP fairly.
- **Role of End-User Innovation in IP:** Tools should help project teams assess whether ideas proposed by end-users (through advisory boards or other input channels) are considered general feedback or genuine innovative contributions that requires IP protection
- **Fair Credit and Compensation for End-Users:** End-users providing innovative ideas should receive fair recognition and potential compensation for their contributions. Tools need to ensure these contributions are tracked and considered in IP and commercialization discussions.

List of possible tools to be developed based on this case:

- **IP Management Platform for Consortiums:** A tool designed for consortium-type projects, enabling partners to track contributions from academia, industry, and end-users. It would integrate confidential information sharing and track ideas as they develop into potential IP asset, like product features.
- **Feedback vs. Innovation Tracker:** A system that categorizes end-user contributions, distinguishing between usability feedback and innovative ideas that may have IP implications. This helps in recognizing valuable inputs that may influence the product's design, features or functionality.

- **End-User Contribution Recognition Tool**: This tool tracks transparently tracks contributions made by end-users and ensures fair compensation, if those contributions leads to innovation. It could integrate royalty agreements or other incentive mechanisms if innovations from end-users become part of the final product.
- **Confidentiality and Data Protection Dashboard**: A tool for managing and enforcing NDAs within the consortium, ensuring that sensitive research data, and end-user feedback, are handled and protected throughout the co-creation process.

6.2.4. Wearable Technologies for smart car interiors

Background to the example

Company A is operating in the automotive industry. Now that electric cars are becoming more common, drastic technological change can be seen in the car industry. Cars are changing from transportation vehicles into technology and software platforms. This enables cars to play a more robust and varied role in our daily lives. In response to their opportunities, the interior of the car increasingly needs to adapt to these varied use cases.

Co-creation challenge

The aim of the project was to create visual concepts and concrete demos of how future cars utilize varied technologies to add whole new dimensions and use cases for our daily lives. In particular, smart sensors and visualization of the interior of the cars.

The company wanted to investigate how they might utilize technologies like flexible screens, e-ink and wearable technologies in the interior design of cars (seats, consoles, doors..) to provide added value for the owners. How might these technologies make cars more flexible environments? What are the potential use cases for cars in the future? For example, how could cars act as personal office space, entertainment hub or a person's own living room?

Co-creation Process

Sponsor: Company A (automotive industry)

Facilitator: The co-creation action was facilitated by experts from organisation Demola in Finland.

Team: The team included 6 students from different fields of study ranging from software development to usability and media & arts.

Motivation: Participants, mostly university students choose projects that fell into the area of their interests, so they are applying for interesting and collaborative projects where they can work with real organisations. Personal attitude makes a huge difference in the quality of the project outcomes and project workflow. The participants are selected based on the balance between their experience and motivation: the stronger the desire to learn, contribute and test multiple ideas, the easier it is for the participants to advance their knowledge and skills. This has a direct influence on the quality of the results and participants' confidence in pitching their solution to different stakeholders.

Goal: The goal of the co-creation project was to create visual concepts and concrete demonstrators of how future cars might utilise new technologies like flexible screens, e-ink and wearables to add new dimensions and use cases serving daily lives. The target was to create demonstrations of value-adding wearable technologies.

Stakeholders: The student team involved end-users in the validation of the problems and solutions.

Duration: The project lasted around 10 weeks.

Contractual aspects: Company A signed a partner agreement with Demola. This laid out the non-exclusive terms under which they would be granted access to the results.

The students signed the Demola team agreement which agrees the basic foundations of IPR management and license conditions with the team, Demola and the partner organization. This included how any possible payments for exclusive access to results would be divided between team members.

Tools and approach: Demola offers university students the opportunity to do meaningful project studies as part of interdisciplinary team and international community. The co-creative design-thinking process was directly articulated with facilitation process.

IP: Company A identified a few functionalities in the demonstrations that they wanted to patent. They filed the invention reports and paid the team members and invention fee according to their internal company policies. Company A had to decide between acquiring all the IPR from the team to only patenting the relevant parts of the solution. They concluded that they didn't need the full IPR and still the student team could get value out of well-made results.

Results

The main results were 3 different stand-alone prototypes of wearable technologies to demonstrate the full scenarios of their usage.

Lessons learned

Mapping the different aspects of the results would be beneficial as many companies don't know how to patent or realize the potential of patenting just small parts of the whole IP that can emerge from such a project.

Setting a fair up-front price for the 'results' is challenging because is it hard to predict final value. The company A had to decide between acquiring all the IPR from the team to only patenting the relevant parts of the solution. In this case the company decided to file internal company invention reports and pay the team members an invention fee according to the internal company policies. The company concluded that they didn't need the full IPR so the student team could keep the rest of it. It may be better to agree a fair acquisition fee for exclusive rights after the project ends so that there is a fair negotiation for both parties.

Access model

After the end of the project the partner was automatically granted a non-exclusive license to the results; this was the default situation set out in the up-front agreement. This meant that the student team could keep their rights as well as the owners of the IP. However, Company A wanted to secure exclusive rights to the results and decided to offer a lump sum of money to the team. The team accepted and shared the money according to their team agreement between the team members (in this case equally). During the acquisition process company A decided not to acquire all the IPR from the team and only patenting the relevant parts of the solution. They concluded that they didn't need the full IPR so the student team could get value out of the rest of the result.

Intervention points and guiding tools

Key intervention points and actions for transfer of the Good Practice

Intervention point	Stakeholder(s) involved	Critical aspects
Licensing Decision (Before Project)	*All stakeholders*	*Decide on upfront licensing conditions.*
Results Evaluation (During Project)	*All stakeholders*	*Identify and map patentable or valuable innovations.*
Protecting or Patenting Decision (Post-Project)	*All stakeholders*	*Determine which parts of the project to patent*
Exclusive Licensing and Pricing (Post-Project)	*All stakeholders*	*Negotiate exclusive rights and fair acquisition fees.*
Post-Project Feedback (After Licensing)	*All stakeholders*	*Evaluate and improve the co-creation process, feedback and evaluation mechanisms.*

Issues to address in tool development

- **Tracking Contributions**: A tool is needed to track contributions from all team members and ensure that innovation or patentable ideas are documented properly.
- **Fair Value Determination:** There needs to be a system in place to help determine the value of different parts of the solution, especially when deciding on pricing or licensing terms after the co-creation activities.

List of possible tools to be developed based on this case:

- **IP Mapping Tool**: A tool to map the different aspects of project results, helping stakeholders to identify which parts can be patented and which parts should remain open for use by the other stakeholders.
- **Contribution Tracking System**: A system that tracks individual contributions, ensuring that all co-creators are properly credited for their ideas and efforts, especially when IP is involved.
- **Patent Decision Support Tool**: A system that helps companies or stakeholders decide which parts of the solution to patent, and whether they need exclusive or non-exclusive rights.

6.2.5. Developing new ways of lead generation in insurance industry

Background to the example

Company A is a leading non-life insurer with a strong presence in the region – the largest branch network among insurers with a loyal customer base. Branch sales (sales on the spot, in the office) is the main reason for an impressive market share in household property insurance. Banks are growing significantly as a sales channel for household property.

Market penetration is very low despite relatively low insurance cost (e.g. 50-60 EUR a year for 60m2 apartment). The estimate is that just 1/3 of all households in country have insurance. It is common practice that rather than taking protective measures by seeking up insurance, people are counting on post-incident support from municipalities or charity institutions e.g. in the case of severe accidents such as fire.

Co-creation challenge

Company A wanted to investigate how to make people more aware of the risks to household property and the availability of low-cost solution that is insurance and how to get them to respond to increased awareness by taking out insurance. They also wanted to understand what the barriers were to people seeking insurance actions when awareness of the risk and solution was clearly established and how best to overcome these barriers.

Co-creation Process

Sponsor: Company A from the insurance sector.

Facilitator: The co-creation action was facilitated by experts from organisation Demola in Finland.

Team: The co-creation team consisted of 6 students from different fields of study ranging from software development to finance and user experience design.

Motivation: Participants, mostly university students choose projects that fell into the area of their interests, so they are applying for interesting and collaborative projects where they can work with real organisations. Personal attitude makes a huge difference in the quality of the project outcomes and project workflow. The participants are selected based on the balance between their experience and motivation: the stronger the desire to learn, contribute and test multiple ideas, the easier it is for the participants to advance their knowledge and skills. This has a direct influence on the quality of the results and participants' confidence in pitching their solution to different stakeholders.

Goal: The goal of the co-creation project was to demonstrate concepts for fresh interfaces for insurance company customers.

Stakeholders: The student team involved customers of the insurance services in the validation of the problems and solutions.

Duration: The project lasted around 10 weeks.

Contractual aspects: Company A signed a partner agreement with Demola. This laid out the non-exclusive terms under which they would be granted access to the results.

The students signed the Demola team agreement which agrees the basic foundations of IPR management and license conditions with the team, Demola and the partner organization. This included how any possible payments for exclusive access to results would be divided between team members.

Tools and approach: The co-creative design-thinking process was directly articulated with facilitation process.

Results

The main result was the new interface for customers to manage existing and purchase new insurance services.

Access model

Access was laid out in the co-creation agreement. This allowed for access by both the company and the student team. The main thing the commercial partner licensed was the conceptual logic of the service and the graphical elements of the implementation.

Lessons learned

The student team included 3rd party material in their solutions/ demonstration purposes – in particular graphical elements. Such use of 3rd party material for demonstration purposes in permitted and even encouraged by the co-creation process, but the team failed to communicate during the co-creation to the partner which parts of the demonstration were 3rd party materials. This led to significant problems for the partner when they implemented parts of the results into their existing services only to discover that they had used IP to which they did not have agreed access. This issue should have been identified and flagged up at a very early stage of the co-creation process.

