LICENSING AND ACCESS TO **HEALTH TECHNOLOGIES**

Overcoming the obstacles to public return on public investment in R&D

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Irene Bernal Carcelén Ph.D
Advocacy & Research Manager, Salud por Derecho

Jaime Manzano Lorenzo
Research & Advocacy Officer, Salud por Derecho

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ACRONYMS

AUTM	Association of University Technology Managers
COVID-19	Coronavirus Disease 2019
C-TAP	COVID-19 Technology Access Pool
COVAX	COVID-19 Vaccines Global Access
EU	European Union
GPG	Global Public Goods
HICs	High Income Countries
IP	Intellectual Property
IPR	Intellectual Property Rights
K&TT	Knowledge and Technology Transfer
LMICS	Low- and Middle-Income Countries
mRNA	Messenger Ribonucleic Acid
MC12	WTO 12th Ministerial Conference
NIH	National Institutes of Health
PROS	Publicly Funded Research Organisations
RC	Research Centre
R&D	Research and Development
TRIPS	Trade-Related Aspects of Intellectual Property Rights
TTO	Technology Transfer Office
WHO	World Health Organization
WTO	World Trade Organization

1. INTRODUCTION

A biomedical research ecosystem can be considered to be made up of several actors collectively creating a value chain in the public and private sphere[1] where each link is essential, and in which the public sector plays a major role in basic and applied research.[2] The result (and added value) of publicly funded and supported research is nonetheless frequently transferred to the private sector, and the capacity to control or influence critical matters, such as price-setting of health technologies or management of intellectual property (IP), is therefore lost. During the COVID-19 pandemic, the development of new health technologies supported by the public sector occurred at a speed never witnessed before.[3] Despite this, large parts of the world have been excluded from equitable access to vaccines, treatments, and diagnostics.

In this context, new emphasis has been placed on the need for making biomedical innovation a global public good (GPG),[4] in the sense that others cannot be excluded from consuming it, i.e. nonexcludable, and consumption by one party does not decrease the quantity available for other parties, i.e. nonrival. However, the non-excludability of a good, as is the case for biomedical knowledge, is dependent on political choices[5] and the IP rights (IPR) architecture that governs and shapes current biomedical innovation, which can then turn a public good into a commodity that is excludable and rival in consumption.[6] Whereas the GPGs approach is crucial for explaining the necessity of public investment in research and development (R&D), this approach does not capture the full extent of the complexity of public return and risk-taking in the biomedical innovation ecosystem.[7,8] Hence, what appears to be critical is the governance of medical knowledge aimed at protecting and fulfilling public interest.[9–12]

As such, publicly funded and supported research organisations (PROs) play a key role in biomedical knowledge governance. During the early stages of the COVID-19 pandemic, from January 2020 to September 2021, public research organisations and universities filed almost the same number of patent applications as private companies for COVID-19 vaccines and therapeutics.[13] Likewise, PROs were at the origin of important health technologies needed to address the pandemic, later patented by private companies.[14,15] In this sense, strategies designed by public research institutions with regards to the management of biomedical IP are considered to have an impact on the global accessibility of health technologies.[16–18] There seems to be a consensus, with some exceptions among PROs, about patenting as an unavoidable path to commercialisation.[19] Such an assumption has a clear impact on the actions of a variety of actors also influencing knowledge and technology transfer (K&TT) strategies.[20] There are different mechanisms available to work towards downstream equitable access that can be achieved via the use of non-exclusive licenses or inclusion of conditionalities as safeguards ulterior accessibility.[21]

The above-mentioned issues will be approached in this research. The first part will describe the current context and how COVID-19 has presented an opportunity to build upon initiatives to ensure more equitable and affordable access to health technologies. Some crucial concepts and ideas found in the literature will also be referenced. Secondly, results from the field research carried out based on seven interviews, five with research centres dealing with public funding and two with experts, will be shared, highlighting the logic of the technology transfer process and barriers to pursuing non-exclusive licenses. The last part gathers main conclusions and recommendations.

Overall, this document aims to identify obstacles and hurdles to the public return on public investment in PRO and suggest remedies and solutions, considering recent developments in the context of pandemic response and international cooperation.

2. CONTEXT

The current biomedical innovation model has often been pictured as essentially market-driven, therefore not providing an adequate response to the health needs of billions.[22] The COVID-19 pandemic has brought the consequences of this imbalance to the forefront, with it representing a moral breaking point. It is not only the distribution of mortality and morbidity patterns of COVID-19 across the world that has been unequal, the distribution of health technologies and the medical knowledge that underpin them also followed a pattern of exclusion.[23,24]

In the face of global socioeconomic disruption, with a World Health Organization (WHO) estimated death toll of 14.9 million worldwide up to the end of 2021 alone,[25] massive public funding for R&D was mobilised to respond to the pandemic, mainly by means of large-scale vaccination programmes. While the publicly funded knowledge behind these tools should have been treated as a global public good to effectively address the emergency[26] with conditionalities to avoid monopolies, the reality is that pharmaceutical companies retained control over the IPR and, ultimately, product distribution.

