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DIFFERENT APPROACHES TO INCENTIVIZE VOLUNTARY LICENSING

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Lead researchers:
Adán González and Luis Villarroel V.

Research assistant:
Francisca Bustos D.

Design:
Josefa Quezada

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CONTENTS

LIST OF ACRONYMS

Acronym Meaning

- TRIPS/TRIPS Agreement
- Trade-Related Aspects of Intellectual Property Rights
- IP Intellectual Property
- WHO World Health Organization
- MPP Medicines Patent Pool
- C-TAP / H-TAP COVID-19 Technology Access Pool / Health Technology Access
- Program
- NIH National Institutes of Health (United States)
- CSIC Higher Council for Scientific Research (Spain)
- OTT / TTO Technology Transfer Office
- LMICs Low- and Middle-Income Countries
- SDGs Sustainable Development Goals
- ESG Environmental, Social and Governance
- CSR Corporate Social Responsibility
- R&D Research and Development
- MSF Doctors Without Borders (Médecins Sans Frontières)
- PRV Priority Review Voucher
- SLB Sustainability-Linked Bonds
- USD US Dollar
- LPV/r Lopinavir/Ritonavir (antiretroviral used against HIV/AIDS)
- TDF Tenofovir Disoproxil Fumarate (antiretroviral medication)

- HCV Hepatitis C Virus
- HIV/AIDS Human Immunodeficiency Virus / Acquired Immune Deficiency
- Syndrome
- WIPO World Intellectual Property Organization
- UNICEF United Nations Children's Fund
- UN United Nations Organization
- CSR Corporate Social Responsibility
- COVID-19 Coronavirus Disease 2019

I. INTRODUCTION AND METHODOLOGY

A. INTRODUCTION: Knowledge transfer as an instrument for sustainable development and social value

The transfer of knowledge generated by universities and research centers, as well as private companies, constitutes a strategic component for its social appropriation and the generation of public value. The conditions under which this knowledge is transmitted, adapted, and made available to various social actors directly impact its capacity to contribute to sustainable development.

In particular, these processes can strengthen objectives such as good health and well-being (SDG 3), quality education (SDG 4), industry, innovation, and infrastructure (SDG 9), as well as the reduction of inequalities (SDG 10). From this perspective, knowledge transfer should not only seek to maximize profits but also respond to principles of equity, economic efficiency, inclusion, and social justice, thereby maximizing its social value in the public interest and collective well-being.

In this context, voluntary licenses that respond to principles of socially responsible licensing have emerged as a key mechanism to facilitate the transfer of technology and intellectual property (IP), promoting an ethical and more equitable distribution of technologies, especially in the health sector, as well as addressing other public interest considerations, as will be explained further.

However, the adoption of voluntary, socially responsible licensing by IP holders, particularly in the private pharmaceutical industry, has been limited. Therefore, it is essential to identify the challenges and incentives required at both the global and national levels. This paper seeks to provide insights into these challenges.

B. BACKGROUND

1. Objective of the study

The purpose of this study is to identify and analyze the incentives that can encourage universities, research centers, companies, and public or private organizations to adopt voluntary licensing models oriented toward equitable access and other social values.

Various incentives, including financial, regulatory, intangible, and reputational, have been examined to integrate social responsibility into technology transfer decisions. Likewise, we have analyzed how national innovation policies can complement voluntary approaches to create a more conducive environment for cooperation, equity, and sustainability in innovation. While the principles developed in this study apply to various types of technologies, the analysis draws on experience with voluntary licensing in the field of health technologies, where access gaps and technology-transfer challenges are particularly significant.

C. METHODOLOGY

The development of this report was based on a qualitative and interpretive design, combining a documentary review with semi-structured interviews with key stakeholders. The methodology was structured into three main components:

1. Document review

This study involved a comprehensive review of relevant literature discussing voluntary licensing incentives, including reports from the WHO, the MPP, and other international organizations, as well as academic articles and policies related to access to medicines and intellectual property management. The search for relevant literature focused on key terms such as “voluntary licensing,” “technology transfer incentives,” socially responsible licensing,” “patent pool,” “C- TAP” (H-TAP), and “MPP.” This study also involved a review of databases. In addition, documents shared by stakeholders during the research process were incorporated to complement the findings.

2. Semi-structured interviews

Semi-structured interviews were conducted with 36 representatives of various interest groups, including:

- WHO and MPP officials involved in voluntary licensing initiatives.
- Representatives or officials of the private pharmaceutical industry with experience in
- intellectual property licensing.
- Civil society organizations advocating for equitable access to medicines.
- Managers of university technology transfer offices.
- Experts, scholars in IP policy and global health.

Customized interview guidelines were developed for each stakeholder group, with questions designed to explore the types of incentives used, barriers to adoption, and recommendations for best practices. The interviews were conducted virtually via platforms such as Zoom and lasted approximately 30 to 60 minutes. The selection of interviewees was based on their experience and elevance to the topic and was complemented by a "snowball" strategy to identify additional contacts that would enrich the analysis.

3. Data analysis

The data collected through the document review and interviews were analyzed using a basic coding approach. A coding guide was developed from the themes identified in the document review and adjusted to reflect the interviewees' perspectives. Key topics included: types of incentives for voluntary licensing (financial, intangible or non-financial, regulatory, and strategic); internal and external factors that affected or hindered their effectiveness; and recommendations for their implementation. Data triangulation was processed with help of tools of artificial intelligence, linking documentary findings with interviewees; perceptions, providing a diverse representation of perspectives, including those from developing countries.

D. CONCEPTUAL FRAMEWORK

Socially responsible voluntary licensing in the public interest or for social responsibility is considered a mechanism that may improve access to technologies essential to sustainable development. This approach aims to reconcile the commercial exploitation of intellectual property rights with both the societal interest in ensuring that the benefits of innovation are equitably accessible and that the transfer of such knowledge is respectful of other public-interest considerations. In fact, such licensing practices can also stimulate innovation and research by fostering collaboration, knowledge exchange, and the development of technologies that address public needs.

1. Understanding Voluntary Licenses

Through voluntary licenses, patent holders willingly grant other entities the right to use their intellectual property, enabling the production and distribution of essential technologies or medicines. These agreements operate under mutually negotiated terms that balance access objectives with the rights holders interests.

Voluntary licenses typically include several key conditions. These may encompass royalt payments (usually a percentage of net sales, commonly around 5%), geographical restrictions that often exclude high- or upper-middle-income countries, and price controls for products marketed by the licensee. Additional terms may include limitations on the use of active ingredients (for example, requiring their acquisition from authorized distributors) and grant-back clauses that oblige the licensee to grant the patent holder licenses on any improvements made to the original invention. Many licenses also include provisions for the transfer of technology and know-how to facilitate local manufacturing capacity.

These licenses are typically non-exclusive, promoting competition among generic manufacturers, which in turn reduces drug prices. A notable example is Gilead's non-exclusive licenses for Tenofovir Disoproxil Fumarate (TDF), which generated significant cost decreases (Wirtz et al., 2020, p. 20). In practice, these licenses for medicines are usually directed toward manufacturers in low- and middle-income countries with high disease burdens—such as those facing HIV/AIDS or hepatitis C epidemics—enabling them to produce affordable versions of essential treatments (Simmons et al., 2019).

2. Voluntary licenses: classification and relevant cases in the health sector

Among the most relevant categories of voluntary licenses are non-exclusive licenses, which, by not limiting the number of licensees, encourage healthy competition among generic manufacturers, thereby reducing prices and improving accessibility to medicines, in addition to increasing healthcare efficacy, adherence to treatments, and reducing the risks of resistance, therapeutic failures, and mortality (Wirtz et al., 2020). Prominent examples include Tenofovir. Disoproxil Fumarate (TDF), licensed by Gilead to multiple manufacturers in 117 countries through the Medicines Patent Pool (MPP), covering 90.5% of people with HIV in LMICs (MPP, 2011), and Remdesivir, licensed during the COVID-19 pandemic to producers in Egypt, India, and Pakistan (Oliveira, 2020, p. 105).

Additionally, royalty-free licenses, frequently motivated by institutional or reputational objectives, eliminate royalties to maximize the impact on public health, as in the case of Lopinavir/Ritonavir (LPV/r) for pediatric use, licensed by AbbVie free of charge in 102 countries, covering 98.8% of children with HIV in the developing world (MPP, 2014), or Abacavir, licensed by ViiV Healthcare for 99.3% of children with HIV in LMICs (MPP, 2013).

Another significant group includes licenses with royalties or tiered prices, which typically incorporate a percentage of net sales (commonly 5%) or reduced prices in LMICs, while maintaining higher prices in high-income countries to prevent parallel imports. Although these licenses, such as Gilead's Sofosbuvir, which combined tiered prices of $1200 USD per treatment in eligible countries with generic licenses at $684–750 USD (Assefa et al., 2017, pp. 2–3), or Novartis' Nilotinib with a 5% royalty in seven middle income countries (MPP, 2022), have been criticized for not promoting as robust competition as nonexclusive licenses, they are helpful in small markets or with production limitations.

Licenses managed by patent pools, such as the MPP or the Health Technology Access Programme (H-TAP), play a crucial role in negotiating transparent and non-exclusive terms, facilitating technology transfer, and diversifying production around the world, as seen in the case of COVID-19 technologies under H-TAP (Oliveira, 2020, pp. 103-104). Finally, licenses can vary in their territorial scope, ranging from national, such as dolutegravir in specific countries, to global, as seen with the NIH COVID-19 technologies, which adapt to global health needs.

3. Voluntary licensing and socially responsible licensing

Voluntary licensing, as explained, occurs when a rights holder willingly authorizes others to use its intellectual property under mutually agreed terms, typically to encourage collaboration, stimulate innovation, or expand access to markets without coercion or a regulatory mandate.

Socially responsible licensing, in turn, extends this framework by embedding ethical and social considerations into the licensing process. It ensures that intellectual property is managed in a way that is responsive to public welfare, particularly access to essential medicines, technologies, and knowledge in low- and middle-income countries. Socially responsible licensing explicitly integrates social impact principles, often through provisions such as the retention of research rights, obligations to develop the product, affordable pricing, non-exclusivity clauses, and equitable access provisions.

4. Socially Responsible Licensing Principles

In the United States, Socially Responsible Licensing (SRL) principles have undergone significant development since 2007, when a group of universities led by Stanford reached consensus on nine foundational principles. These guidelines have progressively shaped university licensing practices to prioritize the public interest, safeguard academic freedom, and ensure equitable access to technologies. In particular, universities are encouraged to retain rights for research and education, structure exclusive licenses responsibly by setting clear development milestones, and ensure access to essential technologies for underserved populations.