Intervention points and guiding tools

Intervention points and actions for transfer of the Good Practice

Intervention point	Stakeholder(s) involved	Critical aspects
IP Auditing and Transparency (During Development)	*All stakeholders*	*The issue with 3rd-party materials was a significant problem that could have been avoided through ongoing IP audits.*
Clear Communication on IP Usage (Early Project Stages)	*All stakeholders*	*The use of 3rd-party content should have been flagged early on to avoid complications. Transparency in the source of materials is critical for avoiding legal issues.*
IP Ownership and Risk Assessment (Before Implementation)	*Owner of the IP*	*The company discovered IP issues only after starting to implement the solution. A formal IP ownership review before project completion would have helped avoid this risk.*

Issues to be addressed in Tool Development

- **IP Compliance and Transparency:** Tools must ensure that 3rd-party materials used in project results are clearly documented and communicated to all parties.
- **Risk of Unintentional IP misuse:** The toolset should help co-creation teams avoid using IP they don't own or have permission to use.

- **Documentation and Licensing**: A clear, ongoing record of IP ownership and licensing agreements must be maintained, to avoid problems later in the project lifecycle.
- **Clear Communication Protocols:** Establishing formalized communication channels to ensure all stakeholders are aware of the IP status throughout the project.

List of possible tools to be developed based on this case:

- **IP Auditing Tool**: A system that regularly checks the IP used throughout the project, highlighting any potential issues related to 3rd-party IP, content or ownership.
- **IP Ownership and Risk Assessment Tool**: A framework that guides teams through evaluating potential IP risks before project outcomes are commercialized.
- **Communication Tracker for IP**: A tool for clearly documenting the source of materials, ensuring that teams mark whether content is original, licensed, or borrowed from 3rd-party sources.
- **Results Evaluation and IP Mapping Tool**: A post-project tool to track the long-term usage of the co-creation outputs and ensure that IP issues are resolved during the implementation phase.
- **Licensing Decision Tool**: A guide that assists teams and partners in navigating licensing agreements, ensuring clarity on rights and responsibilities for all parties involved.

6.2.6. High-speed camera capturing

Background to the example

Company A was based in the field of research-intensive high-tech business. They were aware that, until recently, camera speeds were only allowing users to capture the beginning and the end of certain processes; they were not able to capture what happened in between. Significant changes in camera technology had opened up new opportunities for use e.g. the ability to capture the explosion of firecracker or popcorn kernel or critical moments in welding processes. The company wanted to obtain insights into the different domains where this new technology could be used in the media and advertising industry.

Co-creation challenge

The company wanted to identify different use cases that could promote the opportunities offered by this technology. What might be the business opportunities if they could capture? What was currently 'missing'? Was there an existing need already that they were not aware of yet? What different phenomena could be captured with this technology?

Co-creation Process

Sponsor: Company A from the sector of research-intensive high-tech business.

Facilitator: The co-creation action was facilitated by experts from organisation Demola in Finland.

Team: The team consisted of 4 students from different fields of study ranging from marketing, imaging tech and media studies.

Motivation: All those involved were primarily motivated by the topic. Participants, mostly university students choose projects that fell into the area of their interests, so they are applying for interesting and collaborative projects where they can work with real organisations. Personal attitude makes a huge difference in the quality of the project outcomes and project workflow. The participants are selected based on the balance between their experience and motivation: the stronger the desire to learn, contribute and test multiple ideas, the easier it is for the participants to advance their knowledge and skills. This has a direct influence on the quality of the results and participants' confidence in pitching their solution to different stakeholders.

Goal: The goal of the co-creation project was to demonstrate concepts for new marketing focused use cases for high-speed camera capturing.

Stakeholders: End-users were included in the validation of the problems and solutions.

Duration: The project lasted around 10 weeks.

Contractual aspects:

Company A signed a partner agreement with Demola. This laid out the non-exclusive terms under which they would be granted access to the results.

The students signed the Demola team agreement which agrees the basic foundations of IPR management and license conditions with the team, Demola and the partner organization. This included how any possible payments for exclusive access to results would be divided between team members.

Tools and approach: The co-creative design-thinking process was directly articulated with facilitation process.

IP: The main IP assets created were the different use cases and concepts of consumer marketing utilizing the technology.

Results

The main results were multiple concepts on how to use the high-speed camera capture to show previously unseen phenomena regarding consumer products.

Access Model

The results were ground-breaking for the partner's future business strategy and under the contract they had the right to exploit them. However, it was also clear to them that they didn't have the internal competences to exploit, regarding marketing expertise. After discussions with the student team it was agreed to establish a joint venture to "spin-out" the consumer marketing focused business from the high-tech research business. This was a win-win situation where the team got to continue their work on the topic and the partner could bring the technology and some financial backbone for the newly established company.

Lessons learned

Forming a diverse team with different skills and experience was crucial for the outcome. The selected student team was extremely focused on marketing. This was not an area of strength for the company.

It took some time to build the confidence of the student team and trust between the different parties before they were ready to commit to a joint venture commercialisation path with the company partner. Building trust and confidence was critical for the selected route to market.

Intervention points and guiding tools

Intervention points and actions for transfer of the Good Practice

Intervention point	Stakeholder(s) involved	Critical aspects
Joint Venture Anticipation	*All stakeholders*	*Identifying the potential for a joint venture at the beginning of the project to facilitate smoother transitions later on.*
Support for Establishment	*All stakeholders*	*Actively assisting in the formation of the joint venture as the project concludes to capitalize on the developed IP.*
Team Dynamics Assessment	*Owner of the IP*	*Regularly evaluating team interactions to foster trust and collaboration among diverse stakeholders.*

Issues to be addressed in Tool Development

- **Trust-Building Mechanisms:** Development of tools that facilitate exercises aimed at building trust and rapport among project stakeholders
- **Commercial Route Identification:** Tools that assist teams in identifying and evaluating potential market opportunities for their innovations.
- **IP Rights Management:** Resources that help manage and document IP rights and obligations throughout collaborative ventures to mitigate risks.

List of possible tools to be developed based on this case:

- **Joint Venture Planning Tool-kit:** A set of resources designed to guide teams through the process of establishing a joint venture, including templates and best practices.
- **Technology Transfer Framework:** A structured approach that outlines the steps for effective technology transfer between industries, ensuring alignment and clarity.
- **Trust-Building Workshop Tool:** A facilitation guide for conducting workshops aimed at enhancing trust and collaboration within project teams.
- **Market Opportunity Evaluation Tool:** A tool that helps teams assess and prioritize potential commercial routes for their innovations based on market needs.
- **IP Rights and Obligations Tracker:** A system for maintaining ongoing records of IP rights, responsibilities, and agreements among project partners.

6.2.7. Expanded broadcasting

Background to the example

The future of television is in live-tv, which will engage consumers in a new way to participate directly with the content they are using. Company A was a large player in the media industry, searching for new web concepts that create new brands or expand the existing (TV) ones.

Co-creation challenge

Company A wanted to identify and explore 'consumer-alluring' and a competitive way to spend time, in an emotional and entertaining way. Their focus was identifying ways that a consumer can share her/his experiences with other users and participate through additional screen interface like mobile phone or tablet (Second Screen Dimension). Live entertaining tv-shows, sports events, festivals are a few examples of the formats they wanted to consider. In additional, their ideal app would be available independent of platforms, be simple and easy to use and free of charge for the consumer.

Co-creation Process

Sponsor: Company A (large media industry player)

Facilitator: The co-creation action was facilitated by experts from organisation Demola in Finland.

Team: The co-creation team consisted of 4 students from different fields of study ranging from signal processing, UX design and software development.

Motivation: Participants, mostly university students choose projects that fell into the area of their interests, so they are applying for interesting and collaborative projects where they can work with real organisations. Personal attitude makes a huge difference in the quality of the project outcomes and project workflow. The participants are selected based on the balance between their experience and motivation: the stronger the desire to learn, contribute and test multiple ideas, the easier it is for the participants to advance their knowledge and skills. This has a direct influence on the quality of the results and participants' confidence in pitching their solution to different stakeholders.

Goal: The goal of the co-creation project was to demonstrate solutions to engage and enable participation of live show audiences into a programme.

Stakeholders: End users

Duration: The project lasted around 10 weeks.

Contractual aspects:

Company A signed a partner agreement with Demola. This laid out the non-exclusive terms under which they would be granted access to the results.

The students signed the Demola team agreement which agrees the basic foundations of IPR management and license conditions with the team, Demola and the partner organization. This included how any possible payments for exclusive access to results would be divided between team members.

IP: The main assets were the source code for the early phase demo of the tool and further development concepts.

Results

The main result was an AI-powered "sensing" tool for Twitter (now X) to sense the larger audiences' feelings and attitude towards the action on the live show.

Lessons learned

The project topic was extremely broad, so the team spent lots of time looking for different applicable use cases. In hindsight the project could have been designed to more specific context.

Having the partner and facilitators build the confidence of a student team is critical to ensure that they are bold enough to test the start-up path. In this respect, hearing “seasoned veterans” saying that the solution might have ‘legs’ hugely increased the chances of the team continuing to develop the results.

The results were exciting for the partner, but as big media industry player they feared the solution would not be developed further fast enough within the company and a route to market that replied solely on their direct exploitation of results might have failed.

Access model

Due to the concerns of the media company that the internal environment would not be agile enough to allow the solution to be developed sufficiently quickly they agreed with the co-creation team that the team would set up a start-up to continue the development. The company positioned themselves as the start-up’s first customer, able to offer huge visibility for the solution in their upcoming live shows.

Intervention points and guiding tools

Intervention points and actions for transfer of the Good Practice

Intervention point	Stakeholder(s) involved	Importance
Joint Venture Anticipation	*All stakeholders*	*Identifying the potential for a joint venture at the beginning of the project to facilitate smoother transitions later on.*
Support for Establishment	*All stakeholders*	*Actively assisting in the formation of the joint venture as the project concludes to capitalize on the developed IP.*
Team Dynamics	*All stakeholders*	*Regularly evaluating team interactions to foster trust and collaboration among diverse stakeholders.*

Issues to be addressed in Tool Development

- **IP Ownership and Clarity:** Tools should help ensure clarity in IP ownership when projects transition to start-up models for further development.
- **Supporting the Start-up Journey:** Tools must be developed to assist co-creators in managing the complex transition from co-creation project to start-up, including legal, financial, and operational aspects.
- **Fast-tracking Innovation:** There is a need for tools that help assess and select the fastest and most viable commercialization routes, especially when company processes are slow.