Despite numerous calls to improve access worldwide, distribution of initially limited vaccine supplies revealed stark inequities between countries and regions, reflected in vaccination rates.[27] The same patterns were reproduced in later phases of the pandemic when treatments were sought - mainly Global North countries could access these.[28] Therefore, several initiatives to improve access conditions were launched. The first critical step to achieve equity in the distribution of any COVID-19 health technology is to access the health technologies per se, for which protection of IPR might represent a major obstacle.[29,30] In that regard, the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement provides mechanisms, known as flexibilities, ratified in the Doha Declaration of 2001, to limit the extent of patent protection for medical products in response to public health needs. One of these flexibilities is the compulsory licensing of patents to facilitate the generic manufacturing of biomedical technologies. In short, these mechanisms acknowledge the barriers that the IPR system might entail, particularly for low- and middle-income countries (LMICs),[31] and offer solutions for countries to manage IPR with the flexibility needed to protect and adequately respond to public needs.

However, existing TRIPS flexibilities were considered inadequate to address the pandemic, both in scope and timeframe. In October 2020, South Africa and India proposed a temporary waiver of certain IPR provisions of the TRIPS agreement, which was formally supported by over 60 co-sponsors among World Trade Organization (WTO) membership, and strongly opposed by the majority of high-income countries (HICs).[32] This waiver proposal attempted to overcome the limited usefulness of the TRIPS flexibilities in the context of a pandemic and achieve global and timely access to vaccines and other heavily patented health technologies. However, after over 18 months of discussion, what came out of the WTO's 12th Ministerial Conference (MC12) of June 2022 was a ministerial decision which looks more like an export exemption, far from what was envisaged at the beginning of the pandemic.[33]

Further, several internationally backed initiatives to alleviate structural K&TT barriers were developed to facilitate voluntary licensing agreements that could foster global equitable access. In this regard, the Solidarity Call to Action, launched by Costa Rica and supported by the Director-General of the WHO, set the bases for the subsequent COVID-19 Technology Access Pool (C-TAP).[34] C-TAP was a platform created to share IP, know-how and other related data that could contribute to enhancing and diversify production of COVID-19 health technologies through non-exclusive agreements and multi-stakeholder collaboration worldwide.

This initiative was accompanied by the temporal mandate expansion[35] of the Medicine Patent Pool (MPP) to cover COVID-19 products (including vaccines) and involvement in C-TAP as implementing partner (along with the Open COVID pledge and the UN Technology Bank).[36] This recognised the trajectory of the patent pool in improving access to other life-saving medicines for LMICs through non-exclusive voluntary licences.

One relevant element included in the Solidarity Call to Action was to encourage governments and R&D funders to include clauses in publicly funded and donor-funded agreements in the form specifying access provisions "through global non-exclusive voluntary licensing".[34] This initiative was echoed by other funding providers, such as the European Commission's temporary framework to fund COVID-19 related R&D under the condition of granting non-exclusive licences to third parties in the European Economic Area.[37] Furthermore, the Commission launched the "Manifesto for EU COVID-19 Research",[38] to facilitate access-related guiding principles for European Union (EU)-funded grant recipients working on COVID-19 prevention, treatment, and testing. It stated that signatories would grant non-exclusive, royalty-free licences for a limited period of time to the IP generated with EU funds. As of 21 June 2022, over 500 organisations have signed up even though the document is not enforceable.[39]

Likewise, the Coalition for Epidemic Preparedness Innovations (CEPI), a public-private partnership playing a lead role in the COVAX facility, requested funding recipient vaccine developers to grant equitable access and ensure effective technology transfer processes.[40] Meanwhile, the WHO has established a COVID-19 mRNA vaccine technology transfer hub to contribute to scale up, diversifying production and enhancing health technologies accessibility, with a special focus on LMICs.

Other pandemic institutional commitments appear in the academia technology transfer arena. The COVID-19 Technology Access Framework set up the guidelines to grant non-exclusive, royalty-free licences of IPR during the current pandemic. Initially signed by Stanford and Harvard Universities, along with the Massachusetts Institute of Technology, it collected over 20 signatories, mainly from US academic institutions.[41] Much broader support was given to the COVID-19 Licensing Guidelines developed by the Association of University Technology Managers (AUTM), which proposed a similar licensing strategy.[42] Despite these efforts, a recent study showed that, in the UK context, universities did not modify their institutional patenting and licensing strategies at the beginning of the pandemic, with the exception of the Universities of Edinburgh and Oxford.[43] Such pledges remain voluntary and are not enforceable.

