Developing National Life Sciences Capacity Through Voluntary Technology Transfer

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Background/Context

The COVID-19 pandemic starkly exposed the fragility of global health supply chains. Unprecedented surges in demand strained the availability of critical inputs and materials, revealing how easily essential biomedical supply lines can be disrupted (Lancet, 2021). Vaccine manufacturing efforts faced shortages of glass vials, syringes, specialized reagents, and other upstream components, while "vaccine nationalism" emerged as wealthy nations secured preferential access to early vaccine supplies, leaving many low- and middle-income countries behind (Otu et al., 2021). Countries with advanced purchase agreements claimed the first doses for their own populations – in some cases accumulating stockpiles sufficient for multiple booster rounds – while lower-income nations waited for initial shipments (Serhan, 2021).

The global biopharmaceutical, or "biologics," market also represents a significant market opportunity. It accounted for nearly $300 billion in revenue in 2021 and continues to grow at high single-digit rates. Increasingly, the most modern and effective treatments and vaccines are derived from more complex biologics as opposed to more traditional small molecule drugs and older vaccine technology.

Thus, both fear and optimism have motivated policymakers to seek to develop local capability to manufacture vaccines, biologics, and other treatments. On the one hand, they desire healthcare sovereignty, wanting to avoid being last in line during the next health crisis. On the other, they see significant opportunities to develop high-value life sciences industries that can drive economic growth.

However, modern biologics manufacturing presents unique challenges compared to traditional pharmaceutical production, as these large molecules are produced in living organisms or extracted from biological materials, making their production processes complex and knowledge-intensive. For example, the Pfizer-BioNTech mRNA COVID-19 vaccine had a 50,000-step manufacturing process involving 280 separate inputs sourced from 86 different suppliers, with many of those materials being novel components not previously used at industrial scale (Park & Baker, 2021). Developing such a process

essentially "from scratch" in 2020 required massive investment and iterative innovation under intense time pressure.

Even after a process is established, expanding production involves extensive know-how transfer. Manufacturers must have the sophistication to maintain quality control to ensure that each step – often performed in hermetically sealed bioreactors and sterile environments – meets exacting standards. They also must have knowledge of and the capacity to meet regulatory requirements for their own and multiple export markets.

The complexity of biologics manufacturing thus has led to a highly specialized industry structure where manufacturing, finishing, and distribution are distributed among many cooperating companies. Developing the necessary expertise to participate in these global value chains presents significant challenges.

These challenges can be daunting for emerging economies that desire to develop their own capacity for economic and health security reasons. These capacities typically cannot be developed from the ground up – at least not in a manner that is effective in world markets.

In response, some policymakers have proposed mandatory technology transfer policies, such as compulsory licensing of trade secrets and patents, to accelerate domestic capability development. Yet mounting evidence suggests that an approach based on voluntary cooperation and strategic capacity-building is far more effective for establishing sustainable life sciences industries (Taylor et al., 2021).

Relevance/Original Contribution

This research makes several original contributions to understanding how emerging economies can successfully build sustainable life sciences sectors through voluntary cooperation and enabling public policies.

- First, it systematically documents how countries have leveraged voluntary technology transfer to develop biologics manufacturing capacity, providing a grounded, evidence-based framework for action rather than relying on abstract normative arguments or anecdotal critiques.
- Second, it illuminates the paradoxical dynamics by which intellectual property protection, particularly for trade secrets, can enhance rather than impede knowledge sharing by creating structured confidentiality assurances.
- Third, it explores the specific enabling policies and institutional conditions that governments can implement to attract investment and technology transfer while fostering domestic innovation capabilities.

The analysis challenges conventional wisdom that treats intellectual property protection as a barrier to technology access. Instead, it demonstrates how IP rights enable the trust

necessary for complex technology transfer in biologics manufacturing (Brant & Schultz, 2021). This perspective is particularly relevant amid ongoing international debates about access to and pricing of health technologies and efforts to design effective pandemic preparedness frameworks at the World Health Organization, WTO, and regional bodies.

Whereas much of the global IP debate remains focused on abstract normative questions or anecdotal critiques of the current system, this paper provides a grounded, evidence-based framework for action. It shows that voluntary mechanisms—when paired with sound policy, investment, and governance—have not only proven feasible but are also essential for long-term sustainability and innovation.

Research Questions/Hypothesis

This paper addresses two interrelated research questions:

1. What institutional and strategic conditions enable effective voluntary technology transfer for biologics manufacturing in emerging economies?
2. How do these voluntary approaches compare in effectiveness and sustainability to coercive mechanisms such as compulsory licensing or forced disclosure of trade secrets?