List of possible tools to be developed based on this case:

- **Start-up Commercialization Agreement Tool:** A tool to create and manage agreements that facilitate the transition of co-creation project results into start-ups while ensuring fair IP management.
- **Mentoring and coaching Support System:** A structured feedback tool that connects co-creators with seasoned professionals to build their confidence and guide start-up paths.
- **Agile Route Evaluation Tool:** A framework to evaluate different commercialization routes (internal vs. start-up) and recommend the most efficient one based on project specifics.

6.2.8. Other collected Co-creation examples

There are several examples of co-creation where intellectual property (IP) was acquired or transferred from end-users or other external partners. These cases highlight how companies collaborate to develop new products, services, or technologies, often resulting in IP ownership transfer or shared rights. Emerging tools are shown at the end of each cluster of examples.

Customer-Driven Innovation with IP Transfer

In this co-creation model, companies invite customers or external communities to participate in the innovation or product development process. By crowd-sourcing ideas, designs, and innovations, companies tap into the creativity of a wide audience. Intellectual Property (IP) in these cases is typically transferred from customers to the company, often in exchange for financial compensation or public recognition.

Several companies have adopted this approach, including:

- **Lego** with its *Lego Ideas* platform, where fans submit new product ideas that the company may develop and market.
- **Threadless**, a fashion company that provides customer-submitted designs for t-shirts and apparel.
- **Local Motors**, an automotive company that holds design challenges to crowdsource vehicle designs.
- **Quirky**, a platform for product inventions where users submit ideas for consumer products, and successful submissions lead to IP transfers.
- **Starbucks** with its *MyStarbucksIdea* platform, where customers suggest innovations in products and services, some of which are implemented by the company.

These examples have in common to reach a large number of individuals. Typically, online platforms are used for this, which automate collaboration, information sharing and also contracts. It is typical that IP and rights are left behind in these crowdsourced co-creation examples. In addition, these are often campaign-type activities, without shared values or genuine cooperation.

These examples are described and analysed individually in more detail below. Common intervention points and tools are then summarised.

6.2.8.1. Crowdsourced Product Innovation

Industry: Toy Manufacturing

Type of IP Involvement: IP Transfer from Customers

Background to the example

Lego Ideas is an online co-creation platform where Lego enthusiasts (end-users) submit ideas for new Lego sets. Customers submit their designs, which are then voted on by the Lego community. If a design receives enough votes and is selected for production, Lego acquires the rights to the design, and the creator receives a percentage of the sales.

IP

The “Women of NASA” Lego set, designed by a fan, is a prime example. After receiving over 10,000 votes on the Lego Ideas platform, Lego reviewed and approved the design for production. Lego acquired the rights to the design, and the fan received a share of the profits as compensation for the transfer of her IP.

Impact

- Customer-Driven Innovation: End-users have a direct hand in product creation, making them co-creators.
- IP Ownership: Lego acquires IP from its fanbase, turning customer ideas into official, marketable products.
- Loyalty and Engagement: By involving customers in product development, Lego fosters strong community loyalty and engagement.

6.2.8.2. Customer-Generated Designs

Industry: Apparel (Fashion)

Type of IP Involvement: IP Transfer from Customers

Background to the example

Threadless is a fashion company that crowdsources designs for its t-shirts and other products from a global community of artists and customers. The designs are submitted by users, and the community votes on their favourites. Winning designs are produced and sold by Threadless, and the original designer receives royalties while transferring ownership of the IP to the company.

IP

A designer submits an original illustration, and if it wins the voting round, Threadless acquires the rights to the design for use on apparel. While the artist retains some rights (such as the right to showcase the design in portfolios), Threadless takes over the commercial rights to produce and sell the merchandise.

Impact

- **IP Monetization**: Customers and designers are incentivized to create and submit work in exchange for royalties, allowing them to monetize their creativity.
- **Community Involvement**: Threadless creates a symbiotic relationship where customers drive the brand’s product offering through IP contributions.

6.2.8.3. Customer-Suggested Innovations

Industry: Food & Beverage

Type of IP Involvement: IP Transfer from Customers

Background to the example

Starbucks launched the **MyStarbucksIdea** platform, which allowed customers to submit ideas for new products, services, or operational improvements. Some of the ideas submitted by customers have led to new product innovations and operational changes, with Starbucks acquiring the IP rights to these customer-generated ideas.

IP

Customers suggested improvements such as **Starbucks' mobile payment system** and **free Wi-Fi**, both of which were implemented by the company. While these operational innovations may not always be

formally patented, Starbucks effectively acquires the IP (in terms of ownership over the idea) once it is implemented, without formal compensation to the customer other than public recognition.

Impact

- **Customer-Driven Innovation**: Customers provide valuable IP (in the form of ideas and solutions) that Starbucks can own and implement across its global stores.
- **Customer Engagement**: MyStarbucksIdea fosters customer engagement by giving them direct input into the company's innovations.

6.2.8.4. Community-Designed Products

Industry: Automotive

Type of IP Involvement: IP Transfer from Customers

Background to the example

Local Motors, an automotive company, uses a crowdsourcing approach to design its vehicles. The company hosts design challenges where customers and automotive enthusiasts submit their designs. Winning designs are developed into actual vehicles, and Local Motors acquires the rights to the designs, paying the designers in return.

IP

The **Rally Fighter**, one of Local Motors' most successful vehicles, was designed through a co-creation competition. The winning designer transferred the IP rights to Local Motors in exchange for compensation and recognition.

Impact

- **Co-Created Innovation**: Customers actively contribute to the design and development of vehicles, with Local Motors acquiring the IP for commercial use.
- **Engagement and Ownership**: The community feels a sense of ownership and pride in the vehicles they helped create.

6.2.8.5. Consumer Invention Platform

Industry: Consumer Products

Type of IP Involvement: IP Acquisition from Customers/Inventors

Background to the example

Quirky is an online platform where inventors submit product ideas, which are voted on by the community. If an idea is selected for production, Quirky acquires the rights to the IP and provides the inventor with a portion of the profits from product sales.

IP

An example is the Pivot Power flexible power strip, invented by a Quirky user. After submitting his idea, Quirky selected it for production, acquired the IP, and produced the product, sharing profits with him.

Impact

- **IP Commercialization**: Quirky helps end-users and inventors monetize their ideas by acquiring their IP and turning their inventions into market-ready products.

- **Incentivizing Creativity**: Inventors are motivated to contribute to the platform due to the potential for financial rewards and public recognition.

6.2.8.6. Open Lab for Drug Discovery

Industry: Pharmaceuticals

Type of IP Involvement: IP Licensing and Acquisition

Background to the example

GSK's **Open Lab** initiative encourages external researchers and biotech companies to collaborate on drug discovery, particularly for neglected diseases. GSK often licenses or acquires IP from these external collaborators to bring new drugs to market.

IP

Through its Open Lab partnership with **Tres Cantos Open Lab Foundation**, GSK collaborated with researchers on developing novel treatments for malaria. The IP generated from these projects was often licensed to GSK, giving the company the ability to further develop and commercialize the drugs.

Impact

- **Faster Drug Development**: GSK could acquire and license early-stage IP, allowing it to develop drugs more quickly.
- **Cost Efficiency**: By sharing R&D efforts and acquiring IP from external sources, GSK reduced the costs and risks associated with traditional drug development.

6.2.8.7. Connect + Develop Open Innovation Programme

Industry: Consumer Goods

Type of IP Involvement: IP Acquisition through Open Innovation

Background to the example

Procter & Gamble (P&G) is one of the pioneers of open innovation with its **Connect + Develop** program. The initiative encourages inventors, startups, research institutions, and other companies to co-create new products and technologies with P&G. Through this program, P&G acquires intellectual property (IP) from external partners, transferring ownership of the innovations for use in its own product lines.

IP

One of the most notable IP transfers is the **Swiffer** cleaning product line, co-created with an external partner. P&G acquired the IP related to the Swiffer system after identifying it as a solution to a cleaning need that traditional mops couldn't address. The IP transfer gave P&G the exclusive rights to develop and commercialize Swiffer under its brand.

Impact

- **Faster Innovation**: By acquiring external IP, P&G shortened the product development cycle.
- **New Market Entrants**: Co-creation with external partners allowed P&G to introduce products that it may not have developed internally.

6.2.8.8. Ecomagination Challenge

Industry: Energy and Sustainability

Type of IP Involvement: IP Acquisition via Crowdsourcing

Background to the example

GE's **Ecomagination Challenge** was launched to crowdsource ideas for cleaner, greener technologies. It invited startups, research institutions, and individual inventors to submit ideas related to energy efficiency and sustainability. GE selected winners from this pool and invested in their projects. As part of the process, GE negotiated rights to the IP generated by the startups.

IP

GE's partnership with **Solexant**, a solar technology startup, led to the acquisition of IP related to thin-film solar energy solutions. Through the collaboration, GE invested in Solexant's technology and acquired certain rights to the IP, enabling GE to incorporate it into its renewable energy portfolio.

Impact

- **IP Acquisition**: GE was able to fast-track its innovations in the renewable energy sector by acquiring IP from external innovators.
- **Collaborative Innovation**: The challenge model facilitated access to groundbreaking technology that fit GE's long-term strategy.

6.2.8.9. Open Innovation for Sustainable Packaging

Industry: Consumer Goods (Sustainability)

Type of IP Involvement: IP Licensing and Acquisition

Background to the example

Unilever uses co-creation extensively in its **Open Innovation** program, which seeks partnerships with startups, research labs, and suppliers to develop sustainable products and packaging solutions. In many cases, Unilever licenses or acquires the IP created through these collaborations.

IP

One key example is Unilever's partnership with **Innoget**, a global open innovation network. Through this platform, Unilever collaborated with multiple startups focused on creating biodegradable and recyclable packaging solutions. Several of these technologies were either licensed to Unilever or acquired outright, allowing the company to integrate sustainable materials into its product lines.