While the initial apparent support of diverse institutions and stakeholders, including PROs, for the above-listed pandemic-related initiatives seemed promising, difficulties rose in the implementation of the statements and fulfilment of public commitments, as reflected in the C-TAP initiative. Although 43 governments have officially endorsed this initiative, there are only two entities that have concluded licence agreements with the C-TAP, both of them public research institutions: first, the Spanish National Research Council and more recently the United States National Institutes of Health (NIH). Of these, only the first has actually licensed a product. It is worth noting that to date no private company has engaged with the C-TAP. To this extent and given the difficulties in transforming statements and pledges into concrete actions, it is worth asking what barriers PROs face when attempting to engage in technology transfer to multiple stakeholders through non-exclusive licensing or contributing to pools of patents and other data-sharing mechanisms.

2.1 Determinants of Licensing Strategies

When an innovation is successfully developed at a PRO, the technology transfer offices (TTO) face a choice of what licensing strategy to implement, as the PRO can grant an exclusive licence or multiple non-exclusive licences. Alternatively, PROs could also publish the research results via open access for all interested parties. The licensing strategy to be adopted is determined by a range of factors that will lead to the selection of different strategies with various degrees of exclusivity. The literature suggests that the nature of the invention, the technological and competition situation in the particular field, as well as the type of licensee entity will affect the chosen strategy.[44] The theoretical understanding in relation to the nature of the invention is that those innovations in an embryonic stage would demand an exclusive licence to attract private investment, while more generic or developed innovations could be licensed in non-exclusive terms.[45] However, some studies have shown that other characteristics of the innovation, such as product maturity, might not impact on the selection of the licensing strategy to such a great extent, but that it is more closely linked to other factors such as:

- The lack of capacity at the transfer units.[46]
- Communication channels with research teams.[47]
- Negotiation processes,[48,49] bargaining position.[45]
- Financial constrains that affect negotiation practices.[50]
- Market knowledge.[51]

Furthermore, the reviewed literature provides relevant information about general characteristics of the PRO regarding overall licensing strategies and performance, such as the size and prestige of the centre.[52,53] Additional studies identified further impediments to transfer practices, including cultural barriers and bureaucratic constraints.[50]

Whereas the number of options available, as seen above, would potentially imply a wider degree of variety in licensing practices, the literature shows that, in the biomedical sector, PROs must navigate an environment where exclusivity is the norm. A systematic review and qualitative study,[21] with the aim of addressing how medical knowledge is exchanged between PROs and private companies, found that only exclusive licences were dealt with in the reviewed studies, and that this was the default strategy to succeed in attracting industry investment. While studying the perceptions around medical knowledge transfer, the authors observed that they were built around the following blocks:

1. The marketing of a product requires large investments.
2. Accessibility conditionalities, such as those related to affordability, generally equate to a decrease in future revenue.
3. Research institutions have a worse bargaining position in the negotiations than private companies.
4. Bringing a medical product to its final state must involve a private company to make it possible.[21]

Although the significant role of the public sector in clinical trials is increasingly recognised in the public and academic debate, the reviewed literature frequently highlights the idea that biomedical innovation often requires large investments in clinical trials and therefore licencees will push hard to get exclusive rights for the patent rights as a means to compensate risk and achieve early market dominance.[54] In terms of IP management in technology transfer, the model aims mostly at privatising and commercialising research outcomes[55] when the objective should be the maximisation of welfare over private value through proper knowledge governance processes. This balance between the dissemination of the R&D results in the public interest and private restriction of access is recurrent in the reviewed literature.[56] Indeed, it is recognised that financial constraints have triggered organisational changes in PROs that have oriented them to a greater extent towards the market, which may ultimately impact the research portfolio.[57] Others have highlighted the importance "of using the exclusive right to ensure inclusion"[58] in the management of biomedical IP to achieve public health objectives. In this sense, public interest can be operationalised in IP management, either through ownership or funding mechanisms, both of which improve bargaining power in negotiations.[58] To ensure the implementation of access conditions, IP licensing agreements should be accompanied by institutional engagement (including at government level), incorporation of provisions for conditional funding, and transparency in agreements emanating from publicly funded research.[59,60] To adopt access conditions, TTOs may also benefit from cross-institutional learning, and the development of indicators that reflect socially responsible licensing practices.[61]

3. METHODOLOGY

Between April 2022 and June 2022, seven interviews were held with publicly funded research organisations and technology transfer experts. A total of five institutions and nine individuals participated in the study.
The three main inclusion criteria considered for the selection of research centres were (1) geographical scope, covering Latin America, Europe, Africa and Asia, (2) percentage of public and/or philanthropic funding greater than or equal to 20% of total institutional budget, and (3) involvement in basic or applied COVID-19 related research. Experts were recruited based on their knowledge and expertise of the biomedical technology transfer ecosystem. Based on this, an initial mapping of 40 institutions was performed using publicly available databases that included COVID-19 R&D and funding.

From the initially identified institutions, a first contact was made with 30 institutions, based on availability of contact information in the public domain. Contacts were initiated via email and, when available, via professional internet social networks.