Additionally, nonexclusive licensing is recommended for basic research tools, and caution is advised when dealing with patent aggregators to avoid entities that prioritize litigation over technology development. A recent NIH policy further requires license applicants to include an Access Plan that guarantees broad and equitable access for both the U.S. population and marginalized groups worldwide. In Europe, SRL principles are integrated into broader guidelines for knowledge valorization, placing a strong emphasis on ethical alignment and societal impact. University licensing should address urgent social and economic needs, such as public health and sustainability goals, and include mechanisms like non-exclusive licenses and fair pricing to promote equitable access for vulnerable communities. Dutch guideline also advocate ethical partner selection, benefit-sharing that respects traditional and Indigenous knowledge, and the explicit exclusion of licensees whose activities conflict with social values, ensuring that licensing activities remain compatible with the universities' core missions of teaching, research, and social benefit. In the context of European knowledge valorization policies, the European Union has consolidated a comprehensive approach that links innovation with social responsibility and sustainability. Instruments such as the Council Recommendation (EU) 2022/2415 and the Commission Recommendation (EU) 2023/499 promote voluntary, socially responsible licensing, combining accessibility and profitability while adhering to ethical and transparent principles. In turn, the Mutual Learning Exercise on Intellectual Asset Management and the Commission Communication on Corporate Social Responsibility (2006) reinforce the need for institutions and companies to integrate social and environmental considerations into their technology transfer strategies. Finally, Directive (EU) 2022/2464 on sustainability reporting consolidates this commitment, requiring companies to report practices aligned with an ethical, inclusive, and common-goodoriented innovation model. In the academic field, socially responsible licensing has begun to be institutionalized in university policies and technology transfer frameworks. Experiences such as the Socially Responsible Licensing Program at the University of California, Berkeley and the "Ten Principles for Socially Responsible Licensing" of the Dutch Federation of University Medical Centers, demonstrate that universities can incorporate global access clauses in their licensing agreements, guaranteeing differentiated pricing, mandatory sublicenses for low-income countries, and commitments to supply through generic manufacturers In Europe, ultimately, a European approach to SRLs proposed impact licensing.

Impact Licensing is defined as a time-bounded permission granted by a technology owner to bring at preferred rates or reduced price an intellectual property, a technology, a product, or a service to a pre-defined (social) market for societal value creation."(European Commission, 2020). It is further elaborated as a voluntary, contract-based approach rooted in six core principles: additionality, intentionality, measurability, total return on assets (TROA), completeness, and participation. The concept aims to balance economic value for technology holders with societal impact, such as advancing Sustainable Development Goals (SDGs). It is exemplified by cases like IKIC Impact Ventures' licensing of thermostatic battery technology for sustainable cooling solutions in lowresource settings (Mantravadi et al., 2025).

5. Benefits of voluntary licenses and socially responsible licensing

Voluntary and socially responsible licensing have established themselves as essential mechanisms for expanding access to critical technologies while preserving legitimate incentives for innovation (WHO, WTO, WIPO, 2020). Their relevance has been recognized by the World Health Organization (WHO) and multiple multilateral organizations, which promote them as complementary instruments to the flexibilities of the TRIPS Agreement, allowing the entry ofnew suppliers into markets with competition restrictions without resorting to coercive measures (WHO, 2023; UN, 2025).

One of the main documented benefits of this model is its direct impact on public health. According to a study published in The Lancet Global Health on voluntary licensing for hepatitis C treatment, countries that implemented such agreements saw a significant increase in the number of people treated (Simmons et al., 2019). This increase in coverage reflects the ability of voluntary licensing to accelerate the availability of safe and effective generic versions, especially in low- and middle-income countries.

At the economic level, voluntary licensing can generate substantial savings for health systems and international funding agencies. The Medicines Patent Pool (MPP) estimates that agreements managed under its model have led to direct savings of US$2.3 billion between 2010 and 2024, plus US$10 billion in avoided expenditure, for a total economic impact of US$12.3 billion. These benefits come not only from price reductions resulting from generic competition, but also from the earlier introduction of priority formulations, such as pediatric formulations, and from the so-called "avoided expenditure resulting from the faster adoption of essential treatments (MPP, Annual Report 2024).

The joint report by MPP and Boston Consulting Group (2024) demonstrates that rights holders participating in voluntary licensing not only improve their institutional reputation and reduce political and regulatory risks but also gain access to new markets through tiered royalty schemes based on income levels. This approach enables the reconciliation of intellectual property protection with equitable access to healthcare and new markets, thereby consolidating a win-win model that combines social impact and economic viability. Voluntary licensing also facilitates technology transfer and local capacity building. Licenses managed by licensing platforms and other mechanisms often include clauses for technical support, knowledge transfer, and compliance with quality standards, thereby strengthening productive and regulatory capacities in recipient countries (MPP, Annual Report 2024). These licensing processes not only democratize production but also contribute to regional industrial development, reducing technological dependence.

Another crucial benefit lies in the model transparency and replicability. Unlike traditional bilateral agreements, platform-driven voluntary licensing publishes essential license terms, territories covered, royalty rates, and quality clauses establishing open and verifiable governance standards (MPP, Annual Report 2024; MedsPaL, 2024).

This level of transparency has been endorsed by the WHO (2023) and consistently recommended by the UN High-Level Panel on Access to Medicines (UN, 2016) as a good international practice, due to its potential to reduce information asymmetries and foster trust among all stakeholders involved.

Finally, the reputational and ethical benefits associated with these models should be highlighted. As highlighted in the joint report by the Medicines Patent Pool (MPP) and the Boston Consulting Group (2024), institutions that adopt voluntary licensing strategies project ethical leadership and institutional coherence, thereby strengthening societal trust and potential international partnerships. This intangible prestige, although difficult to quantify, translates into strategic alliances with multilateral organizations, investors who consider ESG criteria, and global scientific networks committed to health equity (MPP and BCG, "Voluntary Licensing: Right for Health, Smart for Business, 2024).
Universities and research centers, whose essential mission is to generate and apply knowledge for sustainable development and social well-being, can find voluntary, socially responsible licensing a

key tool for fulfilling their public function. The inclusion of socially responsible clauses in individual contracts, such as those embedded within the Coalition for Epidemic Preparedness Innovations' (CEPI) funding agreements with vaccine developers, illustrates how proactive commitments to equitable access can generate transformative downstream impacts in global health equity. CEPI's Equitable Access Policy embeds obligations into each vaccine-development funding agreement, including mechanisms such as affordable and sustainable pricing, manufacturing scale-up, technology transfer, and stockpile commitments (CEPI, n.d.). In CEPI's partnership with Valneva SE for the development of IXCHIQ®, the world's first strictly regulated chikungunya vaccine, these provisions mandated the transfer of manufacturing technology to partners in low- and middle-income countries (LMICs), such as the Serum Institute of India (SII) and Instituto Butantan in Brazil (Valneva SE & Serum Institute of India, 2024). The agreements also stipulated affordable, tiered pricing structures and retention of a Public Health License to enable supply to outbreak-affected regions regardless of ability to pay (CEPI, 2024; Valneva SE, 2024).

II. INTERVIEW RESULTS

This report organizes the results of interviews with various stakeholders into two main sections. The first focuses on identifying the challenges that must be addressed when designing policies or measures to incentivize voluntary and socially responsible licensing. In contrast, the second explores the incentives that could foster it, classified by type. For a more precise analysis, both the challenges and incentives have been differentiated with respect to the private sector in general and to universities or research centers. It is essential to note that, in some instances, several challenges and incentives are relevant to both types of licensees, thereby highlighting their shared and particular nuances.

A. PERCEIVED CHALLENGES IN IMPLEMENTING VOLUNTARY LICENSING IN THE PUBLIC INTEREST

The findings are derived from a systematic analysis of the interviews and the identification of participants main contributions, as outlined in the previously described criteria.

The first subsection examines common perceived challenges in relation to the industry and universities.

The second one presents the difficulties and challenges reported by interviewees regarding businesses and the private sector, organized by frequency of mention.

Similarly, the following subsection addresses the challenges identified in universities and research centers, applying the same criteria. As evidenced by the results, diverse and even opposing positions emerge on key aspects, reflecting the complexity of the topic. This plurality of perspectives not only enriches the analysis but also enhances the interpretive validity of the findings, providing a comprehensive view that can inform future policies and strategies. These elements are detailed below in a structured manner.

B. COMMON PERCEIVED CHALLENGES IN RELATION TO THE INDUSTRY AND UNIVERSITIES

1. Internal misalignment between the different functional areas of institutions holding transferable innovations.

One aspect highlighted in the interviews is the internal misalignment across companies functional areas, which appears to be a barrier to the adoption of voluntary licenses. Management teams (CEOs), sales, research, legal affairs, marketing, and corporate social responsibility (CSR) operate with divergent priorities, hampering coordination and delaying the approval of licensing agreements. This internal fragmentation hinders swift, coherent decision-making, particularly in organizations with complex hierarchical structures, where institutional incentives often fail to align with the goal of equitable access to health technologies. In response, some interviews suggest strengthening interdisciplinary integration and internal strategic alignment so that equitable access goals are aligned with economic sustainability and corporate governance.

Universities also face similar internal fragmentation challenges, as evidenced by the obstacles frequently highlighted in this studys interviews. Additionally, there are significant differences in negotiation and management models across universities, leading to inconsistencies and hindering the development of standardized policies. In many cases, faculties, technology transfer offices (TTOs), and higher authorities, such as vice-chancellors, fail to align their different priorities.
This results in contradictory messages and uncertainty for business partners, undermining efforts to negotiate and incorporate social clauses into university licensing agreements effectively. Within large universities in developed countries, this lack of coordination often stems from highly autonomous departmental structures. In smaller institutions in developing countries, limited resources exacerbate coordination problems and hinder consistent implementation of socially responsible licensing. Additionally, in developing countries, institutional constraints and a lack of intergovernmental coordination hinder the creation of coherent, enforceable regulatory environments. An interviewee from a university in a developing Latin American country emphasized the need for public institutions responsible for science and production to set clear policies that require access and sustainability clauses in partnership agreements and contracts.

2. Legal and regulatory uncertainty

Another challenge reported by interviewees in this study is the difference in regulatory standards across countries. Companies would have to adapt contracts to disparate national regulations, which increase costs and the risk of non-compliance. From a business perspective, this regulatory patchwork would complicate the implementation of uniform licenses, especially in low- and middle-income countries with heterogeneous legal frameworks.

In universities, interviewees also highlight regulatory and administrative obstacles that limit the practical implementation of access or social responsibility clauses. The lack of clear legal frameworks, the ambiguity of concepts such as "equitable access," and the voluntary nature of many available tools hinder their effective implementation.

3. Financial Gap

Another significant challenge is the lack of funding for early-stage projects, which creates a structural gap between basic research and licensing readiness. Many small biotechnology firms and academic laboratories that develop promising health technologies, particularly those targeting low- and middle-income countries, lack the resources to advance to critical stages such as clinical trials, preclinical validation, or bioequivalence studies. This financial bottleneck often delays or prevents early collaboration with organizations that manage voluntary licensing or technology access initiatives.