Impact

- **Sustainable Innovation**: By acquiring and licensing IP from smaller partners, Unilever was able to quickly incorporate eco-friendly solutions into its packaging and production processes.
- **Accelerated Time to Market**: Open innovation with IP transfer allowed Unilever to bypass lengthy R&D processes and implement ready-to-market technologies.

6.2.8.10. Healthcare Innovation Partnerships

Industry: Healthcare

Type of IP Involvement: IP Co-Ownership and Licensing

Background to the example

Philips has partnered with universities, research institutions, and healthcare startups to co-create medical devices and healthcare solutions. In these partnerships, IP related to jointly developed technologies is often shared, transferred, or licensed between Philips and its partners.

IP

In collaboration with **BioTelemetrix**, a medical technology startup, Philips co-created a remote monitoring system for patients with chronic conditions. As part of the co-creation agreement, Philips acquired exclusive rights to the underlying IP, while BioTelemetrix retained certain IP for specific applications.

Impact

- **Product Innovation**: Co-creating healthcare solutions allowed Philips to expand its medical device portfolio with cutting-edge technology.
- **Shared IP Benefits**: By acquiring exclusive IP rights, Philips could market the technology globally, while the partner retained rights for niche applications.

Common Outcomes and Results

This type of co-creation produces very different types of innovation material and results that vary and are not uniform in quality. Some of the results can be completely worthless and wasted from the client's point of view, a kind of innovation spam. Outcome and results typically include the following three elements:

Product Innovation: This model has led to the creation of new, customer-designed products, such as the *Women of NASA* Lego set or Local Motors' *Rally Fighter*.

Customer Engagement: By giving customers a direct hand in the development process, these companies build strong community engagement and loyalty.

IP Monetization: Customers who contribute to these platforms are often compensated through royalties (as seen with Threadless and Quirky) or other incentives.

6.2.8.11. Exploitation of results and IP

The primary exploitation of these co-creation models is through the acquisition of customer IP. Companies use customer ideas as commercial products and innovations, leveraging the creativity of their communities without having to develop ideas internally. For example:

- **Lego** and **Threadless** acquire full commercial rights to customer submissions.
- **Starbucks** implements customer suggestions for improvements but doesn't always formalize the IP transfer.
- **Local Motors** and **Quirky** reward inventors with financial compensation or profit-sharing, in exchange for acquiring commercial rights to their designs.

This model also enhances brand loyalty and deepens customer relationships, which is an indirect benefit of co-creation.

Intervention points and guiding tools

Key intervention points and actions for transfer of the Good Practice

Intervention point	Stakeholder(s) involved	Critical aspects
Launching the crowdsourced co-creation campaign	*Customer or consumers*	*Managing the large volume of customer submissions and ensuring a streamlined review and selection process.*
When the customer submits an idea or other contribution	*Client, Customer*	*Ensuring fair and transparent IP transfer agreements that satisfy both the company and the contributors.*
Co-creatior engagement	*Client, Customer*	*Encouraging sustained customer engagement through incentives like royalties, recognition, and community involvement.*

Issues to be addressed in Tool Development

- A system to track and manage customer contributions, ensuring that contributors are compensated promptly and fairly.
- Tools to simplify the legal complexities of IP transfers, particularly for non-professional contributors.

List of possible tools to be developed based on this case:

- **IP Transfer and Compensation Tracker**: Monitors the transfer of IP and the corresponding royalties or compensations.
- **Customer Innovation Management System**: A platform for managing the submission, voting, and selection of customer-generated ideas.
- **Community Engagement Dashboard:** Tracks customer involvement and engagement metrics to help optimize the platform's effectiveness.

Industry-Academia and Startup Collaborations with IP Licensing or Acquisition

This co-creation model focuses on partnerships between companies and external entities like startups, universities, and research institutions. These partnerships often result in the licensing or acquisition of IP, allowing companies to rapidly innovate without having to internally develop technologies from scratch.

Examples include:

- **GSK**'s *Open Lab* initiative, which encourages external researchers to collaborate on drug discovery for neglected diseases.
- **Procter & Gamble (P&G)**'s *Connect + Develop* program, through which the company acquires IP from external innovators to develop products like the *Swiffer*.
- **GE**'s *Ecomagination Challenge*, where the company invests in startup-driven technologies focused on sustainability and energy efficiency.
- **Unilever**'s *Open Innovation* program, which acquires or licenses sustainable packaging innovations from startups and research institutions.

Outcomes and Results

The following outcome and result types are typical that the involving parties produce or gain in co-creation activities like this:

Accelerated Innovation: These partnerships allow companies to quickly bring innovative products to market. For instance, P&G shortened its product development cycle by acquiring the *Swiffer* system through co-creation.

Shared R&D: Collaborative efforts lower the costs and risks associated with research and development. For example, GSK's Open Lab collaboration on malaria treatments accelerated drug development while sharing research costs.

Sustainability: Initiatives like GE's Ecomagination and Unilever's Open Innovation have produced environmentally friendly technologies, addressing global challenges like energy efficiency and sustainable packaging.

Exploitation of results and IP

The key outcome in this cluster is the acquisition or licensing of IP from external innovators. This allows companies to integrate cutting-edge technologies and solutions without investing in lengthy internal R&D processes. Some specific examples include:

- **GSK** licensing drug-related IP to bring treatments to market faster.
- **P&G** acquiring external innovations, as seen with the Swiffer product line.
- **Unilever** acquiring IP related to biodegradable packaging solutions.

By collaborating with startups, universities, and research institutions, companies gain access to innovative technologies that complement their strategic goals and/or create agility into their processes.

Intervention points and guiding tools

Key intervention points and actions for transfer of the Good Practice

Intervention point	Stakeholder(s) involved	Importance
Launching the co-creation activities	*All stakeholders*	*Establishing strong partnerships with external innovators and managing shared IP ownership.*
Co-creation focus and scope defining	*All stakeholders*	*Aligning the goals of the company and the external partner to ensure mutually beneficial outcomes.*
IP and knowledge transfer	*All stakeholders*	*Developing systems for tracking the contributions of external innovators to ensure IP is correctly managed and compensated.*

Issues to be addressed in Tool Development

- Handling complex legal agreements related to IP licensing and co-ownership, especially across international cooperation.
- Ensuring transparency and accountability in co-development efforts, including clear definitions definition expectations of contributions.

List of possible tools to be developed based on this case:

- **IP Licensing and Ownership Tracker:** Tracks IP ownership, licensing agreements, and ensures proper usage rights.
- **Collaborative Research Platform:** Facilitates communication, data sharing, and project management between external partners and the company.
- **IP Contribution Management Tool:** Helps track and manage the individual contributions of external collaborators in shared IP projects.

Social and Non-Profit Co-Creation with Shared Knowledge or Open Innovation

While corporations may be dominant in the co-creation space, co-creation also happens in other areas.

Many **Non-Profit Organisation**s engage in co-creation to solve social issues. For example, organizations like Wikipedia operate as co-created platforms where users contribute content, and everyone benefits from the shared knowledge. **Public Sector**, like governments are increasingly involving citizens in co-creating public services. Initiatives like participatory budgeting, where citizens directly decide how to allocate a portion of public funds, are a form of co-creation. **Open-Source Software Communities** an open-source projects such as Linux and Mozilla Firefox are driven by co-creation, where developers from around the world contribute code and ideas to build software collaboratively. These communities are built on voluntary collaboration rather than corporate incentives.

Examples of this co-creation model include:

- **Wikipedia**, a non-profit platform where users co-create content, contributing knowledge freely to the global community.
- **Linux** and **Mozilla Firefox**, open-source software projects where developers from around the world collaborate to build and maintain software.
- **Participatory Budgeting**, a public sector initiative where citizens co-create public services by voting on how to allocate a portion of public funds.

Outcomes and Results

The following outcome and result types are typical that the involving parties produce or gain in co-creation activities like this:

- Shared Knowledge and Innovation: Platforms like Wikipedia and Linux enable the global exchange of ideas, leading to continuous improvement of shared resources.
- Community Ownership: These models foster strong community involvement, where participants feel ownership over the co-created outcomes.
- Social Impact: Initiatives like participatory budgeting give citizens a direct role in shaping their communities, promoting transparency and public engagement.

Exploitation of results and IP

In these co-creation models, the emphasis is on sharing rather than owning IP. The Linux and Mozilla communities, for example, operate under open-source licenses, allowing anyone to use or improve the software. Similarly, Wikipedia allows free use of its content, encouraging global collaboration.

This model is less about commercial exploitation and more about the advancement of shared knowledge and public resources. However, there are still opportunities for companies or governments to capitalize on innovations generated through these collaborative efforts, for example by exploiting the results commercially under the Creative Commons license.

Intervention points and guiding tools

Key intervention points and actions for transfer of the Good Practice

Intervention point	Stakeholder(s) involved	Importance
Operating the co-creation activity at large scale	*Platform operator*	*Ensuring sustained community participation and maintaining a high level of contribution quality.*
IP and licensing policy	*Platform operator*	*Managing the governance and structure of open-source or non-profit collaborations*
IP and knowledge transfer	*Platform operator*	*Developing mechanisms to protect the integrity of shared IP in an open-source environment.*

Issues to be addressed in Tool Development

- Ensuring that open-source contributors are recognized and incentivised for their efforts, even without direct financial rewards.
- Developing governance frameworks for community-led initiatives that can maintain the quality, continuum and integrity of contributions.

6.3. Crisis Scenario examples

6.3.1. Preventable Crisis – Equitable Access

6.3.1.1. Netherlands EA policy

The 'Dutch Global Health Strategy 2023-2030'[16] embeds 'Responsible access' into national policy. It recognises that a third of the world's population has no access to essential health services and that the COVID-19 pandemic demonstrated that the public health situation in the Netherlands is intrinsically linked to global developments and challenges. It highlights the need to support the Sustainable Development Goals and in particular SDG 3, on good health and wellbeing for all. Its three pillars include preparing for and responding to health crises.

Among other priorities it highlights **international pandemic preparedness** with a focus on: **global access to medicines and health products**.