An informed consent form was shared with participants prior the interview date, and written informed consent was collected. Interviews lasted between 25 and 60 minutes, depending on the length of answers, and were conducted through access-controlled video conferencing. A semi-structured interview guide was used, including questions related to licensing policies and protocols, licensing strategies and perceived barriers, accessibility clauses, public funding, stakeholders' involvement, collaboration with knowledge-sharing platforms and impact of COVID-19 on their practices.

After transcription, codes were identified, and every transcript was independently reviewed. Whereas the 20 most frequent codes above the sample mean were presented in the results section, all codes were analysed so that no relevant information was left out. All codes are presented in Annex 1, indicating whether they were either deductively coded, based on a predefined set of codes generated from the literature review, or inductively coded, based on the qualitative interview data itself.

4. RESULTS

The aim of this study was to identify barriers that PROs face when licensing their products under more open licensing agreements, which could ensure better access to affordable health technologies. In the literature and the discussion, the underlying assumption is that non-exclusive strategies, as well as other IP sharing mechanisms, would facilitate broader access to health technologies. In this sense, the field research included questions[a] related to this which connect to other ideas and insights.

The results presented reflect the qualitative analysis of seven interviews, five of them with technology transfer units at PROs and two with individual experts. The scope of this study is thus limited to these seven respondents and should be considered more as a pilot study with some patterns deductively identified through the first phase of literature review. These patterns were confirmed with the field research, and others were added, to clarify current barriers faced by research centres.

It is important to highlight that, out of the 25 PROs contacted worldwide, we had an acceptance rate of 20%. The low response and acceptance rate lead us to infer that this field needs to establish more fluid communication bridges with other areas beyond the strictly commercial ones, as tech transfer units are now closed spaces that are difficult to access, even for potential allies from other constituencies.

As part of the data analysis, 45 codes have been tagged, 85% of which were deductive codes developed from the literature, and 15% were inductively coded during the analysis for a total 373 results. Graphic 1 presents the frequency of the twenty most referred to codes.[b] These codes represent the core of the analysis due to their greater presence, but also reflect exceptions when the pattern was less homogeneous. At the end of this section, a summary of the results is represented in Graphic 2.

Graphic 1. Code Frequencies

[a] Refer to methodology for the key topics of the interview guide.

[b] See methodology.

4.1 Licensing Policies and Strategies – Exclusivity vs Non-exclusivity

In practical terms, PROs usually have guidelines and general standardised processes for dealing with the licensing of the R&D results, which in some cases are subject to quality control. However, decisions on a product-by-product basis seem to be the norm, which can make each process very specific. In this sense, technology licensing strategies can vary depending on the nature of each result, but also depending on the field of research. This differentiates the biomedical field from others, such as engineering. Whether or not these product-dependent practices are acknowledged, the biomedical field is perceived as exclusivity-prone.

Based on this idea, it is important to highlight the perception that most of the licensing in the biomedical field is based on exclusivity and support for "spin-offs", which may involve finalising development and scaling-up production, although there are exceptions in some cases. In such situations, either no patent application has been submitted, and consequently there is no exclusive IP issue on the transfer process, or spin-offs are not a viable option for the PROs. The data suggests that the more systematized the licence policy, and the more market-oriented the PRO, the more attractive it becomes to the companies.

The type of partners involved in product development is important as each partner has its own attitude towards licensing. This, in turn, makes every project specific, with some companies more open to discuss and explore new models of licensing beyond full exclusivity. Thus, licence processes must also be adapted to new ways of working, such as consortiums, networks and platforms, while keeping in mind funding providers' conditions. In this sense, funding providers are becoming more familiar with tech transfer processes and, in their grant conditions, have a say in this, giving their role the potential to be very powerful in terms of access provisions.

TTOs and the lead scientist remain in communication about the transfer process, often moving beyond mere feedback and establishing tight collaboration and communication channels with the scientific team and the companies in a triangular dialogue. Their position at this stage gives a new dimension to licence policies: effective communication between the parties and capacity-building among researchers about the K&TT process.

According to our findings, there is diversity around access provisions in licensing practices. With some exceptions, many of the responses confirm that there are no access provisions included into their licence processes. However, some PROs appear to have established red lines while negotiating an agreement. Certain changes are emanating in this regard, and certain matters linked with access provisions have become more common in public debate since the pandemic.

4.1.1 Barriers to Licensing in Non-exclusive Terms: Obstacles and Practices

Overall, our results indicate that licensing a product is far from an easy task and a number of circumstances can influence the process. This, in turn, has a significant impact on the type of licence (if any) that is ultimately granted. The results have been clustered based on different obstacles identified by interviewees and their interlinkage.

The first barrier is related to the characteristics of the **product itself**. The main goal for TTOs is to reach the market. However, they sometimes face hurdles either because the product is still in a very early stage and not mature enough, as will be explained below, or simply because it is not interesting to companies. Another related aspect suggested by our research is that the evolution of certain diseases may move faster than the innovative product development, affecting the prospects of finding market space. For instance, if a potential vaccine for a specific variant of a virus, evolution of mutations might render the product less clinically and commercially attractive once it is finally developed.