The central hypothesis is that voluntary technology transfer, when supported by appropriate public policies and institutional frameworks, offers a more effective and sustainable path to building biologics capacity than coercive alternatives. A corollary hypothesis is that legal protections for intellectual property—especially trade secrets—paradoxically enhance knowledge sharing by creating the trust and structure necessary for collaboration.

Research Methodology

This research employs a comparative case study approach that combines analysis of published literature with extensive primary research. Our methodology obtains data and insights from four main sources:

1. Primary interviews with government officials, industry executives, and policy experts in Brazil, South Africa, Argentina, and Indonesia. These first-hand accounts provide unique insights into the challenges, successes, and policy considerations that shaped these countries' biologics manufacturing development. Our research team has conducted several key interviews to date, with additional conversations scheduled to complete our data collection prior to the conference. These countries exemplify the four voluntary pathways to biologics capacity we describe below.

2. Findings from industry and policy reports on the role of IP and cooperation in vaccine manufacturing during the pandemic, including analyses from the Africa CDC and the Duke Global Health Innovation Center (e.g., Taylor et al., 2021).
3. Practical insights from recent work on trade secrecy, based on interviews with IP counsel and manufacturing experts from leading global firms,
4. Secondary literature on IP policy, innovation systems, and pandemic response from various scholars and organizations, supplying facts as well as doctrinal and theoretical insights.

This mixed-methods approach allows us to validate published accounts with on-the-ground experiences and perspectives from key decision-makers. Our ongoing primary research is designed to capture nuanced aspects of technology transfer that may not be fully reflected in the literature, particularly the institutional and interpersonal dynamics that facilitate successful knowledge sharing. We expect to complete this primary research and integrate it into a full paper draft before the conference.

(Preliminary) Results

The research identifies four distinct but overlapping pathways by which emerging economies have successfully entered or advanced within the biologics manufacturing sector through voluntary cooperation:

1. **State-supported strategic initiatives**: Countries like Brazil have successfully implemented comprehensive government-led programs that foster public-private partnerships to rapidly develop domestic biologics capabilities. Brazil established approximately 100 "Public-Private Partnerships" (PPPs) focused on biologics production, with 30 specifically targeting biologics manufacturing. These partnerships match Brazilian manufacturers with non-Brazilian biologics producers, exchanging knowledge transfer for secure market access. Crucially, Brazil achieved this by partnering with originator companies to license know-how, rather than by nullifying IP rights. This approach has effectively reduced Brazil's dependence on imported biologics, which previously consumed approximately 30% of its universal healthcare system budget.
2. **Backwards integration strategy**: Countries including South Africa and Turkey have successfully entered biologics value chains by starting with less complex operations like "fill and finish" before gradually advancing to higher-value activities. This approach allows countries to build capabilities incrementally while establishing relationships with global technology partners. For example, South Africa's Biovac Institute initially focused on packaging and distribution before moving to fill-and-finish operations and eventually developing capabilities for manufacturing drug substances. During the COVID-19 response, South African

firms like Aspen Pharmacare entered fill-finish contracts for the Johnson & Johnson vaccine, gaining experience in regulatory compliance and sterile production (Africa CDC et al., 2023).

3. **Leveraging adjacent expertise**: Countries like Argentina have successfully redirected relevant expertise from related fields, such as agricultural biotechnology, toward healthcare biologics manufacturing. Argentina built on its pre-existing strengths in agricultural biotechnology to enter the biosimilars market, using familiar fermentation-based processes and regulatory parallels. Over time, Argentina fostered close links between its agricultural genetic engineering industry and its nascent biopharmaceutical industry, allowing know-how to flow across sectors (Otu et al., 2021). This unique cross-pollination enabled Argentine firms to start producing complex biologics like biosimilar monoclonal antibodies. This approach has enabled Argentina to create a significant biosimilars industry, saving an estimated $400 million in healthcare costs while developing export markets.
4. **Systematic expansion of R&D capabilities**: Countries such as Indonesia have successfully transformed established research institutes into commercial biologics production operations through systematic capability development. Indonesia's Bio Farma evolved from a research-oriented institute into one of the world's major vaccine manufacturers through a long-term strategy executed in sequential five-year plans. Early on, the Indonesian government facilitated technology transfer for polio vaccine production, transforming Bio Farma from a research outfit into a producer by tasking it with manufacturing the oral polio vaccine for national use. After mastering this process, Bio Farma expanded operations through contract manufacturing partnerships with producers in India and elsewhere (Otu et al., 2021).

Across these cases, voluntary cooperation—often protected by trade secret agreements—was essential. During the COVID-19 pandemic, trade secret protection enabled rapid scale-up of manufacturing partnerships between innovators and contract manufacturers. This included "knowledge-rich" transfers of tacit know-how, often between direct competitors, who relied on contractual and legal safeguards to protect shared information (Diamond & Abutaleb, 2021).