Under its goals and approaches the strategy recognises that that are obligation on states to ensure that healthcare facilities, services and products are, amongst others,: 1) sufficiently available; 2) accessible (physically, financially and on the basis of non-discrimination, and 3) of good quality.

The strategy lays out an initial course of action based on the Netherlands role as an innovator, connector and advocate. This includes in the context of equal access to vaccines, besides promoting local production and improving country-readiness the Netherlands will also donate any excess supplies of vaccines to countries that need them. In addition, the Netherlands commits to exploring what international agreements could be made to secure the security of supply for medical products to other countries and other countermeasures in the event of a pandemic. It also sees opportunities to help make access to medical products quicker, fairer and more affordable by voluntarily sharing technology and know-how to build up or use local production capacity.

Interestingly, although the strategy highlights the Netherlands role as an innovation and commits to an integrated approach involving investment, innovation, trade and knowledge, it stops short of calling for equitable access to research outputs. In addition, equitable access is not part of the current policy of the Dutch Research Council (NWO) who funds most of the state sponsored research in the Netherlands.

[16] Downloadable at https://www.government.nl/documents/publications/2023/03/29/dutch-global-health-strategy

6.3.1.2. NL Ten principles for Socially Responsible Licensing (SRL)

The FNU (Netherlands Federation of University Medical Centres) recognises that University Medical Centres sometimes needs to work together with commercial parties and grant licenses to companies in order to enable research results to be translated as quickly as possible into an application.

The NFU 'Ten Principals for Socially Responsible Licensing'[17] highlights the need to be socially responsible when approaching licensing transactions to arriving at a **reasonable price and the availability of medicines**. In this content, SRL means that 'account must be taken of the effective availability of the products or services to be developed based on the licensed knowledge'.

The expression 'equitable access' is not used in the principals, and the original impetus of the initiate was focused on lowering the financial burden on the Dutch healthcare system from expensive medicines and does not refer to LMIC. The principals are designed to encourage Dutch academic institutions to set conditions when arranging licensing agreements and transferring their licences to manufacturers to ensure the accessibility of any medicine developed. These focus on transparency and discussions with the licensee on price setting.

However, the principals also note the need to work together to get the principles for socially responsible licensing on the agenda within the EU and worldwide and work towards international agreements in this field

The objectives of **reasonable price** and the **availability of medicines** make this relevant part of the PC equitable licensing scenario. It provides a Good Practice example for others to consider, adapt and adopt.

Of the 10 principals, of most relevance to PC and EA are 9 and 10:

9). In certain countries, licences provide space to encourage or ensure marketing access or development, where possible. They can also offer possibilities to encourage or ensure application in certain sectors.

The knowledge institution can use the licensing agreement to exercise some guidance in the way in which the licence holder markets a product or service to be developed. To compensate for this restriction of the licence holder's freedom, the knowledge institution can, for example, waive certain payments, or make another concession to the licence holder.

For example, it could be determined that products will be offered in due course at a reduced rate (based on 'cost-plus') in **developing countries**. Other possibilities include **non-exclusive licences (partially) in certain countries, the right to grant them, agreements about a lack of protection in certain countries, agreement not to enforce such rights or grant access to local producers**. The extent to which such agreements are possible depends partly on the commercial possibilities in developed countries, the cost of developing the product further, and the importance that the licence holder attaches to social responsibility. The possibility to guide offered by the licensing agreement can also be used to promote preferential access of the product in the Netherlands, for example in the context of research. Or, in a more coercive manner, as compensation for obtaining marketing authorisation.

[17] See https://www.nfu.nl/sites/default/files/2020-08/19.4511_Ten_principles_for_Socially_Responsible_Licensing_v19-12-2019.pdf

When granting the licence, the access to certain sectors can be considered. Semi-exclusive licences (exclusively for certain sectors), if sufficiently distinctive, can give partners room and security and offer a chance of **wider use**.

10). Licences ensure that the price-setting of the final products and/or services does not endanger accessibility.

A patent offers the patent holder/licence holder a legal monopoly. That can have undesirable consequences, particularly with products or services for which there is a widespread or even urgent need, like medicines and medical devices. When arranging a licence, it can therefore be agreed that **the partner will endeavour to make a reasonable commercial effort to ensure that the final price of the product or service will not hinder its availability in a particular market**. The criterion to determine what is acceptable depends on the context at the time that the product or service is marketed. That is more realistic than setting a price in advance, although the development can take years. Such an agreement protects against excesses, when knowledge supported by public funding leads to products that are unaffordable for the public. Likewise, there should be an agreement that this arrangement will not be undermined by the partner setting unreasonably burdensome conditions that make availability unnecessarily complex or unfeasible.

6.3.1.3. The Wellcome Trust: embedding EA into grant contracts

The Wellcome Trust is an independent global charitable foundation dedicated to improving health through research. The Trust uses returns from its investments to fund further work, usually taking a 25% share in revenue and/or equity. In general, the organisation does not receive donations or government grants and do not raise money from the public.

Equitable access is embedded in Wellcome Trust principals for funding. The organisation is committed to making the results of the research it funds 'affordable, appropriate, adapted and available, particularly in LMICs'.

Funded projects must all adhere to the Wellcome **intellectual property policy**, **equitable access to healthcare interventions statement** and **guidance on commercialisation agreements**.

The Wellcome Trust usually requires that grantees seek formal consent for commercialisation of results, giving them a very high level on control over the action. Companies must always obtain written consent before entering into transactions to develop or commercialise Wellcome funded IP, and bespoke revenue-sharing terms may apply. However, Wellcome waive this requirement for researchers working at not-for-profit institutions, under standard grant agreements, subject to certain conditions.

The Trust uses a number of mechanisms to help it achieve its equitable access goals. These include:

- **Contractual mechanisms**
- **Appropriate application of IP**
- **Licensing provisions to address commercialisation agreements in low- and middle-income countries**
- **Promotion of transparency to support innovation and access to products**

For more detail see the associated Case Study.

Wellcome also supports appropriate sharing of information to encourage innovation and broaden equitable, timely access. This is designed to create a better shared understanding of the relationship between the **costs of research and development, the price of products and appropriate levels of return**.

Conclusions and tools

In conclusion The Wellcome Trust offers examples to policy makers and other funding organisations of how to embed equitable access into policy and practice to achieve equitable access.

This can take the form of

- Clear statements and principals
- Contractual mechanisms
- Appropriate application of IP rights
- Tailored licensing provisions

6.3.1.4. The Gates Foundation: Seeking Global Access

Global Access is a concept developed by the Gates Foundation to ensure that the results of foundation-funded projects will have positive impact on the beneficiaries served by the foundation's work.

Global Access requires that

(a) the knowledge and information gained from a Programmatic Investment be promptly and broadly disseminated, and

(b) the Funded Developments be made **available and accessible at an affordable price** to the intended beneficiaries.

Within the Global Health and Global Development programs beneficiaries are the people most in need living in developing countries, and within the U.S. programs they include low income students, students of colour and first-generation college students, and the educational systems serving these communities.

The Gates foundation acknowledges that obtaining IP protection for certain technology or information in certain markets is an appropriate component of Global Access, provided that these IP Rights are managed in such a way as to ensure the broadest possible access to those most in need. Additionally, rights held by third parties must be evaluated to ensure they do not interfere with the objective of ensuring the availability and accessibility of the Funded Developments to serve target beneficiaries, including in terms of cost, quantity, supply and delivery.

Global Access Requirements

Alongside the right to conduct or require due diligence on an organisation, the Foundation may also require:

- a "**Global Access Strategy**" or "**Global Access Commitments Agreement**" from partners, explaining their plans to achieve their goals and further the foundation's charitable objectives, including the identification of third party IP Rights and relationships arising in connection with the research, development, manufacturing, marketing and/or distribution of the Funded Developments, and the related IP management strategies, licensing structures, data management plans, and pricing frameworks.
- a **humanitarian license** or other IP Rights in Funded Developments and essential background technology. In those cases where the foundation does reserve a humanitarian license, it does so as necessary to ensure that either the foundation or a sub-licensee has the rights necessary for the development, manufacture and distribution of Funded Developments to achieve Global Access.
- periodic updates on progress and ongoing efforts to achieve Global Access.

In particular, as part of the Global Access Strategy the Foundation may require:

Development and Post-Project: plans and/or strategies regarding the use, development, manufacturing, marketing, post-project development, commercialization, distribution and sustainability of the Funded Developments, including:

- how the Funded Developments/results of the project will be incorporated into products or services (as appropriate) and manufactured, distributed in and used to fulfil the Global Access objectives. These plans should take into consideration the existence of and necessary licenses to background IP, IP that arises under the project, and third-party IP as well as how the licenses will ensure the affordability and accessibility of the product to the target beneficiaries.

- anticipated post-project development, commercialization and sustainability hurdles that might have to be addressed to ensure the Global Access objectives could be met, and describe the assumptions used to identify these potential hurdles.
- how the broader product, service or markets (including any dual markets) may be leveraged to help create a sustainable solution for Global Access to the Funded Developments.
- other commitments to ensure that products and services incorporating Funded Developments are accessible and affordable to our target beneficiaries.

For medicines the Development and Post-Project plan is typically activated by regulatory approval of a drug e.g. when it becomes clear that it will be possible to place it on the market.

Humanitarian licenses

The Gates Foundation humanitarian license is composed of 2 standard clauses:

- Global Access Commitment
- Humanitarian License

The latter states that:

Subject to applicable laws and for the purpose of achieving Global Access, You grant the Foundation a nonexclusive, perpetual, irrevocable, worldwide, royalty-free, fully paid up, sublicensable license to make, use, sell, offer to sell, import, distribute, copy, create derivative works, publicly perform and display: Funded Developments and Essential Background Technology.

"Essential Background Technology" means Background Technology that is (i) owned, controlled, or developed by You, or in-licensed with the right to sublicense; and (ii) either incorporated into a Funded Development or reasonably required to exercise the license to Funded Developments. You confirm that You have retained sufficient rights in the Funded Developments and Essential Background Technology to grant this license. You must ensure this license survives the assignment or transfer of Funded Developments or Essential Background Technology. On request, you must promptly make available the Funded Developments and Essential Background Technology to the Foundation for use solely under this license. If You demonstrate to the satisfaction of the Foundation that Global Access can best be achieved without this license, the Foundation and You will make good faith efforts to modify or terminate this license, as appropriate.