These barriers are also associated with the research stage of pharmaceutical innovations. A distinction is made between what represents

a high-risk investment, due to the necessity of costly additional development phases, such as clinical trials, or low-risk investment, such as mature, ready to commercialise innovations. This concept is closely linked to the necessity for private investors to have a good competitive position. Thus, if the innovation requires high-risk investments to progress to different clinical phases, exclusivity-based commercial exploitation is considered the only way to attract such investments. In short, the research stage, along with the nature of the product, will have an impact on the licensing practice pursued.

TTOs must often navigate uncertainty because the product is still in an early phase. This can be a barrier in terms of reduced negotiating power and can negatively affect the prospects of finding a company willing to invest. In line with this, additional public engagement is needed during the latest clinical stages, including physical infrastructure or additional funding mechanisms. This would strengthen PROs' position and assets in the K&TT process, while also creating new alternatives for licensing. As pointed out by participants, this must be understood within a financially constrained context where product development mandatorily requires a clinical phase but no funding options for independent clinical trials are available. It was suggested that independent bridging institutions could greatly assist in closing this gap.

A second barrier identified is that of the **market itself**. For instance, in certain countries the private biotech business ecosystem is extensively developed and active, whereas in others it might not be ready to absorb all the innovation. The perception is that the architecture of the current market system demands exclusivity, especially regarding pharmaceuticals.

In that respect, it seems much easier to opt for **non-exclusivity** when the TTO is in one of the following scenarios: 1) it is defined from the outset that the product[c] will be licensed in non-exclusive terms and is unilateral supported by the research institution; 2) the deal is related to a research process instead of a product; 3) the product has many applications, and the licencee company has capacity for only one of them; 4) the final development of the product does not need large investments and could be introduced into the market relatively fast; 5) the licensing partner does not require an exclusive licence; 6) specific and targeted funding which contains non-exclusivity provisions as part of the tech transfer policy.

A third barrier is **organisational-level obstacles** related to PRO or TTO capacity. This is a very common weakness revealed in institutional analysis and whether their means respond to their demands and expected results. In broad terms, there is the perception that an exclusive licence is easier to manage than dealing with non-exclusivity. TTOs would encounter less complexity in licensing to just one entity, instead of having to manage multiple licencees for one product. Additionally, the size of the PROs and the TTO or the lack of sufficient human and financial resources are a key part of this puzzle since PROs and TTOs also have their own delivery and performance objectives.

"Another barrier to avoid non-exclusive licensing (..) is that institutions can manage exclusive licences more easily than non-exclusive ones. [...] Regarding an exclusive licence, the goal of research institutions is to licence the patent before it costs too much money, before entering the national phases, because later on it is very expensive." **[Participant #9]**

[c] Term product is used, but also includes process.

Therefore, it seems difficult for the public system to deal with the administrative burden that non-exclusive licences could entail, and, in some cases, it is even considered beyond TTOs' remit. In addition, IP-related processes have an implied cost, and management of non-exclusive licence agreements could have a greater impact on their budgets. In that context, financial constraints are identified as well within the technology transfer process per se, which would include investment in infrastructure, human resources, and capabilities. A final barrier is identified on an institutional level. The K&TT environment is usually perceived as a technical space rather than a place where institutional policies and access strategy could play a significant role. Consequently, this may have an impact on TTOs, placing them as purely technical units with no real autonomy and disconnected from institutional decision makers' capacity to influence changes in IP policies. However, in some cases, it is recognised that there is a need for institutional alignment between the institution senior management, the scientist and the TTO during the licensing process.

As mentioned above, in some cases scientific teams become very active in the commercial part of their innovation. As highlighted by a participant, the traditional and most common mindset of academia is to consider patents as rewards. This can be identified as an additional obstacle to multiple stakeholders licensing inside PROs.

4.2 Market Dynamics versus Public Interest

The idea that exclusivity is an expected and unavoidable market requirement seems to be widespread. Most TTOs are embedded in the business model adopted by pharmaceutical companies, assuming the market perspective. This contrasts with the traditional view of PROs and universities as institutions devoted to knowledge dissemination towards the wider public. They would generally licence technology to the partner that can best develop it into a final product and commercialise it in the shortest possible time. This idea is linked with some opinions that highlighted the current biomedical innovation ecosystem as being predominantly speculative, with a structure that leaves little room for new and alternative models to be accepted more broadly.

In addition, market competition shapes both funding providers and multi-stakeholder initiatives, and/or public and private initiatives. As such, consortia operate not only as producers of R&D results, but also as mechanisms to raise and compete for funding and private investments. They operate in a funding environment that is supposed to breed competitive market dynamics with a sense of urgency to reach society (or rather the market) as soon as possible, leading to the perception that PROs might not be able accomplish it alone.