Consequently, several interviewees emphasized the need to establish bridge financing mechanisms to sustain these projects through proof-of-concept and translational phases, enabling their eventual inclusion in voluntary or socially responsible licensing frameworks.

4. Need to Strengthen Capacity-Building in Socially Responsible Licensing

Within universities, another major obstacle identified by interviewees is the high turnover of personnel in Technology Transfer Offices (TTOs), which undermines the consolidation of negotiation skills and the accumulation of institutional experience. This instability is particularly acute in public universities across the developing countries, where limited budgets and short-term contracts discourage professional continuity and long-term training, thereby weakening collaboration with the private sector.

In contrast, in high-income countries, staff turnover is often driven by competition among institutions for specialized professionals. Yet, the outcome is similar in both contexts: a loss of strategic continuity and reduced capacity to implement or maintain responsible licensing practices. Furthermore, the lack of familiarity, experience, and technical knowledge in access-to- medicines and global health issues reinforces this weakness, limiting universities' ability to negotiate and enforce social impact clauses in licensing agreements.

5. Perception that early licensing may affect a product's market positioning

Another barrier identified by some interviewees is the perception that early voluntary or socially responsible clauses may negatively affect a product's market positioning. This concern is especially pronounced among start-ups, small biotechnology firms, and university spin-offs, which often view early licensing as a potential signal of reduced exclusivity or diminished commercial potential. According to interviewees, this perception can discourage investors and limit opportunities for acquisition or strategic partnerships with larger pharmaceutical companies.

To address this challenge, they emphasized the need to develop balanced licensing strategies that highlight the commercial advantages of responsible licensing—such as access to emerging markets, enhanced reputational value, and the potential for long-term sustainability through partnerships with global initiatives like the Medicines Patent Pool (MPP) or the Health Technology Access Pool (HTAP), which promote both innovation and equitable access.

Similarly, universities and public research institutions may hesitate to include access or affordability clauses in early-stage agreements, fearing that such provisions could dilute potential profits or weaken their negotiating position with private companies. This concern is particularly acute during the initial stages of technology transfer, when dependence on commercial partners for development funding can make institutions more deferential to corporate interests. In these cases, exclusivity is often seen as a "dealbreaker" that takes priority over social impact. Overcoming this perception requires not only flexible commitments, such as the accessibility plan provision elaborated by the University of California, Los Angeles (UCLA) and the Medicines Patent Pool (MPP) in 2021[1] (Medicines Patent Pool, Upstream access, 2024). This initiative is not only awareness-raising and evidence of the strategic benefits of SRL, but also clear institutional policies that safeguard both public interest and market competitiveness.

6. Voluntariness of the terms

A recurring issue identified by interviewees concerns the voluntary nature of current principles and tool kits, which significantly limits their systemic impact. While international initiatives and policy frameworks—such as socially responsible licensing UC Berkeley template 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:
(SRL) guidelines, voluntary licensing platforms, and responsible innovation toolkits— have raised awareness and promoted best practices, their non-binding nature often leads to inconsistent implementation. In particular, these tools lack mandatory provisions or enforcement mechanisms related to product affordability, accessibility, or equitable distribution. As a result, their adoption largely depends on the goodwill or reputational incentives of participating institutions rather than on enforceable commitments.

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7. Uncertainty in demand and procurement in LMICs

Another major barrier identified by interviewees is the uncertainty in demand and procurement in low- and middle-income countries (LMICs). This unpredictability— driven by fluctuating public health budgets, variable donor commitments, and fragmented procurement systems—wasfrequently cited as a justification for the low rate of technology transfer and voluntary licensing. In such contexts, companies and universities struggle to project returns on investment, as purchase volumes are often uncertain and national reimbursement capacities are limited. This financial risk discourages firms from engaging in technology transfer or scaling up local manufacturing, as production at full capacity without a guaranteed offtake can lead to substantial losses, perpetuating supply shortages in vulnerable regions. Experts emphasized that enhanced transparency and data sharing, particularly regarding national procurement plans, disease burden estimates, and donor-funded purchasing forecasts, could significantly reduce this uncertainty andmake markets more predictable. They pointed to the licensing of dolutegravir through the MPP as an emblematic case of how predictable demand and alignment with public health needs can foster sustainable licensing models. The dolutegravir license facilitated widespread access to affordable antiretroviral therapy, benefiting an estimated 20 million people and contributing to preventing 1.8 to 1.9 million deaths between 2014 and 2023 (MPP, 2023; WHO, 2022). These experiences illustrate that greater coordination between procurement agencies, governments, and licensing mechanisms can transform market uncertainty into a driver of equitable and sustainable access.

8. Lack of information and metrics to evaluate the concrete results of non-exclusive or socially responsible licensing mechanisms

The lack of information, transparency, and evidence on the concrete results of nonexclusive or socially responsible licensing mechanisms was a concern. This lack of data makes it difficult to assess their impact. It might create uncertainty among universities and companies regarding the effectiveness of such approaches, which could discourage them from adopting them. Some institutions perceive that this lack of evidence can discourage potential partners or investors, who might prefer traditional monopolistic schemes.

Metrics and incentive structures normally focus on indicators such as the number of patents, licenses, or royalties collected, rather than on the social outcomes of technology transfer. Additionally, the lack of clear metrics to evaluate the social impact of licensing policies makes it difficult to justify

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decisions to university rectors or councils that do not translate into immediate economic benefits. Without verifiable indicators, TTOs struggle to demonstrate the value of responsible agreements and sustain strategies that prioritize equitable access.

The lack of monitoring tools also prevents measuring outcomes such as coverage, affordability, and the speed of product implementation, keeping the debate at a theoretical level. Some interviewees propose moving forward with the creation of monitoring and evaluation systems to measure variables such as price, availability, population coverage, and the speed of market introduction. Longitudinal studies would also enable the tracking of the impact of responsible licensing clauses over time and justify their inclusion in contracts.

C. PERCEIVED CHALLENGES IN RELATION TO THE INDUSTRY

According to those interviewed, particularly about pharmaceutical companies, the following challenges are observed in implementing voluntary licensing in the public interest:

1. Business model based on exclusive rights

A central challenge lies in integrating voluntary licensing in the public interest into corporate business models that have historically relied on exclusive intellectual property (IP) rights to maximize shareholder value and finance future innovation. In the traditional pharmaceutical and biotechnology model, patent and know-how exclusivity remain a core mechanism for recouping research and development (R&D) costs and attracting private investment (OECD, 2021; WIPO, 2023).

However, this structure often conflicts with broader public health objectives that depend on non- exclusive or socially responsible licensing to facilitate wider access to essential technologies (WHO, 2021; UNDP, 2022). In practice, most observed cases of voluntary licensing in the public interest reveal that companies tend to retain control over IP rights in markets considered commercially attractive, maintaining exclusivity even in middle-income countries such as many in Latin America, where direct sales to higher-income segments are prioritized (MSF, 2020). By excluding these markets from voluntary licenses, often justified on grounds of commercial sensitivity, firms prevent the entry of generic competition, thereby sustaining higher prices (MSF, 2022).

This selective territorial strategy illustrates how current business models remain anchored in exclusivity-driven incentives, posing a structural barrier to the broader adoption of equitable and socially responsible licensing frameworks.

2. Risk aversion and perceptions of lack of quality in local production

Another reported challenge concerns companies risk aversion, particularly regarding the quality and production controls of potential partners for generic alternatives. In this regard, companies have expressed concerns that weak controls over local production and insufficient technical capacity could compromise their quality standards, potentially posing health risks, triggering legal conflicts, and affecting their global reputation.

According to the interviewees, this risk would justify their caution, given the difficulty of selecting partners in markets with weak regulations or in sectors with lower industrial capacity.

In contrast to these assertions, other interviewees note that the limited technology transfer and the low number of licenses in the region are closely linked to limited investment in local production and a lack of a high-risk investment culture, which explains this phenomenon, especially in areas such as biotechnology.

Thus, while companies tend to base their refusal to license technologies on alleged concerns about quality and production control, these reasons are seen by other stakeholders as a discourse that reinforces technological dependence and limits the creation of local capabilities. Similarly, companies are estimated to have concerns about creating medium- or long-term competitors through these technology transfers, which would also explain this exclusion.

3. Parallel imports and smuggling

Interviewees cited the risk of parallel imports and product diversion often as a justification for maintaining strict control over distribution channels and limiting the scope of voluntary licenses (MPP, BCG, 2024). Pharmaceutical firms express concern that lower-priced products supplied under voluntary or tiered-pricing schemes in LMICs could be re-imported into higher-priced markets, thereby eroding their pricing strategies and market segmentation (OECD, 2018).

This perceived risk often leads to a preference for closely supervised or geographically restricted transfers, which, in turn, constrains scalability and reduces the potential reach of voluntary licensing initiatives in LMICs.

However, some interviewees note that empirical evidence of significant leakage or smuggling is scarce and is often overestimated relative to its actual occurrence, and could be mitigated through improved supply-chain traceability, serialization, and transparent distribution monitoring, rather than by restricting technology transfer.

4. Political and institutional risks in destination countries

Political and corruption risks in destination countries are another mentioned challenge, as geopolitical instability, distrust of procurement processes, and suspicion of weak institutions discourage companies from investing in these regions, which are perceived as unstable.

In this regard, some consider corruption an exaggerated excuse, while others see it as a real threat and propose strengthening local institutions to create reliable regulatory frameworks that encourage collaboration.

5. Lack of experience in managing multilateral contracts

Some participants argued that patent pools or multilateral licenses would require more legal and-compliance resources than bilateral agreements. This administrative complexity would consume time and specialized personnel, discouraging participation in collaborative initiatives.

On the contrary, some participants argue that this perception exaggerates the difficulties, as pools would offer long-term efficiencies by standardizing processes, reducing negotiation times, and improving coordination, without compromising access standards.

6. Apprehension of international litigation or arbitration

Additionally, some interviewees associate risk aversion with an apprehension of international litigation or arbitration. Companies view contractual disputes in foreign jurisdictions with unpredictable legal systems as potential risks. According to companies, this concern increases their caution when negotiating in unstable markets, as they prioritize legal certainty.

However, some external experts argue that these risks are manageable through clear contracts and dispute resolution clauses, suggesting that the perception of insecurity may be exaggerated to justify reluctance.

7. Confidentiality and know-how

Another concern raised by interviewees concerns technology transfer and the protection of know-how. Companies perceive risks to the security and confidentiality of technical information during licensing, which could threaten their competitive advantage, especially in advanced technologies.

However, some interviewees believe that these risks could be mitigated through robust security protocols and advocate for collaborative frameworks that protect sensitive data without hindering technology transfer.