Conclusions and tools

In conclusion, like the Wellcome Trust, the Gates Foundation offers examples to policy makers and other funding organisations of how to embed equitable access into policy and practice to achieve equitable access.

This can take the form of

  - Clear statements and definitions including of end beneficiaries.
  - Management of IP rights;
  - Clear reference to 'Essential Background Technology'
  - Use of Development and Post-Project plans

- Use of humanitarian licenses[18]

[18] See https://docs.gatesfoundation.org/Documents/Humanitarian-License-Nonbinding-FAQ.pdf

- Clear guidelines and answer to FAQ

6.3.1.5. Embedding Equitable Access into intuitional policy and practice: MPP and HEIs

The Medicines Patent Pool (MPP) is working with 'up-stream' technologies providers at Public Research Organisations (PROs) to help them mainstream Equitable Access into their institutional policy and licensing agreements. PROs and their commercialisation units who have taken this step to-date include **Columbia University** (Technology Ventures), **University of California Berkeley** (Intellectual Property & Industry Research Alliances (UCB IPIRA)) **University of California, Los Angeles Technology Development Group (UCLA TDG)**, the **Innovative Genomics Institute** (IGI) and **Erasmus University of the Netherlands.**

The approach can address equitable access through overarching institutional policy, licensing practice or a combination of the two. It is largely directed at exclusive licenses for drugs and therapeutics.

Policy statements

Policy statements indicate the need for "Global Social Responsibility" or "Humanitarian Access" or similar phrases in technology transfer of research results and in particular in licensing, to reflect the Mission of the institution and Not for Profit status.

Licensing Clauses

Embedding equitable access into licenses is seen as a way to give an overall policy approach 'teeth'.

Typically individual clauses address:

- Humanitarian Purposes
- Royalty free access in some territories
- Pricing transparency
- **Affordable Action Plans (AAP)**
- Progress and royalty reports

The AAP is a direct result of the work of the MPP and echoes approaches taken by the Gates Foundation (Global Access), Wellcome Trust (Equitable Access), CARB-X (Stewardship and Access Plan) and the CEPI (Equitable Access). The AAP:

- Requires licensees to submit a plan of how they will achieve affordable access for the licensed product(s) in low- and middle-income countries, with strategies and timelines.
- Requires licensees to identify countries in which the licensee has no intention of commercializing.
- Only requires the submission of the plan when it is reasonably certain that the licensed product will be commercialized – i.e., within a specified amount of time of having received regulatory approval, which allows the licensee to focus energy and resources on the critical research and development activities needed to advance a technology and only develop the plan if/when the product is ready for market launch.
- Allows the licensor to call upon a "designated entity" with relevant public health expertise to assist in conversations with the licensee regarding the access plan.

Individual examples of how licensing agreements reflect equitable access are shown below

University of California, Los Angeles

The **University of California, Los Angeles**' Technology Development Group (UCLA TDG) has implemented a practice of including in its patent license agreements to UCLA's biopharmaceutical innovations a provision requiring its licensee to provide and implement an "Affordable Access Plan" (AAP). The intent of the AAP provision is to encourage UCLA's licensee, if and when it receives U.S. Food and Drug Administration (FDA) approval, to develop and implement plans for supporting affordable access to the UCLA patented drug in low- and middle-income countries (LMICs), which plans may include collaborating with governments and non-profit organizations.

The AAP provision arose out of efforts among UCLA leadership regarding whether and how UCLA can play a role in ensuring that underserved communities in LMICs have affordable access to technologies originating from UCLA. UCLA TDG and the MPP had several collaborative conversations regarding the challenges university TTOs have had in identifying contract language of substance which would influence its licensees' behavior with regard to pricing and marketing strategies but not deter pharmaceutical partners from taking a license.

A review by the university of good practices led them to conclude that all of these reports stress that the primary goal of patent and licensing policies and practices is to maximize the further development, use, and beneficial social impact of these products. Revenue and profit should not be the primary motivation. The UCOP Guidelines note that '*developing successful practices is an evolving process, for an issue as complex as balancing access by developing countries to biomedical products with ensuring timely and appropriate development and commercialization of the product*.' If the approach is too prescriptive, licensees may be discouraged because of a perceived need to overcome too many obstacles in product development.

Initially the UCLA incorporated the following provision into their licensing agreements:

As part of its public mission to bring products to the marketplace, UCLA strives to enable underserved populations, which have limited access to adequate quantities of medical innovations arising from UCLA's laboratories, to have access to these innovative products. Licensees are encouraged to consider these populations' interests when marketing and selling Licensed Products.

While this language was well received by licensees during negotiations, UCLA leadership explored ways to improve it and to enable UCLA to have a material impact on the goals of ensuring affordable access to drugs originating from its campus.

As a result of discussion with the MPP the UCLA made the decision to add a provision requiring its licensee to provide and implement an AAP. The AAP provision requires the licensee to identify shortly after receiving FDA approval:

- A specified set of low- and middle-income countries ("LMICs") in which the Licensee does not intend to commercialize the Licensed Products (the "Non-Commercialized Territory"); and
- Licensee's and/or its Sublicensees' plans (including strategies and timelines) reasonably intended to support affordable access in LMICs and Non-Commercialized Territories, such as through licensing or partnerships including with non-profit organizations.

The AAP provision also provides UCLA the ability to initiate discussions among its licensees and key stakeholders, such as MPP, who have the experience necessary to effectively enable affordable access to LMICs. The hope is that by encouraging discussion and shining a light on these issues early in the

licensee's marketing and commercialization plans, UCLA's licensees will be more apt to take steps to more effectively address affordable access issues.

To date, UCLA TDG has been successful in incorporating such a provision in its biopharmaceutical license agreements and has received minimal pushback from its licensees.

For a copy of the full AAP provision see Appendix A (page 6) at this link:

https://regents.universityofcalifornia.edu/regmeet/dec20/h12.pdf

University of California Berkeley (UoCB) 'Humanitarian Purposes'

The UoCB now reflects EA into policy and license for 'Humanitarian Purposes' and this is clear in the **exclusive licensing template for therapeutics and diagnostics**. This includes the need for an AAP.

See: https://ipira.berkeley.edu/sites/default/files/sample-exclusive-equity-license-agreement-therapeutics-diagnostics.pdf

Policy statement

As part of its public mission to bring products to the marketplace, the UoCB uses good faith efforts to enable underserved communities, which have limited access to adequate quantities of medical innovations arising from UoC's laboratories, to have affordable access to these innovative products.

Example exclusive license and relevant Humanitarian Purposes' clauses[19]

(Note that the UoCB is referred to in Agreements as REAGENTS')

2.5 "HUMANITARIAN PURPOSES" means (a) the use of LICENSED PRODUCTS and LICENSED SERVICES for research and development purposes by any nonprofit organization or other third party, anywhere in the world that has the express purpose of developing the LICENSED PRODUCTS or LICENSED SERVICES for use solely for protection from, treatment of, or diagnosis of Neglected Diseases in a Low- or Middle-income country as that term is defined by the World Bank (hereinafter "LMI COUNTRY(IES)"); and (b) SALE of LICENSED PRODUCTS and LICENSED SERVICES in LMI COUNTRIES at or below the cost of manufacture and distribution.

3.3. Humanitarian Purposes.

(a) REGENTS further reserves the right to license REGENTS' PATENT RIGHTS to any third parties solely for HUMANITARIAN PURPOSES. Such licenses for HUMANITARIAN PURPOSES will (i) expressly exclude the right of the third party licensee to export or SELL the LICENSED PRODUCTS from a LMI COUNTRY into a market outside of the LMI COUNTRY where LICENSEE has introduced or will introduce a LICENSED PRODUCT and where REGENTS' PATENT RIGHTS exist (such markets hereinafter the ''LICENSEE MARKETS") and (ii) require the third party licensee to create and maintain distinctive trade dress and trademarks that clearly distinguish third party LICENSED PRODUCTS and LICENSED SERVICES from LICENSEE'S LICENSED PRODUCTS and LICENSED SERVICES, (iii) require such third party LICENSEE's sale of LICENSED PRODUCTS and LICENSED SERVICES in such LMI COUNTRIES be at or below cost. For avoidance of doubt, such third party licensee may be permitted to export LICENSED PRODUCTS from

[19] See https://ipira.berkeley.edu/sites/default/files/sample-exclusive-equity-license-agreement.pdf

the LMI COUNTRY of origin to other LMI COUNTRIES and all other countries that are mutually agreed to by REGENTS and LICENSEE; and

(b) Notwithstanding the foregoing, prior to issuance of any such license to REGENTS' PATENT RIGHTS to a third party, REGENTS will notify LICENSEE of its intention to grant such license so that LICENSEE may have the opportunity to fill the anticipated market need itself and/or to engage in discussions for a sublicense with such third party in accordance with the procedures set forth in Paragraph 4.8. In the event any LICENSED PRODUCT SOLD in any LMI COUNTRY by any such third party according to the provisions of Paragraph 3.3(a) is exported, re-SOLD or otherwise introduced in any LICENSEE MARKETS, LICENSEE will provide REGENTS with written notification thereof, and if such exportation, re-sale or introduction does not cease within ninety (90) days after the date of such notice, then an amount equal to the retail price of LICENSED PRODUCT so exported, re-SOLD or introduced to such LICENSEE Market will be credited to royalties due to REGENTS hereunder.