> "The R&D funding programmes themselves, (..), which are so competitive, create this market dynamic, having to maintain the competitive advantage so that they can keep competing for funding, so that they can get the resources, relations with companies, etc." [Participant #9]

As previously mentioned, TTOs are both result- and market-oriented, as they must ensure their innovation reaches the market, while complying with their own assessed results and target indicators. Regarding market access, the need for backing from a business strategy is sometimes perceived, which generally applies to exclusivity or spin-offs, and less often to non-exclusivity or wider access policies.

Licensing to multiple parties implies good market knowledge, but also a clear and defined strategy by the PROs and resources to bring multiple stakeholders on board. When consortia or public-

private initiatives are the model, issues such as its size and nature shape the knowledge governance processes. Companies that are part of the consortia will have preferential access to results and the knowledge generated will be managed in a competitive manner, with stakeholders using data results to gain a competitive advantage for the consortia. Indeed, IP management becomes an issue for the market and the R&D/ consortia team, but also an integral part of the pharmaceutical business model. This is explained as a complex issue for transfer units, requiring a medium-term strategy that research centres sometimes do not have, as well as institutional support, budget allocation and funding providers' IP conditions.

In contrast to difficulties with implementation reportedly associated to non-exclusive licences, the market seems more open to accept "semi-exclusive licences", which are seen as more feasible to implement. Semi-exclusive licences are described as exclusive licences, in which different access requirements are considered, with exclusivity being contingent on fulfilling these requirements. In particular, global access clauses in relation to minimum volumes, price or maximum margins were highlighted as a mechanism to regulate market dynamics that could hinder access. Other models, such as patent pooling or voluntary mechanisms, are also incorporated in the market. These are perceived as facilitators of downstream access, although with limitations.

4.2.1 Public Interest and Access Provisions

Public interest is recognised as an objective to be achieved by PROs, either formally with Socially Responsible Licensing (SRL) provisions, or more informally as part of a narrative of what drives their action. It is understood that research centres contribute to innovation, which happens thanks to knowledge and resources generated with public support and therefore should have a societal impact. However, this impact is seldomly specified or quantified and, in most cases, is related to licence provisions in the Global South, rather than considering the public interest of society at large, both North and South. Often, public interest is linked to the need of additional funding to facilitate a knowledge governance independent of market dynamics. In this sense independent clinical trials or funding instruments with similar aim (i.e., Open Science) are seen as good mechanisms that could help to achieve this goal.

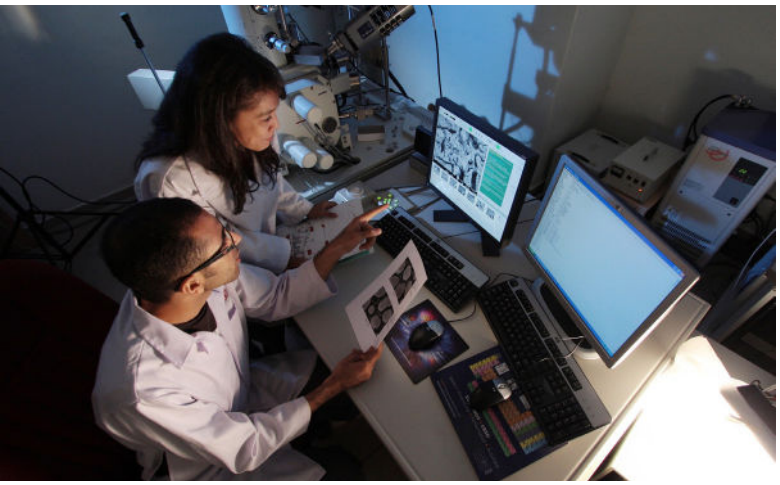
> "I think what we need is a public institution that run the clinical trials for pharmaceutical products to kind of bridge these problems because, in the end, the company takes over the trials but if the funding is public and happened in public places then why not create a mechanism that bridges that gap..." [Participant #8]

Adequate legal frameworks, clear definitions, and effective institutional support are needed to fully consider public interest while transferring technology, and to pursue a broader strategy that ensures the concept of public interest is part and parcel of negotiation agreements. In addition, this level includes the business-oriented narrative, which is very much part of technology transfer. However, the limited access to certain health technologies in many countries—which have greatly increased and become evident during the pandemic—are perceived as the reasons behind the more open discussions on access taking place at PROs and decision-making levels. This shift would have implications for the type of licence agreements.

A) Access provisions

Access provisions are perceived as part of the expected changes which should be embedded into K&TT practices and policies, going beyond COVID-19 agreements. Although these are not detailed by the interviewees, the process seems to define what conditions exist and when they could apply. Patterns have been clustered around four main ideas.

Firstly, the importance of the role of the funding providers in introducing conditions favourable to public interest in grants and calls. Excessive conditions may hinder private companies' interest. It was therefore proposed to find the balance in licence agreements between global access conditions, R&D engagement, and economic return to ensure the public funding is utilised appropriately and the developed product reaches society.