8. Shareholder pressure

Regarding economic factors, several interviewees agree that a profit-maximizing business logic would influence decisions on voluntary licensing. In this context, shareholder pressure would play a significant role, as investors could interpret this type of licensing as a partial surrender of profits or as a threat to the traditional investment recovery model. Thus, in the interviews, some people indicated that this pressure would limit their room for maneuvering and generate internal resistance, especially when licensing is perceived as contrary to immediate financial interests.

To reverse this trend, it is suggested that strategic communication be strengthened to highlight the economic and reputational value of voluntary licensing, emphasizing its potential to increase brand visibility, expand markets, and enhance the company's social commitment. In this view, empirically demonstrating that access strategies can generate both social impact and sustainable economic benefits would be key to aligning corporate interests with global health objectives.

9. Lack of alignment with global pricing strategies

Tiered pricing policies could conflict with the terms of voluntary licenses if this information is used to pressure prices down in other markets, posing a risk to the portfolio's overall commercial management. According to interviews, some companies are concerned that low prices in LMICs will be used as a benchmark to reduce margins in high-income markets, affecting their profitability structure.

D. PERCEIVED CHALLENGES FOR UNIVERSITIES AND RESEARCH CENTERS

From the perspective of interviewees affiliated with universities and research centers, voluntary licensing offers a strategic opportunity to align the production of academic knowledge with principles of social equity and universal access to health innovations. However, several obstacles exist, which vary significantly between the Developed and the Developing countries. The following challenges were identified from the interviews. It is worth noting that the list is comprehensive of all remarks received; however, a few may be anecdotal in nature and not indicative of a consensus.

1. Lack of metrics and prioritization of the social impact of the transfer

The lack of prioritizing the social impact of technology transfer over commercial implications, even in public institutions, is an important challenge. Incentive structures focus on indicators such as the number of patents, licenses, or royalties collected, rather than on the social outcomes of technology transfer. Additionally, the lack of clear metrics to evaluate the social impact of licensing policies makes it difficult to justify decisions to university rectors or councils that do not translate into immediate economic benefits.

Without verifiable indicators, TTOs struggle to demonstrate the value of responsible agreements and sustain strategies that prioritize equitable access. The lack of monitoring tools also prevents measuring outcomes such as coverage, affordability, and the speed of product implementation, keeping the debate at a theoretical level. Some interviewees propose moving forward with the creation of monitoring and evaluation systems to measure variables such as price, availability, population coverage, and the speed of market introduction. Longitudinal studies would also enable the tracking of the impact of responsible licensing clauses over time and justify their inclusion in contracts.

2. Power imbalances in negotiations

Finally, strategic obstacles expose significant power imbalances in technology transfer negotiations, where universities frequently concede to companies' exclusive demands to secure partnerships.

This tendency stems from multiple structural factors, including financial constraints and dependence on private investment for high-risk stages such as clinical trials; limited market intelligence and negotiation capacity within universities; the inherent uncertainty of early-stage innovations that weakens their bargaining position; administrative burdens linked to managing non-exclusive licenses; and persistent pressures from business models that equate equitable access provisions with diminished profitability.

E. PERCEIVED INCENTIVES FOR VOLUNTARY LICENSING IN THE PUBLIC INTEREST

For analytical purposes, we grouped the incentives collected in the interviews and the literature into four broad categories: financial, intangible, regulatory or administrative, and strategic. Each category will address different aspects that, together, will contribute to creating a favorable environment for technological cooperation and global access to innovation, covering key issues such as profitability, institutional reputation, institutional efficiency, and risk management, among others.

1. Financial incentives

Financial incentives seek to make voluntary licensing attractive to the licensor from an economic perspective, offering tangible benefits to licensees who engage in voluntary licensing in the public interest. Several interviewees suggested that financial incentives would help maintain business profitability while not sacrificing access to and public health objectives.

2. Intangible incentives

Intangible incentives aim to offer non-economic benefits that encourage companies and rights holders to participate in voluntary licensing programs. On the one hand, greater commitment to corporate social responsibility improves a company's image and strengthens its institutional reputation. This recognition can generate a competitive advantage by strengthening trust among consumers, investors, and governments.

3. Regulatory and administrative incentives

Regulatory and administrative incentives aim to simplify bureaucratic processes and reduce the costs of technology transfer, thereby facilitating the market entry of licensed products and ensuring that technologies reach countries in need more quickly and efficiently.

4. Strategic incentives

Strategic incentives are linked to companies' ability to manage risks and strengthen their market position through voluntary licensing decisions. Under this logic, voluntary licensing is understood not only as a measure of social responsibility but also as a smart business strategy that balances sustainability, reputation, and global expansion. In turn, this mechanism would strengthen institutional partnerships with universities, public agencies, and other key players in the innovation ecosystem.

F. PERCEIVED INCENTIVES FOR THE INDUSTRY AND UNIVERSITIES

1. Financial incentives

a). Conditioning of public and private financing

It has been noted that establishing requirements and public-interest priorities, such as nonexclusive licensing and other conditions, helps align resource use with global equity principles, thereby strengthening collaboration between the public and private sectors.

This approach institutionalizes social responsibility throughout the R&D cycle, ensuring that funded investments generate tangible, sustainable social benefits, as outlined in several of the access policies that have been adopted, including the NIH Intramural Research Program Access Planning Policy (NIH, 2025), the Global Access Commitments Agreement incorporated in some projects funded by Bill & Melinda Gates Foundation (CureVac GmbH Bill Melinda Gates Foundation, 2015), CEPI's Equitable Access required in all funding agreements (CEPI, 2018), and CARB-

X's "Stewardship & Access obligations in Sub-Award Agreements" requiring the elaboration of an access plan outlining what strategies they will deploy to ensure responsible stewardship and appropriate access in low- and middle-income countries (LMICs) (CARB-X, 2021).

Conditioning public and private funding on the adoption of voluntary licensing agreements is a strategic mechanism to align innovation with public-interest objectives. By requiring that recipients of government or institutional funds, such as research centers or private companies, grant fair access to the technologies they develop, governments help prevent publicly financed research from becoming the basis for exclusive, profitoriented monopolies.

b). Tax incentives and benefits for socially responsible or voluntary licensing

Fiscal instruments can be designed to reward entities that align intellectual property (IP) management with public-interest objectives. Incorporating socially responsible licensing (SRL) or voluntary licensing (VL) clauses into IP contracts—such as non-exclusive licensing, equitable pricing, or technology transfer to low- and middle-income countries—can, in some cases, qualify for preferential tax treatment through indirect mechanisms like charitable deductions or innovation-focused incentives.

The experiences of various jurisdictions demonstrate how fiscal instruments can be structured to foster voluntary, socially responsible licensing by rewarding the dissemination of publicly beneficial technologies.

The OECD (2023) notes that to address failures in the market for research and development, governments worldwide strive to boost R&D investment among firms using financial support instruments. In this regard, Patent Box or Innovation Income Deduction regimes in countries such as the United Kingdom, Spain, and Belgium, which grant reduced tax rates on income derived from qualifying intellectual property, illustrate mechanisms that could be adapted or refined in new legislation to explicitly link fiscal benefits with access-oriented licensing or equitable technology transfer, thus transforming existing innovation incentives into tools for social responsibility. Similarly, the United States' Internal Revenue Code § 170(m), which provides enhanced deductions for qualified contributions to charitable or non-profit institutions, may offer a concrete precedent for recognizing humanitarian or public-interest licensing as a socially valuable fiscal category (IRS, 2024, pp. 13–14, 16). France's Crédit d'Impôt Recherche and Chile's Law 20.241 can also demonstrate how R&D tax credits can stimulate innovation while potentially being expanded to condition eligibility on responsible dissemination practices (France Ministère de l'Économie, CIR, Section 1, para. 3; Chile Law 20.241, Arts. 1–2).

However, experience with existing IP tax regimes reveals significant risks of gaming and profit- shifting without corresponding public benefit. To function effectively as social responsibility tools, any adaptation of these mechanisms must include robust guardrails: clear, measurable criteria for what constitutes "access-oriented or equitable licensing; mandatory public disclosure of license terms and reach; independent verification of access outcomes; and sunset provisions or penalty mechanisms when promised access fails to materialize. Without such safeguards, fiscal incentives risk subsidizing symbolic commitments that generate tax benefits while delivering minimal improvements in actual access or technology transfer.

Finally, the European Commission's Horizon Europe Programme Guide, which integrates Responsible Research and Innovation principles and encourages open access and responsible licensing, shows how public funding frameworks can operationalize these concepts, serving as complementary models for legislation seeking to align fiscal policy with voluntary licensing and equitable access (European Commission, 2023).

c). Public purchase of patents

The public procurement of university-owned or publicly funded patents is presented as an innovative—though still relatively uncommon—incentive through which governments acquire patent rights at a fair value and subsequently either place them in the public domain or license them broadly to third parties.

This model enables universities to monetize research outputs without restricting downstream access, thereby ensuring that socially valuable technologies remain openly available for further development. The proposal draws on historical precedents, such as the 1839 daguerreotype buyout, seeks to decouple financial returns from exclusive market control, and promotes wider dissemination of scientific knowledge.

Building on this logic, a central recommendation for strengthening access-oriented licensing is the creation of a Technology Purchase Consortium (TPC)—a mechanism through which governments collectively acquire rights in strategic technologies, including patents, regulatory data, know-how, and biologic materials.

By pooling financial resources and consolidating negotiating power, the TPC increases governments' leverage when requesting non-exclusive licenses or other access-enabling rights from technology holders who might otherwise preserve exclusivity. Its project-based structure allows Member States to form acquisition groups, define cost-sharing arrangements, and harmonize IP management standards, thereby enabling more efficient and scalable procurement of knowledge assets for public health purposes. This coordinated approach is designed not only to reduce barriers to licensing but also to create sufficiently large and predictable markets that support competitive manufacturing and facilitate downstream technology transfer (Love, 2025).

d). Advance purchase (AP)

Advance Purchase is an incentive designed to encourage and de-risk private investment in the development and production of technologies that meet urgent public needs but lack sufficient market incentives. By guaranteeing a market and providing upfront financing even before a product is available, APs "take the risk out of this process by giving a clear financial commitment that the product, once on the market, will indeed be bought" (Boulet et al., 2021).

During the COVID-19 pandemic, these mechanisms were extensively used by governments and international organizations to accelerate vaccine development and scale up global manufacturing capacity. The European Commission, for example, allocated part of its €2.7 billion Emergency Support Instrument to sign APs with companies securing access to millions of doses while enabling rapid industrial deployment (Boulet et al., 2021).

Beyond their role as financial instruments, advance purchase commitments may generate spillover effects relevant to voluntary and socially responsible licensing. When coupled with transparency, intellectual property (IP) sharing, and technology-transfer obligations, APs may serve as pre-negotiation tools that align commercial incentives with publicinterest objectives. In this way, APs may be viewed as complementary instruments to socially responsible licensing frameworks: they provide predictability and stability for public and private actors while, if properly conditioned, fostering the dissemination of technology, equity in access, and transparency.

