

Global Access Licensing:

An Expert Interview Study with Scientists-Inventors & Directors of Technology Transfer Offices Involved in the Development & Commercialisation of COVID-19 Vaccines

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INTRODUCTION

In the early days of the pandemic, the US Association of University Technology Managers urged universities to adopt time-limited, non-exclusive, and royalty-free licences to support rapid response. Although all authorised vaccines involve at least one public-sector patent, previous studies found that minimal Intellectual Property (IP) measures were implemented by Technology Transfer offices (TTOs) to guarantee wide diffusion of critical health technologies arising from publicly funded research.

OBJECTIVES

- i. To gain insight into how scientists-inventors and TTO directors directly involved in Covid-19 vaccine invention, patenting, and licensing perceive and manage emerging Global Access IP strategies: in pandemics and in peacetime;
- ii. Map criteria for inclusion of technologies and countries;
- iii. Assess the perceived role of conditional governmental and philanthropic funding.

METHODS

- We conducted a thematic analysis of semi-structured interviews with a purposively-selected sample of high-profile scientists and TTO directors in May-September 2023. We distinguish between Originators (patent-owners) and Developers (labs developing or testing the vaccine) and focus on the former. Informants were identified from a small pool, based on published research and the Medicines Patent Pool's *VaxPal* database.
- **Sample:** Informants ($n=7$) were affiliated with top universities in Europe, the UK, and the US ($n=5$), national research labs ($n=1$), and public-private partnerships ($n=1$). Most were male ($n=5$), heading their own research units, and listed as patent inventors; two had established vaccine-focused spin-offs. As a result of the low response rate (no reply: $n=7$), TTO input is limited and perspectives from scientists based in Global South countries were not yet captured.

RESULTS



Scientists and research groups: Limited involvement in IP handling and short-termism

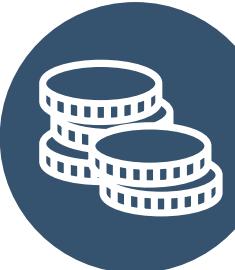
- **IP oversight during the pandemic:** IP negotiation was primarily delegated to university TTO professionals, more so than in peacetime. In parallel, three Informants described free, unconditional knowledge transfer to either industry or to developers in certain LMICs, namely in India and South Africa.
- **The role of formal IP:** IP protection was often described as a tool to **safeguard product quality** and involve large pharmaceutical firms, rather than a commercial barrier, although two scientists reported barriers to accessing key IP-protected components such as adjuvants.
- **Short-termism & non-IP bottlenecks:** Licensing decisions historically focused on immediate research or funding goals, with limited foresight or capacity for large-scale manufacturing and distribution. Scientists highlighted non-IP constraints, including regulatory know-how, clinical trial networks, local production scale-up, and supply chains.



Institutional IP strategies: Too early and too exclusive?

Valorisation strategies vary widely across EU, UK, and North American public-sector patent-holders, before and during the pandemic:

- **North America and the UK - Retaining IP rights and non-exclusive licensing:** TTOs retained IP longer and favoured non-exclusive licensing or distributed manufacturing agreements, leveraging formal IP in negotiating access plans.
- **Europe - Patent ownership transfer and academic spin-offs:** TTOs tend to monetise inventions by quickly selling rather than licensing out their IP rights soon after being granted a patent, to either mature spin-offs or incumbents. Some mentioned efforts to reserve IP rights for LMIC-based firms within semi-exclusive licences, although such clauses were only possible if IP was not transferred.
- **Platform technologies:** Several scientists saw more freedom in starting spin-offs, as licensing IP to established firms may limit the range of indications for further development based on the firm's understanding of the market, while TTO directors cautioned that such IP should remain with the university rather than be transferred to a single spin-off, adding that access requirements are harder to enforce once ownership is transferred.



Governmental and philanthropic funders: The dual impact of IP and supply conditions

- **Access plans and price controls:** Lab heads whose previous projects were supported by major philanthropic funding agencies reported global access clauses requiring end-products to be sold at **cost of production** in LMICs with returns expected from sales in high-income markets.
- **Manufacturing restrictions:** In contrast, informants referred to manufacturing restrictions embedded in BARDA's billion-dollar contracts with selected firms, which gave the US federal government control that hindered global distribution beyond IP constraints.