While critics warned that IP protections—especially trade secrets—would block access to COVID-19 vaccines and treatments, these concerns did not materialize. By late 2021, vaccine supply was ramping up so rapidly that production outpaced distribution in many regions. Companies like Pfizer-BioNTech, Moderna, Johnson & Johnson, AstraZeneca, and Novavax had entered into hundreds of technology transfer agreements with partners around the world. A comprehensive study found that by mid-2022, over 370 manufacturing and supply deals had been executed for COVID-19 vaccines globally

(Brant & Schultz, 2021), the vast majority of which included full transfer of the needed production know-how.

No country ultimately used the WTO's TRIPS Waiver for vaccines, which was partially approved in June 2022, and no evidence suggests that coercive disclosure would have accelerated technology transfer more effectively than the voluntary channels already in use. Instead, intellectual property protection, rather than impeding knowledge flow, facilitated unprecedented collaboration by providing secure frameworks for sharing valuable proprietary information.

The research also identifies key enabling policies that have supported successful technology transfer, including:

1. Regulatory frameworks aligned with international standards, which South Korea implemented to increase the global competitiveness of its manufacturers
2. Strategic investments in workforce development, exemplified by Singapore's programs to attract scientific talent to academic institutions and train engineers and technicians
3. Financial incentives that derisk investments in manufacturing capabilities, as seen in Turkey's purchase guarantees for manufacturers willing to establish facilities in the country
4. Market access policies that create demand certainty, such as Brazil's guarantee of up to 50% market share in public procurement for PPP partners

Discussion of Results/Implications

The evidence supports the conclusion that voluntary cooperation, underpinned by robust IP protections and enabling policy environments, is both viable and preferable for building long-term capacity in biologics manufacturing. These findings carry several important implications for policymakers:

Legal Certainty Enables Trust: IP protections, particularly for trade secrets, are not barriers but essential enablers of cooperation. They provide the legal infrastructure necessary for firms to share sensitive know-how without fear of misappropriation. Technology transfer is likely to result from a sound business case. Governments can make productive interventions by focusing on 'pulling' technology by ensuring demand and supportive commercial and regulatory conditions. By contrast, 'pushing' the transfer of technology through compulsory licensing of trade secrets is likely to yield poor results.

Incremental Pathways Work: Countries that take a phased approach—starting with fill-finish, leveraging existing expertise, or forming trusted partnerships—are better positioned to sustain capability development than those relying on short-term mandates. The case studies demonstrate that there is no one-size-fits-all approach to developing biologics

manufacturing capabilities. Rather, countries must assess their existing strengths and design strategies that leverage these capabilities as entry points into global value chains.

Policy Coherence is Key: Success depends on aligning industrial, health, and innovation policy. Countries must invest in regulatory capacity, workforce development, and incentives for public-private partnerships. The findings underscore the importance of long-term planning and consistent policy implementation. Successful countries have typically implemented strategic plans over multiple years or even decades. Indonesia's Bio Farma, for example, developed its capabilities through a series of five-year plans that included consistent investments in education and training.

Coercive Measures are Counterproductive: Attempts to compel technology transfer through IP waivers or forced disclosures risk undermining the very cooperation they seek to encourage. They also create uncertainty that deters future investment and collaboration. For example, when the Brazilian Senate debated a bill that would have required companies to hand over COVID-19 vaccine recipes and related trade secrets to local manufacturers, industry experts warned that such forced disclosure policies could discourage companies from sharing any information at all, for fear of losing control permanently (Kluwer Patent Blog, 2021).

It is important to critically examine opposing viewpoints on how best to achieve global access to critical biotechnologies. During the pandemic, some experts and advocacy groups argued that normal IP rules and market-driven partnerships were insufficient to address urgent global needs. They proposed more coercive measures such as compulsory licensing of patents, forced disclosure of trade secrets, or broad waivers of IP protections for COVID-related products (Morten et al., 2021).

However, these coercive approaches, while well-intentioned, appear misguided. Simply sharing a patent or a document would not equip a manufacturer to produce an mRNA vaccine or a complex biologic therapeutic, given the tacit know-how involved. Indeed, even proponents of compulsory licensing acknowledge that patents don't disclose the full manufacturing process; that is why some suggested new mechanisms for compulsory licensing of trade secrets specifically (Gurgula & Hull, 2023). Yet, implementing such a scheme would be fraught with practical challenges.