When combined with clear governance standards and publicinterest conditionalities, advance purchase commitments may thus evolve into practical tools for promoting sustainability, fairness, and accountability in health innovation policies.

2. Intangible incentives

a). Reputational benefits

For companies, adopting a strong Environmental, Social, and Governance (ESG) position, an approach that integrates environmental stewardship, social responsibility, and sound corporate governance into business practices, can provide significant reputational and ethical advantages. ESG positioning serves as an intangible incentive that attracts responsible investors, mitigates public criticism, and strengthens relationships with governmental and non-governmental stakeholders.

Beyond ethical considerations, it enables firms to stand out in saturated markets by validating their access and sustainability strategies, demonstrating that it is possible to attract sustainable capital and create longterm value without compromising commercial objectives. Likewise, the alignment of these ESG reports with legal standards emerges as another key intangible incentive, integrating voluntary licensing of public interest into sustainability standards to comply, for example, with European Union directives (Directive (EU) 2022/2464 regards corporate sustainability reporting) and the like, pressuring companies to adopt access practices to maintain legitimacy in regulated markets and positively influence investment decisions and public policies.

Similarly, in the case of universities and research centers. In a context where social legitimacy, transparency, and sustainability are pillars of institutional performance, ethical and reputational leadership becomes a key incentive for adopting voluntary, responsible licensing. Universities and research centers that choose to transfer their innovations in line with principles of equity, particularly in critical areas such as health, agriculture, and the environment, project an image of ethical coherence, public commitment, and global responsibility. This positioning reinforces public trust and expands their capacity to establish strategic alliances with international organizations, investors guided by sustainability criteria, and partners interested in innovation with social impact.

Various civil society organizations interviewed in this study highlighted the importance of strengthening the implementation of socially responsible licensing mechanisms and suggest incorporating more robust external audits and monitoring systems. These measures could help ESG reporting drive structural transformations and promote broader accessibility, moving beyond mere formal compliance toward more effective and sustainable management.

b). Social and media pressure in health emergency contexts

Another factor stimulating voluntary licensing in the public interest, as recognized in our interviews, is the role of social pressure as a legitimate mechanism for channelling public opinion and social expectations.

In contexts of health crises or other high-visibility situations, public demand often encourages companies and universities to engage in socially responsible voluntary licensing, prompting them to address global needs. In turn, companies can seize this opportunity to mitigate potential reputational damage by aligning their corporate decisions with public opinion and media influence.

A core example of this is Yale University's HIV drug Zalcitabine (ddC) which became a turning point for socially responsible licensing when public pressure forced the university to change its license terms with Bristol-Myers Squibb to allow affordable generic production during the AIDS crisis in South Africa, 2001.

Advocacy from civil society groups like Médecins Sans Frontières led Yale to reconsider its stance, demonstrating how public outcry can influence universities and pharmaceutical companies to prioritize global health equity.

This case inspired other institutions to adopt licensing practices that balance commercial interests with societal benefit. Some interviewees emphasized that this mechanism is particularly effective when supported by sustained media campaigns and strengthened civil coalitions. These strategies help maintain public attention and generate lasting commitments, consolidating a structural response that extends beyond short-term emergency actions.

c). Public Awards

Establishing recognition or awards for entities that implement voluntary licensing in the public interest would be enormously beneficial for academic advancement and institutional visibility, especially if awarded by organizations of high social or political standing, such as the United Nations, the World Health Organization, or the World Intellectual Property Organization. One way to implement them would be through annual awards.

In the case of universities and research centers, Symbolic recognition, such as awards granted by international organizations (e.g., UN, UNICEF, or UNESCO), mentions in annual reports, or media visibility, is identified as a personal and collective incentive that reinforces academic motivation and the institutional culture of public commitment.

These distinctions contribute to consolidating a university identity oriented toward the common good and projecting an image consistent with the principles of social responsibility. In many cases, public recognition also facilitates academic promotion and access to new research opportunities, strengthening the reputation and legitimacy of institutions that integrate responsible licensing into their policies.

3. Regulatory and Administrative Incentives

a). Accelerated or preferential review mechanisms

Some interviewees highlighted that priority review mechanisms can serve as powerful incentives for voluntary licensing and innovation in the public interest. A prominent precedent is the Priority Review Voucher (PRV) program administered by the U.S. Food and Drug Administration (FDA). Created by Congress in 2007 under the Food and Drug Administration Amendments Act (Pub. L. 110-85, § 524), the program was designed to stimulate the development of medicines for neglected tropical diseases. It was later expanded to include rare pediatric diseases (2012) and medical countermeasures (2016).

Under this mechanism, a company that obtains FDA approval for a drug treating a qualifying disease receives a voucher that entitles it to expedited review of another drug application, reducing the average review time from about 10 months to about 6 months. Importantly, the voucher is transferable, allowing companies to sell or transfer it to another sponsor through a secondary market.

According to the U.S. Government Accountability Office (GAO, 2020), between fiscal years 2009 and 2019 the FDA awarded 31 priority review vouchers, of which 17 were sold to other sponsors for amounts ranging from US $67.5 million to US $350 million, while 16 vouchers were redeemed to accelerate the approval of other drugs, including treatments for HIV, type 2 diabetes, and rheumatoid arthritis.

Although the GAO noted that the available evidence on the program's direct impact on drug development is limited, it confirmed that the PRV has influenced companies' strategic decisions and created a tradable regulatory incentive (GAO, 2020).

This structure demonstrates how regulatory acceleration can be monetized as a reward mechanism, suggesting that similar approaches could be adapted to encourage voluntary or socially responsible licensing of essential health technologies, where entities that share their technologies under equitable access terms might receive priority treatment in regulatory review or other administrative processes. This type of incentive could be adapted to cases where the technology is licensed on a non-exclusive or socially responsible basis. Some experts have emphasized the need to strike an appropriate balance between regulatory functions and market incentives to preserve the essential mission of public health agencies.

Another complementary incentive relates to the creation of fast-track examination procedures for socially valuable technologies. A precedent already exists in several jurisdictions: the Fast Patent Track for green technologies, which allows accelerated processing of patent applications linked to ecological or sustainable innovations that mitigate environmental impact. For example, in Chile, this expedited route applies to inventions in areas such as clean energy, pollution reduction, and sustainable production processes (INAPI, 2023).

Implementing similar fast-track schemes to promote healthrelated technologies transferred through voluntary or socially responsible licensing would likely be a low-cost and straightforward measure, mainly if supported by the World Intellectual Property Organization (WIPO) through initiatives such as WIPO GREEN (WIPO, 2023). A further model can be drawnfrom the U.S. Food and Drug

Administration's (FDA) Emerging Technology Program, a regulatory framework designed to accelerate review and provide early technical assistance to companies adopting advanced manufacturing practices (FDA, 2023a). The program seeks to improve the safety, resilience, and efficiency of pharmaceutical production systems (FDA, 2023b). If its scope were expanded, it could include voluntary or non-exclusive licensing as an additional eligibility criterion, integrating equitable access considerations into regulatory incentives.

Under such an approach, companies that transfer technologies through voluntary or socially responsible licensing schemes could receive priority review, shorter regulatory timelines, and greater predictability in plant and process approvals. At the same time, those maintaining strict exclusivity would follow the standard procedure.

This would create a dynamic equilibrium between innovation efficiency and social responsibility, transforming ethical collaboration and technology sharing into competitive advantages that reinforce both innovation and equitable access to medicines. Just as companies, universities, and research centers can benefit from vouchers and accelerated approvals. These instruments provide universities with a competitive advantage by enabling reduced product validation and authorization times through technologies with equitable access clauses. In this way, the commitment to equity is rewarded through tangible benefits in regulatory processes.

b). Legal or policy obligations for access planning and promoting responsible licensing

Another emerging mechanism from our interviews is the establishment of licensing policy requirements that compel licensees (or license applicants) to develop Access Plans covering strategies for reaching vulnerable or underserved populations. A recent example is the National Institutes of Health (NIH), which adopted a policy requiring applicants for commercial licenses on NIH-owned inventions (within its Intramural Research Program) to submit plans promoting affordability, availability, acceptability, and sustainability, including for underserved U.S. communities and populations in low- and lower-middleincome countries (NIH, 2025). Additionally, under the WHO Pandemic Agreement (once in force), Article 9.5 calls for parties to develop policies on including in publicly funded R&D grants, contracts, and similar funding arrangements conditions that promote timely and equitable access to pandemic-related health products—including licensing and/or sublicensing, affordable pricing policies, and publication of relevant licensing terms (WHO, 2025).

4. Strategic Incentives

a). Market expansion and portfolio diversification

Market expansion opportunities position voluntary and socially responsible licensing (VL/SRL) as a strategic pathway for companies to enter or strengthen their presence in low- and middle- income countries (LMICs) without undermining profitability in established markets (Gore et al., 2023).

Rather than representing a loss of exclusivity, these mechanisms can function as portfolio- diversification strategies, enabling firms to capture emerging demand and adapt to shifting global health and demographic trends. In particular, voluntary licenses can open new revenue channels in underserved therapeutic areas, facilitate partnerships with regional manufacturers, and reduce barriers to entry in markets previously considered commercially marginal.

According to some interviewees, companies engaging in responsible licensing—such as Gilead Sciences or ViiV Healthcare through the Medicines Patent Pool (MPP)—have achieved substantial market penetration across LMICs while maintaining commercial stability in high- income economies. These experiences illustrate that voluntary licensing not only expands geographic reach but also enhances brand trust and reputational capital, particularly among public health agencies and international funders that prioritize equitable-access policies.

G. PERCEIVED INCENTIVES FOR THE INDUSTRY

According to interviews, the most relevant financial incentives for pharmaceutical companies are those that align with their profitability-focused business models, offering quantifiable returns capable of offsetting the access measures associated with voluntary licensing in the public interest.

1. Financial incentives

a). Geographic segmentation

According to those interviewed, pharmaceutical companies value geographically segmented licensing mechanisms, as they allow them to generate passive income without incurring significant distribution costs by offering generics in peripheral markets. Such schemes would be appreciated for their operational simplicity, adaptability, and ability to align humanitarian goals with fiscal and commercial strategies, without compromising exclusivity in the most profitable markets.

In practice, companies would perceive this approach as a natural extension of their portfolio strategies, maintaining solid returns in high-income regions while contributing to access in more vulnerable contexts. In this regard, several interviewees highlighted the MPP model as a successful example of geographic segmentation. This mechanism enables companies to voluntarily grant licenses for the production and marketing of medicines in low-income countries, while maintaining control over high-value markets.

b). Tiered pricing

Various experts emphasize the importance of reviewing geographic segmentation criteria and strengthening transparency mechanisms to ensure that these models effectively contribute to technological and productive equity. Along these lines, they pr pose moving toward tiered licensing structures that link royalties to verifiable commitments to technology transfer and local capacity development. These proposals also include implementing technical training and tacit knowledge transfer programs, such as internships or on-site technical assistance, to consolidate technological autonomy and strengthen industry.

c). Access to funding under better conditions and sustainability-linked bonds

Another financial incentive highlighted in the interviews is access to preferential financing for investors committed to environmental, social, and governance (ESG) criteria. Within this framework, reduced interest rates are linked to social impact metrics, such as the adoption of voluntary public interest licensing policies, the integration of ethical responsibility into investment decisions, and the attraction of sustainable capital in a financial ecosystem increasingly aware of non-financial risks.