Secondly, while research centres understand that their practices might influence downstream access, inclusion of such conditions has only occurred when they had a significant negotiating position and/or when their partners were receptive to it. Only then are transfer units identified as important enablers of downstream access. However, in order to effectively implement access provisions, an access strategy behind tech transfer practices is required to allow rapid maximisation and return of the innovation investment. On the other hand, many researchers and transfer units are still unaware of their potential role in guaranteeing downstream access.

This is related to (1) clear definitions of access provisions and possibilities and (2) lack of support at the policy level, as mentioned above. This lack of awareness is identified as a barrier to drive change in TTO's practices regarding technology transfer.

Lastly, and regarding IP, research centres can negotiate the governance of the knowledge they generate. According to some participants' views, patents are still a barrier that require discussion. For others, the contribution made by each partner to the project could lead to co-ownership models beyond patent-based. Whereas the main purpose is to create societal impact and public return where IP is not a barrier, the current model has features that prevent this from happening. In addition, research centres and TTO procedures are still very dependent on the legal framework and funding that underpin the technology transfer.

In some specific cases, it seems relevant that institutions aspire to participate in knowledge sharing initiatives. In that sense, the willingness to share background knowledge in a goodwilled negotiation and collaborative way should be assumed. Contrary to what was expected, the issue of transparency has not been as common as other discussed ideas, although it was mentioned. Few interviewees noted that there is a need for greater transparency in how much the public has contributed to a particular innovation and how the impact is going to be measured. As indicators in the TTO do not often relate to societal impact, it is difficult to explain how the public interest that is embedded in the narrative is eventually assessed.

A few participants also expressed that there is a tendency towards opacity in tech transfer practices, which affects documentation disclosure and more detailed information regarding agreements, rendering public scrutiny difficult. This perception is framed under the lack of transparency in the entire R&D process.

B) COVID-19: A window of opportunity

The pandemic context and COVID-19 related access initiatives are seen by some participants as a window of opportunity for change when dealing with licensing agreements for broader access. Some of the patterns identified are:

1. The pandemic context has put everyone to work on the same track with a notable shared sense of urgency. Sharing knowledge, broader access in licence conditions, or specific initiatives to share IP could permeate licence policies.

2. The pandemic is seen as a window of opportunity for certain changes in the business model, which could be applied to other diseases. However, these face the risk of being pushed aside by market forces returning to business-as-usual. In addition, critical analysis should be further developed along with discussions to define, among others, the kind of knowledge that is going to be shared and the mechanisms to proceed.

"Those initiatives are needed, and we need more funding programmes to support those, so that we don't have similar situations like we had during the last two years. When it comes to such a situation with such a disease, knowledge is a public good and this is always the highest value that we have to carry on and to work on that, so I think again here we need more funding initiatives at different levels." [Participant #3]

3. There is a need to review the current patent system with a more open dialogue, assessing its contribution to societal common good and scientific progress (true innovation). This discussion needs everybody on board, including decision-makers, scientists, TTOs, experts, funding providers, and advocates.

4. The COVID-19 pandemic has provoked certain changes related to the presence of global equity dimensions within TTOs. This has helped to put access conditions on the radar when negotiating licensing contracts.

5. International COVID-19 access initiatives are generally perceived as good mechanisms to ensure more equitable production and distribution of manufacturing. However, engagement on this by research centres requires a) time to get familiar with them and to be well expanded with full institutional support; b) specific financial incentives that condition the R&D funding to technology transfer to access initiatives, including independent trials; c) initiatives for the long run; d) companies that are more collaborative, especially with new platforms that can bring new innovations for other diseases. They could be seen as initiatives with high administrative burden and more IP cost, which should also be considered.

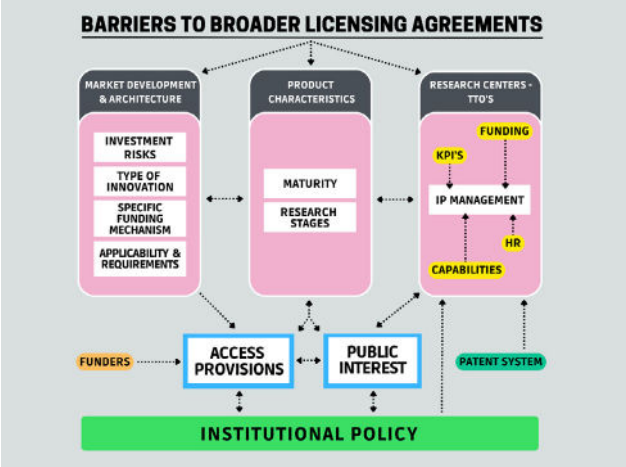
"I do think so…We are exposed to the issue of attempt to transfer technology, things have changed." [Participant #1]

With lesser frequency and in some specific cases, the importance of recent innovations for COVID-19, such as mRNA vaccines to be used widely for other diseases has also been highlighted.