Instead, the research emphasizes the role of knowledge partners in facilitating technology transfer. Successful countries have actively sought partnerships with multinational companies, research institutions, and specialized service providers to acquire the knowledge and capabilities needed for biologics manufacturing. These partnerships often evolve from simple contract manufacturing arrangements to more sophisticated collaborations involving substantial knowledge transfer.

This analysis contributes to a reframing of the global policy debate: Rather than viewing IP as an obstacle, policymakers should focus on how to harness it to structure productive

and scalable knowledge transfer. Future pandemic preparedness frameworks should prioritize institutional readiness for voluntary cooperation over coercive legal mechanisms.

In conclusion, this research provides policymakers with an evidence-based framework for developing high-value life sciences industries that can drive economic growth while enhancing healthcare sovereignty. By focusing on creating environments conducive to voluntary technology transfer and collaboration, emerging economies can successfully build sustainable biologics manufacturing capabilities that position them for leadership in this crucial sector.

Bibliography

Africa CDC, Clinton Health Access Initiative, & PATH. (2023). Current and planned vaccine manufacturing in Africa. Africa CDC.

Arora, A., & Gambardella, A. (2010). Ideas for rent: An overview of markets for technology. Industrial and Corporate Change, 19(3).

Arundel, A. (2001). The relative effectiveness of patents and secrecy for appropriation. Research Policy, 30(4), 611-624.

Baker and McKenzie. (2013). Study on Trade Secrets and Confidential Business Information in the Internal Market. European Commission.

Brant, J., & Schultz, M. F. (2021). Unprecedented: The Rapid Innovation Response to COVID-19 and the Role of Intellectual Property. Innovation Council.

Cohen, W. M. (2010). Fifty Years of Empirical Studies of Innovative Activity and Performance. In Handbook of the Economics of Innovation (Vol. 1, pp. 129–213). Elsevier.

Diamond, D., & Abutaleb, Y. (2021, August 10). 'Act now' on global vaccines to stop more-dangerous variants, experts warn Biden. The Washington Post.

Druedahl, L. C., et al. (2020). A qualitative study of biosimilar manufacturer and regulator perceptions on intellectual property and abbreviated approval pathways. Nature Biotechnology, 38(11), 1253–1256.

Gurgula, O., & Hull, J. (2023). Compulsory Licensing of Trade Secrets: Ensuring Access to COVID-19 Vaccines via Involuntary Technology Transfer. Journal of Intellectual Property Law & Practice, 18(6), 418–431.

Kluwer Patent Blog. (2021, May 12). Brazilian Senate approves bill on the compulsory licensing of COVID-19 vaccines' patents. Kluwer Patent Blog.

Lancet Staff. (2021). Challenges in ensuring global access to COVID-19 vaccines. The Lancet, 397(10278), 1023–1024.

Lemley, M. A. (2008). The surprising virtues of treating trade secrets as IP rights. Stanford Law Review, 61(2), 311-353.

Levine, D. & Sarnoff, J. (2023). Compelling Trade Secret Sharing. U.C. Hastings Law Journal, 74(4), 987-1056.

Lippoldt, D. C., & Schultz, M. F. (2014). Uncovering trade secrets: An empirical assessment of economic implications of protection for undisclosed data. OECD Trade Policy Paper No. 167. OECD Publishing.

Merck KGaA. (2022). Making Biologics: Strategies and Policies for Enhancing Capacity. MilliporeSigma.

Millipore Sigma. (2022). BioManufacturing Resilience: Secure Supply Chains for Biologics. MilliporeSigma.

Morten, C., et al. (2021, June 1). Pharma's secrecy hinders global COVID-19 vaccination. Joe Biden could fix that. Boston Globe.

Otu, A., et al. (2021). Beyond vaccine hesitancy: time for Africa to expand vaccine manufacturing capacity amidst growing COVID-19 vaccine nationalism. Lancet Microbe, 2(8), e347–e348.

Park, A., & Baker, A. (2021, April 19). Exclusive: Inside the Facilities Making the World's Most Prevalent COVID-19 Vaccine. Time.

Park, W. & Lippoldt, D. (2008). Technology Transfer and the Economic Implications of the Strengthening of Intellectual Property Rights in Developing Countries. OECD Trade Policy Papers, No. 62. OECD Publishing.

Risch, M. (2007). Why do we have trade secrets? Marquette Intellectual Property Law Review, 11(1), 1-76.

Schultz, M. F. (2021). Trade Secrecy, Knowledge Sharing, and Cooperation: The Case of Development and Manufacturing Covid-19 Treatments. University of Akron School of Law.

Serhan, Y. (2021, August 26). The Vaccine-Booster Mistake. The Atlantic.

Taylor, A., et al. (2021). Deciphering the Manufacturing Landscape for COVID-19 Vaccines. Duke Global Health Innovation Center Issue Brief.