4.9 **Affordable Access Plan**. Within three (3) months of receiving FDA (or its foreign equivalent's) approval of a LICENSED PRODUCT, LICENSEE will provide the REGENTS with either (a) an Affordable Access Plan (defined below), or (b) a written explanation as to why such an Affordable Access Plan is not needed or infeasible. In the case of (b), LICENSEE agrees to discuss such reasoning with the REGENTS in good faith within one (1) month thereafter ("Initial Discussion") and, if following such Initial Discussion the REGENTS concludes an Affordable Access Plan is reasonable and desired, to provide an Affordable Access Plan to the REGENTS within three (3) months of such Initial Discussion. The "Affordable Access Plan" means LICENSEE'S and/or its SUBLICENSEES' plans (including strategies and timelines) reasonably intended to support affordable access in a) Low and Middle Income Countries as defined by the World Bank Group ("LMICs"), and b) vulnerable, underserved, and special needs populations in the U.S., as defined by the Department of Health and Human Services, such as through licensing or partnerships including with non-profit organizations. To the extent such Affordable Access Plan includes Proprietary Information, LICENSEE will also provide a non-confidential version or statement of such Plan that the REGENTS can make available to third parties:

(a) A specified set of ("LMICs") in which the LICENSEE does not intend to commercialize the LICENSED PRODUCTS (the "Non-Commercialized Territory");

(b) LICENSEE'S and/or its SUBLICENSEES' plans (including strategies and timelines) reasonably intended to support affordable access in LMICs and Non-Commercialized Territories, such as through licensing or partnerships including with non-profit organizations; and

(c) LICENSEE'S and/or its SUBLICENSEE' plans (including strategies and timelines) reasonably intended to support affordable access for the vulnerable, underserved and special needs populations in the U.S.

Within thirty (30) days of the REGENTS' request (but no more often than once annually), LICENSEE agrees to confer with the REGENTS to review LICENSEE'S progress, and to consider in good faith any modifications suggested by the REGENTS, with respect to its Affordable Access Plan ("Progress Discussions"). For clarity, while the REGENTS may invite a designated entity to join either the Initial and/or Progress Discussions under this Paragraph 4.9, such discussions will at all times be made subject to the confidentiality obligations set forth in Article 25 (Confidentiality).

8. PROGRESS AND ROYALTY REPORTS

8.1 Progress Reports. For the period beginning [Date], LICENSEE will submit to REGENTS a semi-annual progress report covering LICENSEE's activities related to the development and testing of all LICENSED PRODUCTS, LICENSED SERVICES and LICENSED METHODS and the obtaining of necessary governmental approvals, if any, for marketing in the United States. These progress reports will be made for all

development activities until the first SALE occurs in the United States. Each progress report will be a sufficiently detailed summary of activities of LICENSEE and any SUBLICENSEES so that REGENTS may evaluate and determine LICENSEE's progress in development of LICENSED PRODUCTS, LICENSED SERVICES, and LICENSED METHODS, and in meeting its diligence obligations under Article 7 (Diligence), and will include (but not be limited to) the following: summary of work completed and in progress; current schedule of anticipated events and milestones, including diligence milestones under Paragraph 7.2; anticipated market introduction dates for the LICENSED TERRITORIES; status of implementation of the Affordable Access Plan and SUBLICENSEE's activities during the reporting period. LICENSEE also will report to REGENTS in its immediately subsequent progress and royalty reports, the date of first SALE.

University of Columbia (UoC) - "Global Social Responsibility"

The UoC generally address the developing world health license issues by insertion of the following general statement as a separate paragraph into an exclusive licensing agreement for relevant technologies.

Section _- "Global Social Responsibility"

During the term of this Agreement, Columbia and Company shall take into consideration the principle of "Global Social Responsibility" in performing the various activities contemplated under this Agreement. "Global Social Responsibility" means facilitating the availability of (Licensed) Products in "Developing Countries" (as defined below) at locally affordable prices, under reasonable circumstances and terms to improve access to such Products in Developing Countries. "Developing Countries" means those countries listed by the World Bank as "Low-Income Economies," as such list may change from time to time. Solely by way of example, the Parties may mutually agree to ***revise royalty rates, adjust the fair market value, consider non-monetary consideration, and/or develop patent strategies in support of each party's dedication to Global Social Responsibility***. (Emphasis added).

For more detail see the full Exclusive License Agreement with Columbia University:
https://www.sec.gov/Archives/edgar/data/1514183/000121390024059821/ea020905901ex10-1_silo.htm

Innovative Genomics Institute (IGI)

Part of IGI's mission is to make genomic medicines affordable and accessible to anyone who would benefit from them. A clear focus is on accessibility for low-income individuals living in the United States, and also on accessibility for individuals in low and middle-income countries.

In late 2021, IGI's Public Impact team, assembled a task force of 30 experts charged with first exploring **key drivers of high prices** and proposing alternative approaches to developing and deploying a genetic therapy that could reach more patients.

The IGI suggest a need to focus on 4 main issues:

Pricing: IGI have developed a dynamic cost-plus model for pricing new genetic therapies that could lead to a sticker price that is 10x less than genetic therapies on the market.

Organization and Funding Models: Besides for-profit corporations (C-corps), non-profit medical research organizations and public benefit corporations (B-corps) offer alternative organizational structures that could, in theory, reduce the sticker price. For these to be successful lower-cost capital (requiring a lower rate of returns) is needed to control costs.

Intellectual property: The IGI suggested that academic technology transfer offices (TTOs) can play a significant role in improving affordability and access via **licenses provisions and requiring access plans**.

Manufacturing: Manufacturing a genetic therapy to stringent regulatory standards is a key driver of cost. IGI has investigated various innovations, point-of-care manufacturing and regulatory streamlining that could lower prices while maintaining safety and efficacy.

For more information see: https://innovativegenomics.org/atf-report/

Other HEIs taking a very similar approach include:

- **Erasmus Medical Center (Erasmus MC) the Netherlands**

The approach at Erasmus University is partly shaped by the currently policy landscape of the Netherlands that has made 'Responsible access' part of their Global Health Strategy 2023-2030 and encourages the adoption of the 10 Principals for socially responsible licensing.

The EMC is committed to availability and accessibility of care in the region. They make an active contribution to the discussion on expensive medicines. For example, they look critically at the most effective use of (new) expensive medicines. In this, they seek cooperation with other hospitals and health insurers.

- **NorthWestern University**

See: https://www.invo.northwestern.edu/documents/invention-disclosure/therapeutics-startup-license-agreement-20190107.pdf

Existing resources and tools

AUTM

Aspects of the equitable access approach can also be seen in the 2012 **AUTM Global Health Toolkit** which offers examples of Examples of Executed Licenses Clauses

https://www.autm.net/AUTMMain/media/Advocacy/Documents/AUTMGHClauseToolkit3-17-12.pdf

6.3.1.6. EA policy and clauses at PROs

HEIs that have begun to incorporating a version of the MPP AAP into their exclusive licences include University Californian Los Angeles Technology Development Group **UCLA** (TDG), **University of California Berkeley** (Intellectual Property & Industry Research Alliances (IPIRA)), **Columbia University** (Technology Ventures), the **Innovative Genomics Institute** (IGI) and Erasmus University of the Netherlands. While the initiative is strongest in the US this is expected to expand into the EU.

Policy statements indicate the need for "Global Social Responsibility" in licensing to reflect the status and Mission of the institution.

Individual clauses address:

- Humanitarian Purposes
- Royalty free access in some territories
- Pricing transparency
- Affordable Action Plans

- Progress and royalty reports

For examples of up-front policy statements and clauses please refer to the Deliverable 2.3 Case Studies.

6.3.1.7. AUTM: Nine Points to Consider in Licensing University Technology

The AUTM 'Nine points to consider' document dates from 2007[20]. It aimed to address the dual goals of nurturing future research and using the innovations of university research to provide the broadest possible benefit to the public.

While many of the issues it addresses are now regarded as classical, it does incorporate an early approach to Responsible Licensing that aligns with Equitable Access.

Namely:

Point 9 Consider including provisions that address unmet needs, such as those of neglected patient populations or geographic areas, giving particular attention to improved therapeutics, diagnostics and agricultural technologies for the developing world

While recognising that the issues inherent in Point 9 are complex require expert planning and careful negotiation it also stated that the principal is simple: Universities should strive to construct licensing arrangements in ways that ensure that these underprivileged populations have low- or no-cost access to adequate quantities of these medical innovations. However, unlike other Points, this early document did not offer any examples of how the issue could be addressed through clause.

The AUTM point 9 suggests that policy and practice for EA should be reflected by a PRO in their documents.

[20] See https://www.autm.net/AUTMMain/media/Advocacy/Documents/Points_to_Consider.pdf

6.3.2. Unforeseen Crisis

6.3.2.1. Rapid development and mass voluntary free licensing of the UCL Mercedes Ventura CPAP device: from first meeting to Regulator approval in ten days

In mid-March 2020 the COVID-19 pandemic was starting to spread. The number of people being admitted to hospital requiring help to breathe was rising sharply. While some patients needed to go on full ventilators, others would be helped if they could access non-invasive ventilation in the form of Continuous Positive Airway Pressure (CPAP) devices. Unfortunately the number of such devices was very low.

A research group from University College London (UCL) joined forces with University College London Hospital (UCLH) and Mercedes-AMG High Performance Powertrains to respond to this need. Their starting point was an existing 'off-patent' CPAP device that had received regulatory approval in the UK many years ago, but was no longer being produced so there was little documentation to support manufacture. Using reverse engineering, including 3D imaging to produce 2D manufacturing drawings, Mercedes-AMG HPP and the UCL team were able to produce the blue-prints and plans needed to for mass production of the device.

Mercedes-AMG HPP had the high quality engineering expertise needed to produce the first devices. These were then rapidly tested by colleague at University College London Hospital on volunteers to produce the test results needed to seek regulatory approval. The device was approved for use by the UK Medicines and Healthcare products Regulatory Agency (MHRA) 10 days after the teams first came together and Mercedes-AMG HPP started to manufacture 100 devices a day. After 4 weeks they had delivered 10,000 devices and demand was still rising from many countries.

The teams made the decision to license all the information needed to manufacture and use the devises free of charge. Download of all the information was subject to approval and made clear the special condition under which the regulatory approval had been granted, namely that the device was a non-CE marked CPAP, given approval for use in the NHS for the interest of public health protection under the Covid-19 pandemic emergency.