Companies particularly value these types of incentives for their ability to reduce capital costs in highly volatile environments, while strengthening their financial resilience and projecting a genuine commitment to sustainability and equitable access.

In this regard, several experts emphasize the importance of strengthening the credibility of these-mechanisms through independent audits and transparent, verifiable metrics that guarantee real impact on the value chain. In this way, ESG-based financing can consolidate itself as an effective tool for promoting structural transformations and maximizing social benefits alongside sustainable profitability.

Within this framework, reduced interest rates and improved credit conditions are tied to social impact metrics, including the adoption of voluntary or socially responsible licensing (SRL) policies, the incorporation of access provisions into business models, and transparent reporting of outcomes.

The 2024 MPP Value Report provides evidence that health equity strategies such as voluntary licensing can directly reduce biopharmaceutical companies' cost of borrowing. Firms that embed access to medicines into their ESG strategies are able to issue Sustainability-Linked Bonds (SLBs) at lower interest rates than conventional debt, translating social responsibility into tangible financial benefits.

For example, biopharmaceutical companies such as Novartis, Sanofi, and Teva structured SLBs tied to measurable access targets in low- and middle-income countries (LMICs). When objectives are achieved, these instruments yield savings of USD 13 million – 34 million annually compared with standard bond rates (MPP & BCG, 2024). Sustainability-linked financing thus functions as both a social and financial incentive, rewarding companies for meeting access-to- medicine benchmarks recognized by the Access to Medicine Index (2022).

d). "Pay or play" schemes

The "pay or play" scheme is among the most innovative proposals to promote socially responsible voluntary licensing. The logic of this proposal is simple: pharmaceutical companies that choose not to engage in socially responsible licensing must pay a surcharge, an on sales of patented products, while those that transfer their patents through platforms or other mechanisms are exempt from this payment. The funds raised are used to fund socially responsible licensing programs, local manufacturing, and drug development for neglected diseases, so that even non-collaborating companies indirectly contribute to maintaining socially responsible practices and equitable access to innovation.

In practical terms, this scheme could be implemented at the national level by creating a National Fund for Access to Health Innovation, funded by a surcharge, such as 2%, on the sale of unlicensed products. These resources would be used to strengthen local or regional production of licensed medicines and support technology transfer policies. At the same time, companies that actively participate in voluntary licensing schemes would not only be exempt from the tax but would also be eligible for additional benefits, such as expedited regulatory reviews or priority in public procurement. Thus, the model has the potential to promote cooperation as a rational and advantageous economic decision.

2. Intangible incentives

a). Mechanisms for reducing quality risk

In the context of global health equity, one of the main concerns associated with voluntary licensing is the perceived risk of compromising drug quality, as originating biopharmaceutical companies fear that generic manufacturers may not meet rigorous standards, thereby impacting patient safety and brand reputation.

However, the MPP indirect license management model effectively mitigates this risk through a comprehensive and proactive approach: it selects reliable sublicensees based on strict criteria, including compliance with Good Manufacturing Practices (GMP), requires prior approval from a Strict Regulatory Authority (SRA) before any national registration, implements post-market surveillance mechanisms to monitor ongoing quality, and establishes robust legal frameworks that ensure alignment with international standards.

This strategy not only protects product integrity but also fosters sustainable collaboration that expands access to lifesaving treatments in low- and middle-income countries, demonstrating that voluntary licensing can be a responsible and humane tool for saving lives without sacrificing quality (MPP, Voluntary licensing: Right for health, smart for business, 2024).

b). Measures to mitigate diversion

Within the framework of global health equity, one of the central concerns linked to voluntary licensing lies in the risk of product diversion, where originator biopharmaceutical companies fear that generic medicines will be sold in an unauthorized manner outside of the intended geographies or distribution channels, which could erode their revenues, compromise the integrity of the markets, and affect availability for vulnerable populations.

However, the MPP indirect license management model addresses this challenge through a series of comprehensive measures: (i) trusted collaborations with partners; (ii) strict sublicensee selection processes ; (iii) requirements for prior approval by a Strict Regulatory Authority (SRA), in addition to national approvals; (iv) postmarket surveillance mechanisms to detect and respond to incidents; (v) rigorous trade design requirements. dress, such as differentiated packaging to avoid confusion; and (vi) solid legal frameworks (MPP, 2024).

c). Mechanisms for collaboration and strengthening mutual trust

Several interviewees emphasized the importance of creating collaborative mechanisms that build mutual trust between licensors and licensees, a prerequisite for the long-term success of voluntary and socially responsible licensing models. Persistent concerns among originator companies, particularly the fear of losing control over manufacturing processes, diversion or facing legal liability for products manufactured by third parties, continue to hinder broader participation in technology transfer initiatives (MPP, BCG, 2024).

Addressing these concerns requires mechanisms that not only ensure product quality and regulatory compliance but also promote shared responsibility, transparency, and technical reciprocity.

Among the most frequently proposed incentives are joint training programs and the systematic transfer of tacit knowledge, including technical visits, exchange residencies, and mentorship schemes between manufacturing teams. These measures consolidate local production capabilities, strengthen regulatory alignment, and foster a shared understanding of production standards and process control. Empirical experience supports this approach. For example, the WHO's mRNA Technology Transfer Hub in South Africa, coordinated with Afrigen and Biovac, incorporates hands-on technical training, knowledge exchanges, and peer auditing systems among partner manufacturers across Latin America, Africa, and Asia—an initiative explicitly designed to build trust through co-development rather than onedirectional transfer (Wellcome Trust, Biovac, 2023).

As an alternative to traditional inspection systems, experts also recommend joint audits conducted by both licensors and licensees to verify compliance with Good Manufacturing Practices (GMP) and other quality benchmarks. This collaborative model ensures accountability without creating new dependency relationships, offering a practical means to manage risk and demonstrate a shared commitment to global health objectives. When integrated into contractual frameworks, these mechanisms not only mitigate legal and reputational risks for licensors but also strengthen trust, transparency, and equitable participation across licensing partnerships.

d). Reduction of legal risks

According to some interviewees, a significant barrier to voluntary and socially responsible licensing is the fear of legal liability arising from third-party licensees manufacturing and distribution of products. Companies expressed concern that they could be held accountable for quality defects, adverse reactions, or regulatory non-compliance in medicines produced outside their direct supervision, even under managed sublicensing schemes. This perception of legal and reputational vulnerability constitutes a powerful disincentive to share technologies or patent rights, particularly in sensitive sectors such as biologics or vaccines.

As one interviewee summarized, "the most important aspect is making the liability for the pharmaceutical company as small as possible." Several experts therefore emphasize the need for regulatory and contractual instruments that clearly define and limit such exposure. To further encourage participation, experts have proposed "safe harbor" frameworks supported by governments or international agencies.

Such mechanisms could provide indemnification or shared-liability arrangements for companies-transferring technology in the public interest, provided that products comply with international quality and oversight standards. These measures would enhance confidence among patent holders, reduce perceived litigation risks, and foster a more enabling environment for socially responsible technology sharing.

e). Exchange of experiences with multilateral licensing platforms

Finally, some interviewees emphasized the importance of facilitating peer learning and experience-sharing among companies that have engaged, or are considering engaging, in multilateral voluntary licensing mechanisms. Creating structured dialogue spaces where originator firms and generic manufacturers can exchange lessons learned, operational insights, and best practices were identified as a critical enabler for scaling voluntary and socially responsible licensing (SRL).

Such exchanges can help reduce the mistrust and uncertainty that often arise from limited familiarity with how these mechanisms function in practice. Participants noted that many firms remain cautious about voluntary licensing due to perceived risks related to quality control, liability, or reputational impact, particularly in markets where oversight capacities are stilldeveloping. Peer-learning initiatives can counteract these perceptions by providing concrete examples of successful collaborations demonstrating that international cooperation is compatible with strict quality standards and commercial viability.

f). Data transparency and the creation of recognition systems or Star Ratings that evaluate manufacturers efficiency and social commitment.

Transparency can be a driver of voluntary licensing and socially responsible licensing. Transparency involves publishing information on production costs, clinical trial results, and procurement on public platforms similar to those of the Global Fund, an international organization that finances programs against HIV, tuberculosis, and malaria, and which is distinguished by its policy of open access to financial and purchasing data.

The approach aims to increase transparency in the pharmaceutical sector, enabling independent audits and the development of recognition systems, or star ratings, that assess manufacturers efficiency and social responsibility. Disclosure of socially responsible Licensing provisions embedded in licensing contracts would enable subsequent funders, such as impact investors, philanthropic organizations, or public agencies, to clearly understand and extend those existing social obligations. By making these commitments visible and verifiable, new funding can reinforce rather than duplicate prior efforts, for instance, by expanding geographic reach, enhancing impact measurement, or aligning with broader goals such as the SDGs and global health equity.

3. Regulatory and administrative incentives

The most important regulatory and administrative incentives are those that are systemically integrated into the research and development cycles. Other regulatory and administrative incentives offer lasting competitive advantages by reducing bureaucratic barriers and aligning regulatory frameworks with equity objectives, thereby facilitating technology transfer to LMICs.

a). Extension of exclusivities or monopolies

Some interviewees emphasized that regulatory exclusivities, such as those granted for orphan drugs, pediatric use, or data protection extensions, can operate as powerful incentives to encourage participation in equitable access or voluntary licensing agreements. These mechanisms provide additional periods of market exclusivity for products addressing unmet medical needs, thereby increasing the attractiveness of collaboration in socially responsible licensing initiatives.

When properly structured, they enable firms to translate public health commitments into competitive advantages, reinforcing incentives for innovation while supporting broader access objectives. Examples from the pharmaceutical sector include data exclusivity extensions, orphan drug designations, and pediatric-use rewards, all of which can be combined with voluntary or socially responsible licensing. In the European Union (EU), for instance, Article 8(3)(a) of Regulation (EC) No. 141/2000 on orphan medicinal products authorizes the holder of a marketing authorization to

voluntarily consent to the marketing of a similar product by another company during the exclusivity period. Similarly, Regulation (EC) No. 1901/2006 on medicinal products for paediatric use provides for a six-month extension of the Supplementary Protection Certificate (SPC) upon completion of pediatric studies, thereby linking extended exclusivity to public-interest research.