Global IP frameworks: Limited influence on university decision-making

- Interviews were conducted while the Pandemic Treaty was under negotiation by WHO Member States. Informants did not consider global IP frameworks to offer pragmatic solutions; TRIPS was seen as more relevant to downstream actors (pharmaceutical firms, civil society) than to universities.

Originators of key Covid-19 vaccine candidates	#patent families involving at least one public applicant	#patent families involving only private applicants	Public patents as share of the vaccine IP portfolio	Mean years since patent filing (as of May 2021)
CureVac	4	18	18%	7.7
Moderna	7	19	27%	5.2
Clover Biopharmaceuticals	1	2	33%	18.7
CanSino Biologics	4	3	57%	7.4
GlaxoSmithKline; Sanofi	6	4	60%	15.2
Novavax	4	2	67%	6.7
BioNTech; Pfizer	18	8	69%	5.2
Janssen	23	2	92%	16
Bharat Biotech; Indian Council of Medical Research	1	0	100%	9
Sinopharm; Beijing Institute	1	0	100%	1
Sinovac	1	0	100%	1
University of Oxford/ AstraZeneca	2	0	100%	5.5
Gamaleya Research Institute	5	0	100%	1
A patent-free vaccine; know-how transferred for further development				
Baylor College of Medicine; Biological E	0	0	N/A	

Table 1. Public patents related to the development of Covid-19 vaccines

Source: Authors' analysis using data from *VaxPal* (1993-2022), accessed 8 March 2023 from <https://www.VaxPal.org> and from Lalani et al., 2023 (doi: <https://doi.org/10.1136/bmj-2022-073747>)

Scientists' experience	IP oversight during the pandemic	"I think in normal times we would get much more involved in the patent and to some extent in the agreement with a partner. But generally speaking, there are professionals in the university who do a lot of that negotiating" (SC04)
	Short-termism & non-IP bottlenecks	"They probably didn't know when they licensed it, it would be for Covid-19 vaccines. They were licensing mRNA technology. So I think they said '95 million! Well, let's have a party'" (SC01)
Institutional strategies		"The first thing you're thinking about normally is not 'how do we manufacture millions of doses of the vaccine?' Normally, when you're starting out with a new product, you're thinking about: 'Can I get the money for the Phase I trial to see if the vaccine is immunogenic?' [...] initially people thought, 'well, why don't we just do that? The university could do that'. But to me, having worked in this field for so long, it was obvious that you must have the whole distribution systems in place" (SC05)
	Non-exclusive licensing	"...That is the main tool that the institute uses. The non-exclusiveness . Because that makes the licences less expensive. And it also doesn't [...] hidden or locked up in just one place. Sometimes a company will buy the IP just to remove it from competition" (SC03)
Funders' conditions	Patent ownership transfer and academic spin-offs	"Under the influence of let's say external lobbying [...], universities are moving into a direction of more uniformity [...] we basically say that there is a cap on the percentage of equity that universities will ask of start-ups in return for the IP [...] Universities will look into transferring IP to the start-up if possible. And that's a rather vague formulation because if it's a platform technology, it wouldn't make sense to transfer it to one start-up. So in those kinds of situations, you would rather see the IP at a university" (TT01)
	The dual impact of IP and supply conditions	"Academic institutions want to maximise the royalty revenue [...] only if a donor comes in and says, 'well, we know what the university's priority is, but we also are going to put a clause in the grant agreement saying that you must license in particular ways with respect to the public sector and/or in developing countries'" (SC06)

Table 2. Themes and illustrative remarks

CONCLUSIONS

- Uptake of IP and access provisions is limited, shaped by short-term commercial decision-making at the university level, institutional incentives, as well as IP and supply conditions installed by major global health funders.
- Early access considerations in research design, North-South collaborations, institutional retention of IP, and enforceable funder conditions were identified as key levers. Non- or semi-exclusive licences with LMIC exceptions, distributed manufacturing, price ceilings linked to production costs, and structured know-how transfer were viewed as the most effective university-led interventions that pertain to ongoing pandemic preparedness debates.
- The Oxford-Serum Institute deal was considered a one-off among universities and should serve as a precedent going forward.

ETHICS & FUNDING STATEMENT

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