Prospective licensees had to meet certain conditions including having local regulatory approval in place, as required in the third party's own country and fully complying with any stipulated conditions, laws and regulations that ensure full patient safety. The terms and conditions also stated that the technical specifications for this CPAP were being shared for humanitarian purposes, to help support the international community addressing pressing demands to care for Covid-19 patients and that there was an expectation that those using these specifications to manufacture these devices would follow the same guiding principles and not seek for commercial gain. In addition, that that the instructions for manufacture should be followed precisely to ensure quality and safety, with no deviations or substitutions.

Application to license the device could be made online. Following human approval all documents and the licensing agreement could be downloaded from a website set up for this purpose. In the 2 weeks that followed release, 1080 downloads were approved and made from more than 100 countries.

The designs and manufacturing instructions for the device were released on Tuesday 7 April. As of May 2020 the team had approved over **1850 requests from 105 countries** spanning Europe, Asia, Africa, Americas and Australasia. Many of these countries and teams were supported to manufacture and adopt through translation, manufacture and distribution. UCL-Venturas are now being used in 29 countries across the globe.

Licensing T&C (Terms and Conditions)

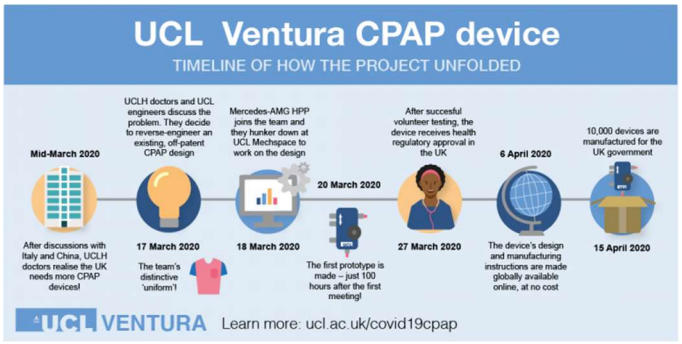
Information needed to manufacture and use the device was only approved for organisations that met a number of criteria including their type and not-for-profit status.

Any manufacture and use of this CPAP by third parties required the third party to have local regulatory approval in place, as required in the third party's own country and needed to fully comply with any stipulated conditions, laws and regulations that ensure full patient safety. It was made clear that the instructions for manufacture should be followed precisely to ensure quality and safety, with no deviations or substitutions.

Support for manufacture and use

The basic information needed to manufacture and use the device was approved for download in conjunction with publicly available information. This included:

- Q&A webinar with the team to support international manufacture
- Q&A webinar on the clinical use of CPAP internationally
- Private Facebook page designed to offer informal space for teams in the process of manufacturing the UCL Ventura CPAP device. Teams could discuss any problems they have, any barriers to manufacture and/or any useful tips that may help others progress.
- FAQ of technical questions
- Instructional video of how to use the CPAP clinically
- Instructions for use of device clinically (written)
- Healthy volunteer test data (clinical)
- UCL Ventura device user manual
- Guidance for international use



Case Study 1 For more information see: https://www.ucl.ac.uk/healthcare-engineering/about-ucl-ventura

Critical success factors

The UCL team highlighted a number of critical success factors in being able to offer the device for licensing so quickly.

- **Regulatory approval**: By starting with an 'off-patent device' that had previously been approved for medical use, the team needed only to demonstrate 'like-for-like' mechanical performance and the results of the volunteer trials.
- **High precision manufacturing capability**: By working with Mercedes-AMG HPP the UCL team knew that they could manufacture the device to the very high specifications demanded for medical devices.
- **Established relationships**: UCL had well established relationships with individuals at UCLH and Mercedes-AMG HPP. This meant that the teams could start collaborating in a highly trustful environment from Day 1.

6.3.2.2. CSIC's SARSCoV-2 detection patent and the MPP: Voluntary free licensing via the patent pool

In 2020, the Spanish National Research Council CSIC filed for patent protection for COVID-19 detection test (EP20382495.8). This was developed by a team of CSIC researchers. The work was financially supported by the Spanish Government and Spanish Medicine and Medical Devices Agency who made it possible to undertake the clinical trials and manufacture and test the assay in Spain. Support was part of a broader initiative to build national capacity to manufacture vaccines in Spain. A license to manufacture the test-kits was signed with a Spanish company. However, this was not exclusive because the CSIC wanted to retain the option of having the technology used more widely.

In 2021 a representative of the CSIC attended a meeting of the European TTO circle and presented the license agreement to the wider technology transfer community. This brought it to the attention of the WHO and the MPP who suggested that the technology be licensed to the C-TAP patent pool where the MPP could help to broker sub-licenses with a focus on LMIC.

The resulting non-exclusive license to the MPP was signed on the 20th November 2021 with the right *'to sublicense to Third parties to encourage generic manufacture and the development of COVID-19 diagnostic technologies'*.

The licence to the MPP contains a number of notable clauses.

3. ROYALTIES

MPP will require Sublicensees to pay royalties on Net Sales of Licensed Products directly to CSIC on a country-by-country basis starting from the date of the first commercial sale of Licensed Products.

Royalties will be paid as described below:

A. Royalty-free for sales to any LMICs for use in any LMIC;

B. In HICs where there is a Patent Right granted and in force in the country of manufacture or sale, a non-creditable, non-refundable royalty of fifteen percent (15 %) payable on Net Sales in the previous calendar year and on a country by country basis and commencing on the date of the first sale of Product and continuing until the expiry of the last-to-expire Patent Right in such country.

C. In HICs where there is no Patent Right granted and in force in the country of manufacture or sale but where Licensee has used the Material for the manufacture of the Licensed Products, the royalty as described in 3(B) will be payable for a period of ten (10) years from the Effective Date.

5. KNOWLEDGE TRANSFER

The license foresees the need for know-how to flow from researchers at the CSIC to sublicenses. A commitment is made by CSIC to make knowledge available while any associated travel and out-of-pocket costs and are foreseen to come from Sublicensee with an acknowledgement that time and costs of KT will be minimised e.g. by electronic exchanges and allocating a sufficient and technically capable workload to knowledge transfer activities.

8. ASSIGNMENT AND SUBLICENSES

8.2. Licenses and sublicenses. MPP and CSIC will discuss and agree upon the identities of interested and suitable Third Parties to whom MPP shall grant sublicences for the purposes of fabricating and/or commercialising the Product. ***MPP will require in the sublicences that sublicensee(s) use commercially reasonable efforts to ensure that the Product(s) be made available in LMICs at affordable pricing***. (Emphasis added)

TRANSPARENCY

The CSIC and the MPP also agreed that a copy of the Agreement as well as all sublicences may be publicly disclosed on the MPP's website.
It can be downloaded at: https://cdn.who.int/media/docs/default-source/medicines/c-tap/c-tap-mpp---csic-license.pdf?sfvrsn=6adf5560_1

Outcomes

This was the first experience of royalty free licensing for CSIC. But following this experience, the Research Council have mainstreamed clauses for LMIC into the Institute IP policy.

6.3.2.3. COVID-19 Compulsory Licensing – the case of Hungary and Remdesivir

While the concept of compulsory licensing received a great deal of attention during the COVID-19 pandemic there are few EU examples of compulsory licenses being granted. An exception was Hungary where the provisions on public health compulsory licensing were introduced into Hungarian law in 2020 as a response to the pandemic and where the trigger for a potential compulsory license is '**unmet supply needs in a health emergency situation declared under and as defined in the Public Health Act'.** An applicant must apply for and obtain a certificate from the Hungarian Intellectual Property Office (HIPO) as the national pharmaceutical regulatory authority.

In November 2020, Richter, a Hungarian pharmaceutical manufacturer, submitted applications for compulsory licenses for three patents concerning remdesivir. This is a drug, approved by the European Medicines Agency, for the treatment of some patients suffering from COVID-19 and pneumonia requiring complementary oxygen therapy. The HIPO granted the compulsory license one week after receiving the application. It was only valid for Hungary.

However, the patentee challenged the decision to grant a compulsory license in the Metropolitan Court, the Metropolitan Appeal Court, the Curia, (acting as the supreme court of Hungary) and finally, successfully, Hungarian Constitutional Court.

In October 2023, the Constitutional Court published its decision and annulled all the decisions made on the subject matter compulsory licence due to the violation of the Fundamental Law of Hungary. This decision was based on whether fundamental law principles had been followed in the process of granting the license including whether the interests of right-holder had been carefully considered in fair proceedings.

The decision was sent back to the HIPO with an instruction to re-evaluate whether the **preconditions for granting a public health related compulsory licence did in fact exist in 2020.**

The Hungarian Remdesivir case raises a number of interesting issues beyond legal process.

1. While the conditions for granting a licence were stated as '*unmet supply needs in a health emergency situation declared under and as defined in the Public Health Act'*, this proved difficult to demonstrate in practice. The patentee Gilead Sciences argued that they, and other companies in the Gilead group, had been supplying Veklury® (remdesivir) in fulfilment of orders placed by the Hungarian government under agreements concluded with Gilead at the European Union level. Hungary, as a Member State of the EU, was part of this scheme.

2. While there were Remdesivir shortages in the USA and other countries, and the price remained very high, Gilead Sciences blamed this on the complexity of the production process and the challenge of scaling it up. Gilead Sciences did not rapidly or strongly utilise out-licensing and left the impression that it would be hard for any other company to replicate the process successfully, possibly as a result as a need for trade-secrets that would not be available in the patent. However Bangladesh is classified as a WTO Least-Developed Country, meaning that it is not required to offer patents on pharmaceutical products and Bangladesh-based companies including Beximco, independently recreated remdesivir and began selling it one month before any Gilead Sciences-authorized partners began production. In contrast to the $3,120 per treatment cost that the United States paid, Beximco's drug cost only $336 per treatment. Other Bangladeshi companies soon also began producing the generic, leading to a growing surplus that allowed Bangladesh to export fifty-thousand vials to six other countries by late July191 and to twenty-one countries by late August.

Equitable access involves not only **availably** but **affordability**. The Hungarian case may suggest that in some cases, compulsory licensing holds the key to both issues.

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