However, some experts warn that these regulatory exclusivity mechanisms can lead to less affordable and equitable access by granting additional exclusive rights. Therefore, several interviewees proposed incorporating clear conditions to ensure that protections are effectively aimed at promoting equitable and sustainable access, ensuring that incentives for socially responsible licensing fulfill their purpose without generating unintended effects.

4. Strategic incentives

a). Credible threat of compulsory licensing

Several interviewees underscored that an essential policy lever for promoting voluntary or socially responsible licensing is the credible threat of imposing compulsory licenses (CLs) or other forms of unauthorized public use, such as government use or march-in rights.

The mere possibility of invoking these legal mechanisms often serves as a negotiation catalyst, encouraging patent holders to engage in voluntary agreements to maintain a degree of control over their intellectual property and avoid reputational or financial risks linked to unilateral government action (Ramani, 2015). Empirical evidence may demonstrate that the use and even the credible threat of compulsory licensing (CL) have actively favoured the negotiation of voluntary licenses and substantial price reductions in medicines.

The experiences of Brazil and Thailand during the HIV/AIDS crisis exemplify this dynamic. In both countries, governments used CL provisions as a negotiating tool with patent holders, resulting in significant concessions. In Brazil, for instance, threats to issue CLs between 2001 and 2003 enabled price reductions of up to 73% for efavirenz and 74% for nelfinavir (Ford et al., 2007) Interviewees also noted that while the TRIPS Agreement provides clear legal grounds for such measures under Articles 31 and 31bis, their implementation remains complex due to administrative, political, and diplomatic barriers. Many low- and middle-income countries (LMICs) face challenges in translating these flexibilities into practice due to limited regulatory capacity, technical expertise, or trade pressures that discourage their use. As a result, experts stress the need to strengthen institutional and legal frameworks to ensure that compulsory licensing can function as an effective and legitimate policy tool rather than a last resort.

b). Direct technology transfer

Another mechanism highlighted during the interviews for implementing voluntary licensing in the public interest was direct technology transfer. This approach is valued for its potential to ensure closer monitoring of production quality, accelerate the global availability of critical health technologies, and balance accessibility with the maintenance of production standards—thus reducing both reputational and legal risks for licensors.

During the COVID-19 pandemic, this mechanism was implemented through various vaccine manufacturing partnerships and regional production hubs, such as the WHO mRNA Technology Transfer Hub in South Africa and bilateral collaborations between developers and institutions in low- and middle-income countries (WHO, 2024). However, several analyses have raised concerns that such transfers, particularly when managed through proprietary or bilateral arrangements, may overlook or dilute publicinterest safeguards embedded initially in the agreements or publicly funded platforms, limiting transparency, equitable access, and long-term local capacity building.

I. PERCEIVED INCENTIVES FOR UNIVERSITIES AND RESEARCH CENTERS

1. Financial Incentives for Universities and Research Centers

a). Reducing patent-related costs

The Social Patent Discount (SPD) provides a direct economic incentive for socially responsible licensing by linking significant reductions in patent fees to the adoption of licensing practices that advance public-interest objectives. Under this proposal, patent holders who grant non- exclusive or socially oriented licenses—facilitated through trusted intermediaries such as HTAP or the Medicines Patent Pool—become eligible for coordinated discounts across the Patent Cooperation Treaty (PCT) system, including international filing, search, examination, national phase entry, and maintenance fees. By shifting fee reductions away from applicant identity and toward licensing behavior, the SPD aligns financial incentives with equitable access goals, rewarding rights holders who structure their commercialization strategies around affordability, transparency, and broad dissemination.

This collective mechanism, implemented through an optional PCT protocol, would create a predictable global framework that reduces the costs of responsible licensing while expanding the pool of technologies available for public health purposes—thereby making socially responsible licensing not only ethically preferable but economically rational (Love, 2025).

Reducing patent-related costs is identified as a relevant incentive, particularly for universities and research centers in developing countries, where intellectual property protection fees often represent a substantial barrier to patenting and technology transfer. Several jurisdictions and institutions have introduced measures to mitigate these costs. For example, the WIPO offers fee reductions of up to 90% for applicants from least developed countries under the Patent Cooperation Treaty (PCT), while national offices such as the European Patent Office (EPO) and the United States Patent and Trademark Office (USPTO) provide fee discounts for universities, small entities, and non-profits. In Latin America, patent offices in Chile, Brazil, and Colombia have implemented reduced filing and maintenance fees for public universities or small enterprises, and India's Patent Rules (2021) explicitly grant an 80% reduction to educational institutions.

Lowering these fees or granting partial or full exemptions for institutions that commit to socially responsible licensing can facilitate participation in open-access and collaborative research frameworks. However, while such measures can alleviate financial constraints and encourage broader engagement with the patent system, they may not be decisive on their own. Their effectiveness depends on complementary policies that enhance institutional capacity, provide downstream support for technology commercialization, and create incentives that reward equitable and socially responsible licensing outcomes. While patent fee reductions offer promising financial incentives for socially responsible licensing,

their effectiveness as public health tools depends critically on ensuring that cost savings translate into genuine access improvements rather than merely subsidizing symbolic commitments. The fundamental risk is that patent holders could secure substantial fee reductions by establishing minimal or superficial licensing arrangements while maintaining effective exclusivity in commercially valuable markets. Without rigorous verification mechanisms, fee discounts risk becoming another form of public subsidy for intellectual property holders that delivers negligible public benefit.

2. Intangible Incentives for Universities and Research Centers

According to interviews, universities and research centers would respond strongly to intangible incentives that do not depend on direct economic benefits but are linked to prestige, ethical values, institutional reputation, and social perceptions of responsibility. These incentives would be essential to promoting voluntary licensing as a practice consistent with the public mission of academic institutions.

a). Social responsibility and equitable innovation rankings

Responsibility rankings serve as symbolic and reputational incentives, granting public recognition to institutions that actively promote equitable access to innovation. These instruments make universities and research centers ethical commitments visible, reinforcing their institutional identity and projecting an image consistent with the principles of sustainability and social justice. Furthermore, they foster constructive reputational competition among peers, encouraging the adoption of responsible licensing policies as part of university excellence standards.

Although social responsibility rankings send positive signals within the international community, some experts argue that their impact on strategic decision-making may be limited if they are not linked to concrete funding or performance evaluation mechanisms. In the absence of objective, transparent criteria, there is a risk that these instruments will become mere declaratory exercises, with no real capacity to transform institutional practices or strengthen equitable access to innovation.

b). Dissemination of empirical evidence on the benefits of responsible licensing

The interviews highlight the importance of empirical evidence as an emerging incentive for the adoption of voluntary licensing. The collection and dissemination of data demonstrating the economic and social benefits of open licenses can persuade governing bodies and funders that openness does not entail a loss, but rather a reconfiguration of value toward sustainable objectives. This approach, by linking evidence to tangible results in innovation, cooperation, and development, helps consolidate an institutional narrative grounded in the profitability of equitable access. Furthermore, growing pressure from investors and stakeholders focused on sustainability reinforces this trend, incentivizing universities to integrate social impact metrics into their technology transfer strategies .

c). Access to research data on the implementation of technologies with social impact

One of the most prominent examples of non-monetary incentives is access to research data linked to social impact projects. Allowing researchers and universities that voluntarily license access to information on the implementation of their technologies in low- and middle-income countries generates both scientific and reputational benefits.

This data can be translated into high-impact publications, comparative evaluations, and improved empirical evidence on the effectiveness of innovations. This can be a low-cost yet highly effective academic incentive that reinforces research staff motivation to participate in voluntary licensing programs and promotes international collaboration.

According to those interviewed, this type of incentive is especially valued for offering a sustainable, non-monetary alternative for the academic sector, strengthening cooperation and knowledge exchange. Its effectiveness, however, is reinforced when ethical and data protection standards are guaranteed, along with transparent, accessible, and high-quality management of shared information. In this sense, establishing clear data governance frameworks and interoperability mechanisms represents a key opportunity to maximize their impact, broadening participation and bridging technological and institutional gaps.

3. Regulatory and Administrative Incentives

a). Regional harmonization of technology transfer policies

Regional harmonization of technology transfer policies, such as those promoted by the European Union, serves as a significant incentive by standardizing best practices across universities and research centers. This type of coordination generates peer pressure that encourages institutions to adopt voluntary licensing as a common standard of responsible behavior. Furthermore, it reduces the administrative costs associated with developing proprietary protocols and facilitates regulatory interoperability, thereby fostering transnational cooperation in joint research and development projects.

4. Strategic Incentives

According to the interviews, strategic incentives would serve as mechanisms for institutional positioning and long-term collaboration, strengthening universities roles in international innovation networks and consolidating their reputations as global players committed to equity and sustainability.

a). Regional or local technological collaboration programs with social impact

At the local level, interviewees emphasize that strategic incentives can take the form of regional or local programs to promote bidding and collaboration for the development of socially impactful technologies. These initiatives strengthen the connection between universities and their local communities, facilitating knowledge transfer and positioning academic centers as key partners in regional development. By aligning innovation with local public policies, sustainable ecosystems that foster cooperation and collective benefit are encouraged.

III. POLICY RECOMMENDATIONS FOR INCENTIVIZING VOLUNTARY LICENSING

The following policy recommendations seek to strengthen voluntary and socially responsible licensing (VSR) to improve equitable access to medicines and health technologies. These proposals are based on identified incentives, such as political pressure, reputational benefits, and conditional funding; obstacles, such as lack of awareness, regulatory barriers, and the voluntary nature of licensing; and practical solutions, such as threats of compulsory licensing and international collaboration. Designed for national governments, the World Health Organization (WHO), and funders, these recommendations promote feasible, evidence-based actions that balance intellectual property protection with the public interest in health.

A. RECOMMENDATIONS FOR GOVERNMENTS

Interviewees agreed that governments must take an active role in creating regulatory, financial, and political environments that make voluntary and socially responsible licensing an attractive practice. The proposals are grouped into four areas: conditionality of public funds, tax and procurement incentives, institutional strengthening, and regional cooperation.

1. Conditioning access commitments and other socially responsible licensing principles

Governments must link state funding for research and development (R&D) to mandatory LVSR clauses, ensuring that publicly funded innovations are affordable and accessible, especially in low- and middle-income countries. This measure transforms public funding into a tool for the common good, preventing scientific advances from being restricted by commercial monopolies. This conditionality aligns the interests of universities, businesses, and the state, reducing subsequent conflicts over intellectual property and ensuring tangible social benefits through non-exclusive, non-geographical licenses.

2. Implement tax and public procurement incentives

Governments should use economic instruments, such as tax incentives or public procurement incentives, to make the LVSR more attractive. These incentives offset the perceived risks to businesses and universities by offering tangible benefits, such as tax reductions or preferences in public tenders. According to some interviewees, “In the case of a company that is going to license, the typical incentives are tax reductions.” These incentives could be extended to the application for invention patents: “You could reduce or exempt patent fees if you make your patent available for licensing.” These measures send clear signals to the market, incentivizing companies to adopt the LVSR by reducing operating costs and improving their competitiveness in public tenders, especially for products that benefit vulnerable populations.