5. LIMITATIONS

One of the main limitations of the study is related to the response and acceptance rate of research institutions, which stood at 36% and 20%, respectively. While the study's sample size has an influence on the external validity of the data, saturation was reached vis-à-vis the research objectives. Due to the anonymity design of the study, there was no possibility of assessing regional differences or variations due to research centre characteristics. Future research should explore these barriers and strategies to overcome them.

Graphic 2. Summary of Results



6. RECOMMENDATIONS

The literature reviewed has anchored the main concepts to approach the research questions. The assumption outlined assesses that non-exclusivity and access provisions are elements that can have great impact on broader affordability and access to health technologies. Such approaches will impact on IP management practices, licensing agreements, tech transfer policies, and ultimately new alternatives to bring publicly funded research institutions' innovations closer to society. Initiatives, such as those boosted to ensure equity in access to COVID-19 vaccines, treatments, and diagnosis, are a good example of mechanisms which can set up a good basis for other diseases. Exclusivity is the most commonly used option when transferring technology by publicly funded research institutions, and most of the barriers identified in the literature reviewed have been highlighted by the field research respondents as well. However, the COVID-19 pandemic has shown great public funding investments on R&D, which has started the public discussion on the issue of public return and how to ensure public interest. Since public and non-profit funders with their financial allocations, along with publicly funded research institutions, contribute enormously to the innovation ecosystem, political and technical measures should be taken. An element that needs to be urgently addressed is therefore how public return, access equity and affordability of health technologies can be ensured. The following recommendations have been outlined to serve that purpose.

Regarding licensing policies:

Exclusivity in contracts and commercialisation of innovations are tied concepts as per the literature and the research. To ensure access equity, affordability, diversified production and manufacturing following the global public goods approach, broader discussion is needed on reforming and finding alternatives to the current system from the core. Changes in licensing policies establishing clear and defined policy commitments at the political and institutional levels will improve downstream access permeating to technical issues.

Regarding the market:

Public interest and social impact must be included in market dynamics. With that purpose, the scope of some concepts, including patents, innovation or access provisions, must be looked at more closely. However, such discussions should be entered into by decisionmakers as well as at the technical level, engaging multiple stakeholders who participate in the innovation chain. The issue of transferring knowledge is a political option.

Regarding funders and financial support:

Funders have a great role to play since many of the access provisions can be incorporated into grant agreements. Such a shift would be assumed by research institutions and tech transfer units. This financial support is needed for an end-to-end project development, which would guarantee investments to complete the clinical phase.

Regarding IP rights:

Barriers for sharing knowledge and IP are identified at different levels. Removing them will entail systemic changes and the reform of domestic and supranational legal frameworks able to address the needs of a multistakeholder space and multiple interests, starting with the interest of society.

Regarding barriers for licensing:

Considered as a political issue, the main obstacles in terms of licensing could be overcome with policies and legal frameworks which include public interest and access provisions in their different mechanisms for licensing. It will entail financial support, strengthening TTO capacities when needed or public interest indicators, among others.

Regarding ad-hoc initiatives:

Initiatives such as those created for the COVID-19 pandemic need to be enhanced, strengthened, and expanded, including to other diseases.

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ANNEX 1

Codes and Type

Nº	Code	Code Type	1*	Nº	Code	Code Type	1*
1	Barriers for licensing	D	7	25	Bargaining power	D	5
2	Change of approach & open discussions	I	7	26	TTO-researcher communication	I	5
3	Public Interest	D	7	27	Competition & market	D	4
4	Public-health-driven innovation system	D	7	28	Long- term research	I	4
5	Multiple stakeholders	D	7	29	Uncertainty & High Risk	D	4
6	Licensing policies	D	6	30	Financialization	D	4
7	Access policies & Conditionalities	D	6	31	Economic return	D	4
8	Access to the market & market strategy	D	6	32	Window of opportunity	I	4
9	TTO technical skills & support	D	6	33	Administrative burden	I	4
10	Funding mechanisms	I	6	34	Spin offs	D	3
11	Product maturity	D	6	35	TTO Performance	D	3
12	Non-exclusive	D	6	37	Incentive	D	3
13	COVID-19 sharing knowledge mechanisms	D	6	37	Royalties	D	3
14	Exclusive licensing	D	6	38	Voluntary sharing mechanism	D	3
15	Global Equitable Downstream Access	D	6	39	Equitable technology transfer	D	3
16	Financial constrains	I	6	40	lack of strategy	D	2
17	Product by product basis	D	6	41	Transparency	D	2

Nº	Code	Code Type	1*	Nº	Code	Code Type	1*
18	Collective knowledge	D	6	42	Patent innovation	D	2
19	IP stewardship	D	6	43	Public goods	D	2
20	TTO legal capacity	D	6	44	Semi-exclusive licence	D	2
21	IP management	D	5	45	Public governance	D	1
22	Knowledge Governance	D	5				
23	Entrepreneurial scientists	D	5				
24	Public-private partnerships	D	5				

* Interviews in which the code is present

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