3. Strengthen institutional capacities and inter-ministerial coordination

Effective implementation of the LVSR requires transparent governance and specialized technical staff, with smooth coordination between the ministries of health, science, and productive development. The lack of coordination between these entities can leave the LVSR as an orphan policy. Thus, some interviewees suggest that key actors, such as the Ministries of Education or Science, should

be involved in establishing incentives. It is recommended to develop permanent inter-ministerial mechanisms and strengthen university technology transfer offices (OTLs) or universities as strategic actors, ensuring the coherent implementation of the LVSR.

4. Promote regional cooperation and joint purchasing power

Regional cooperation strengthens the negotiating position of middle-income countries and generates predictable demand for voluntary licenses. Governments should promote joint purchasing mechanisms and regional funds that provide certainty regarding market volume and sustainability. In this way, regional collaboration can benefit vulnerable populations. These initiatives enable the sharing of regulatory and technical capacities, thereby strengthening the implementation of the LVSR and fostering a more robust political environment for negotiating with rights holders. Finally, joint purchasing power can leverage economies of scale to access better prices.

5. Promoting local initiatives

National and subnational governments could design and implement strategic incentive programs that encourage universities, research centers, and companies to engage in socially responsible licensing. At the local and regional levels, public authorities may develop municipal or regional programs that promote competitive calls, innovation challenges, or collaborative projects to develop socially impactful technologies. These initiatives would strengthen the link between academia and local communities, ensuring that innovations address real societal needs and contribute directly to regional development. By aligning innovation policies with public objectives, governments can foster sustainable ecosystems that promote cooperation, inclusion, and collective benefit.

6. Pooling and reciprocally licensing rights in inventions arising from publicly funded research

Governments are encouraged to establish formal mechanisms for pooling and reciprocally licensing rights inventions arising from publicly funded research as a strategic incentive for socially responsible licensing.

By embedding access-oriented provisions—such as non-exclusive licensing, transparency obligations, and equitable benefit-sharing—into funding agreements and IP management policies, states can shift responsible practices from voluntary exceptions to operational norms. A structured framework for reciprocal licensing, covering both background and foreground IP within a defined health-related field of use, would grant participating countries preferential access to a broader portfolio of technologies.

At the same time, non-participation would result in more limited access to shared knowledge assets. Drawing on successful models from international R&D consortia, this approach demonstrates how tiered benefits, harmonized sharing obligations, and transparent governance can align national self-interest with global health objectives, ultimately positioning socially responsible licensing as a strategically advantageous choice for governments and public institutions alike.

B. RECOMMENDATIONS FOR THE WORLD HEALTH ORGANIZATION (WHO)

Interviewees emphasized that the WHO has a central role in standardizing LVSR as a global public health practice, acting as a coordinating, technical, and legitimizing body. The recommendations are structured into four areas: normative leadership, technical support, metrics and recognition, and strengthening multilateral platforms.

1. Lead the standardization and legitimization of voluntary licensing

The WHO should define international standards of good practice for LVSR and promote them as a reference for governments and funders, granting them political legitimacy and a clear technical framework. The need for a cultural shift led by international organizations is emphasized: You need a cultural shift to make responsible and voluntary licensing more common In the context of the Developing countries, disseminating these concepts requires campaigns. The WHO can develop specific guidelines and model licensing templates that promote transparency, access, and territorial flexibility, helping ministries justify LVSR to the local industry.

2. Lead on transparency by publishing their own EA provisions in agreements

By making these commitments visible and verifiable through a dedicated transparency portal, new funding can reinforce rather than duplicate prior efforts, for instance, by expanding geographic reach in LMICs, enhancing impact measurement aligned with SDG targets.

3. Provide technical assistance and specialized advice

The WHO should support countries in implementing the LVSR by providing legal, financial, and technical assistance, as well as training in regulatory capacities and support for negotiations. Thus, one of the main obstacles in developing countries is the lack of knowledge.

4. Create metrics, indicators, and recognition mechanisms

The WHO should develop a framework of indicators to measure the impact of the LVSR, including prices, coverage, and implementation timelines, and establish recognition systems to highlight good practices. These assessment and visibility systems incentivize companies, universities, and governments to adopt higher standards and generate evidence on the impact of the LVSR.

5. Strengthen multilateral platforms and regional cooperation

The WHO should strengthen platforms such as the HTAP, expand them to new therapeutic and technological areas, and promote regional alliances for joint procurement and information sharing. It is essential to include these issues in the agenda for regional collaboration or regional trade negotiations, such as with PAHO in Latin America. One interviewee highlights the importance of regional collaboration: “My strategic recommendation would be to include these issues in the regional collaboration agenda or regional trade negotiations, such as with PAHO in Latin America.” WHO support lends these platforms political credibility, making the LVSR predictable and sustainable.

6. Global observatory of voluntary and socially responsible licensing practices

The WHO could promote the establishment of monitoring and evaluation systems to assess the concrete impact of voluntary and socially responsible licensing on access to health technologies. These systems should include measurable indicators such as price levels, availability, population coverage, and speed of market introduction.

The development of longitudinal studies is also recommended to evaluate the long-term effects of socially responsible licensing clauses. By systematically collecting and analyzing data over time, such studies would help demonstrate the real contribution of these mechanisms to public health objectives and provide evidence-based justification for their inclusion in future agreements.

Through its normative and convening roles, the WHO could update its Global Health Observatory to collect and disseminate information on socially responsible licensing practices. This would facilitate transparency, foster policy learning, and strengthen coordination among national authorities, research institutions, and industry partners.

7. Create and coordinate an international Technology Purchase Consortium to negotiate collective acquisitions of key health technologies

WHO should lead the establishment of a Technology Purchase Consortium through which groups of Member States can jointly acquire rights to patents, data, know-how, and biologic materials. By pooling financial and political leverage, the TPC would enable more effective negotiation with rights holders, expand affordable access options, and provide structured governance for technology management and licensing. WHO's stewardship would ensure consistency with public health objectives and support downstream technology transfer to qualified manufacturers.

The recommendations for the WHO should be applied as appropriate in similar contexts to other UN institutions like FAO, which also require that technological innovation reach all corners of the world to enable developing goals in their own fields.

C. RECOMMENDATIONS FOR WIPO

1. Establishment of a Work Program on Voluntary and Socially Responsible Licensing

WIPO is encouraged to establish a dedicated Work Program on Voluntary and Socially Responsible Licensing (VSRL) under the Standing Committee on the Law of Patents (SCP). The program should aim to strengthen the use of voluntary licensing to promote inclusive innovation and technology transfer, while integrating social responsibility into the governance of intellectual property. It should also help Member States build the necessary policy frameworks and institutional capacities to design and implement effective licensing mechanisms.

2. Knowledge Generation and Practical Guidance

WIPO should lead the development of a structured process for collecting, analyzing, and sharing experiences related to voluntary and socially responsible licensing. This would help consolidate the growing body of evidence and best practices in this area and provide Member States with practical

models for implementation. WIPO could develop practical tools, including a Reference Manual on VSRL, along with training materials and cooperative networks connecting research institutions, universities, SMEs, and intellectual property offices. To ensure inclusiveness, the Organization should also establish an open, non-binding platform for dialogue and mutual learning, fostering South–South and North–South cooperation and facilitating the sharing of experiences among Member States.

3. Capacity Building through Trilateral Cooperation

WIPO, in collaboration with WHO and WTO, should deepen trilateral cooperation to help countries strengthen their capacity to design, negotiate, and manage voluntary and socially responsible licenses. This initiative should not only enhance technical and legal knowledge but also build confidence and trust among stakeholders involved in licensing negotiations.

4. Incentives for Responsible Innovation

To encourage innovators to integrate social responsibility into their intellectual property strategies, WIPO should explore creating a “Fast-Track for Responsible Innovation.” This would be an accelerated patent examination process for applications that include public interest commitments or voluntary licensing clauses. Such a mechanism could offer tangiblebenefits—such as shorter examination timelines, technical support during application and implementation, and reduced administrative fees—to innovators who align their patenting strategies with principles of accessibility and social responsibility. The initiative would be low-cost and administratively feasible, while providing high visibility to innovators and institutions that choose to transfer technology for public benefit. In doing so, WIPO would reinforce the perception of intellectual property as a tool for cooperation, sustainable development, and equitable growth.

D. RECOMMENDATIONS FOR PUBLIC, PHILANTHROPIC FUNDERS AND PRIVATE INVESTORS

Funders have a structural influence by conditioning the use of funds, defining access standards, and rewarding good practices through access conditionality, donor coordination, innovative investment, and capacity building.

1. Incorporate access and licensing clauses into all subsidies

Funders should require access and LVSR commitments from the start of each project, with verifiable clauses that include published terms, coverage in LMICs, and the possibility of sublicensing. These clauses ensure that investment results are accessible, avoiding generic commitments with no real impact, conditioning funding to LVSR commitments.

2. Coordinate common standards among funders

Funders should align access policies to avoid loopholes that allow companies to seek less demanding partners and create a "common ground" of standards. A joint working group betweenthe WHO, the World Bank, CAF - Development Bank of Latin America and the Caribbean, IDB, World Bank, and other development financing entities, such as UNITAID, and the Wellcome Trust could institutionalize these criteria, strengthening coherence in LVSR funding.

3. Introducing reputational incentives and performance metrics

Funders should incorporate social impact indicators (such as relative price, coverage, and implementation time) into their evaluations and offer public recognition and preferential rates and conditions to reward LVSR commitments on the part of fund recipients.

4. Strengthen technical capacities and support mechanisms

Funders should allocate resources to legal and technical training, the development of guidelines, and advice on negotiating and monitoring voluntary licenses.

5. Creation of bridge funds for early projects

According to those interviewed, it would be advisable for international funders, such as Welcome Trust, Gates Foundation, UNITAID, as well as development private and public institutions, to create continuous funding mechanisms for promising early-stage projects. Inspired by the logic of bridge funds, these mechanisms could extend existing grants to cover critical development phases, such as bioequivalence studies or clinical trials, following models similar to that of the UNITAID Explorer program. Such instruments would ensure a smoother transition to licensing, avoiding the stagnation of products with high potential for public health impact in low- and middle-income countries.

6. Financing institutions and public and private investors should develop and implement innovative financial instruments to incentivize voluntary and socially responsible licensing

Financing institutions like the CAF - Development Bank of Latin America and the Caribbean, IDB, World Bank, and other development financing entities and public and private investors should develop and implement innovative financial instruments, modeling, for example of those implemented for climate change objectives, to incentivize socially responsible licensing.

7. Capacity building in developing countries

Finance projects to build capacity and develop appropriate principles of socially responsible licensing in developing countries, particularly through collaboration among universities and research centers.

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