Considerations for Commercially Viable Vaccine Manufacturing in Africa

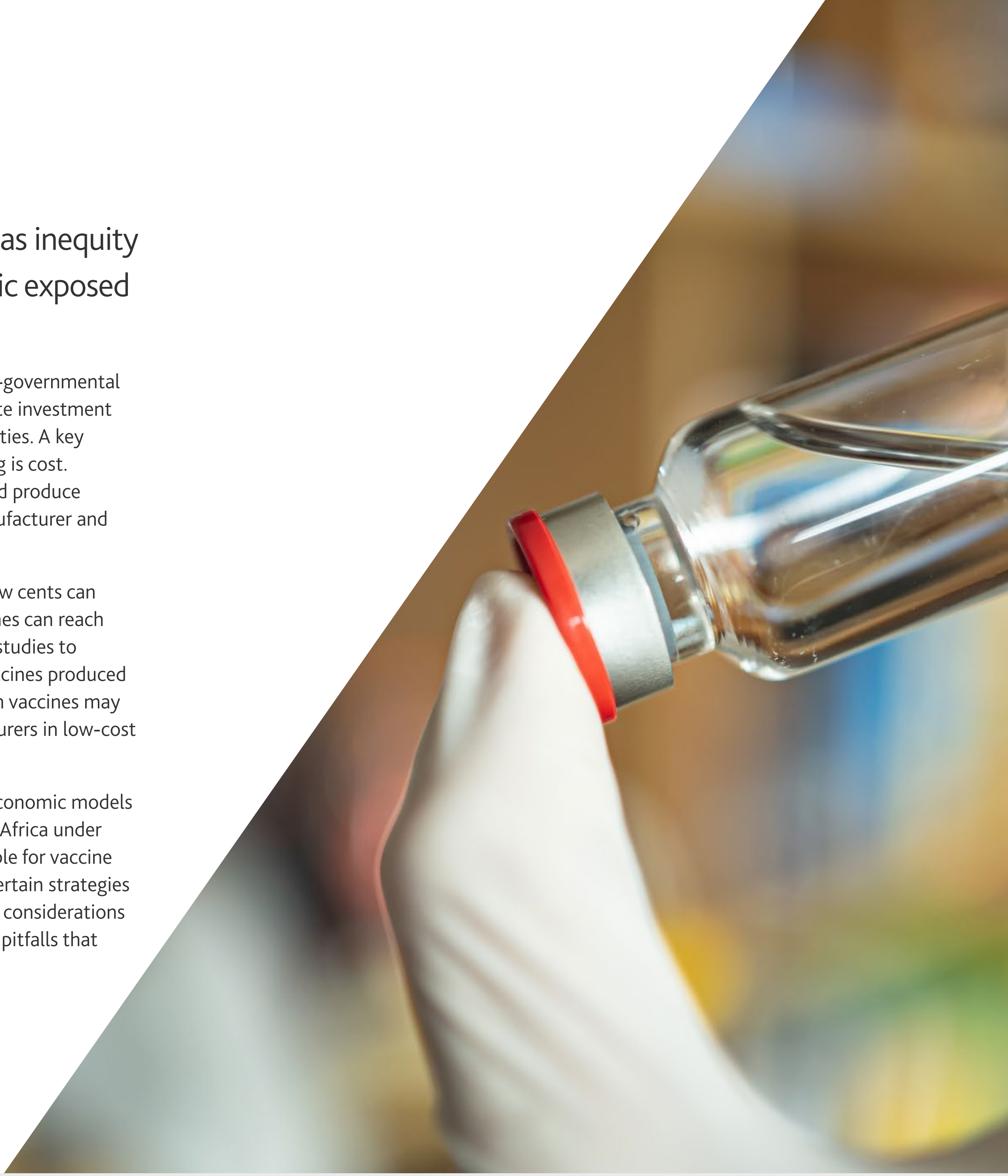
A PUBLICATION JOINTLY AUTHORED BY BDO USA AND KROLL

Calls to enhance African vaccine manufacturing capabilities have been amplified in recent years as inequity in vaccine access during the COVID-19 pandemic exposed constraints of the current supply landscape.

Stakeholders have responded by considering whether governments, non-governmental organizations, and/or charitable organizations should complement private investment and facilitate the development of African vaccine manufacturing capabilities. A key aspect of assessing commercial viability of African vaccine manufacturing is cost. Specifically, it is necessary to understand whether facilities in Africa could produce vaccines that may be sold at a price that is both sustainable for the manufacturer and affordable for developing markets.

In the global public health context, a per-dose cost difference of just a few cents can impact procurement decisions, especially considering that vaccine volumes can reach hundreds of millions of doses. Various stakeholders have commissioned studies to analyze questions around cost and whether effective, quality assured vaccines produced in Africa can be cost competitive with existing offerings, which for certain vaccines may include products sourced from experienced, commercial-scale manufacturers in low-cost locations (e.g., China, India).

Pursuant to these questions, Kroll and BDO have developed a series of economic models aimed at estimating fully loaded production costs for several vaccines in Africa under a range of hypothetical scenarios. The analysis concluded that it is possible for vaccine production in Africa to be cost competitive in the long term but only if certain strategies are employed and certain circumstances are met. The below outlines the considerations for achieving cost competitive manufacturing in Africa and the potential pitfalls that may lead to excessive cost premiums.



Maximize Facility Scale while Maintaining High Utilization

For certain established vaccines, existing commercial scale manufacturers are producing upwards of hundreds of millions of doses per year and have set a low-cost benchmark. Many of these manufacturers benefit from substantial domestic demand (e.g., India, China, Indonesia) in addition to export demand. Cost competitiveness with such manufacturers will therefore require similar economies of scale (and/or realizing relative savings through other means).

All else equal and assuming traditional methods of vaccine production, costs such as labor and depreciation of capital expenditures typically scale at less than a one-to-one ratio with increases in facility capacity; for example, it might be the case that the primary difference between a facility designed to produce 50M doses per year (Scenario 1) and a facility designed to produce 300M doses per year (Scenario 2) is just the size of the equipment (e.g., bioreactors) and the associated infrastructure (e.g., utilities, warehouses) and that the process itself would otherwise be identical. In such a case, there would be limited increases in labor (because effectively the same functions would be required) and capital expenditure, but the associated costs would be spread over several times as many doses, leading to a lower cost per dose at capacity. As such, larger scale facilities will always be cheaper than otherwise equivalent smaller scale facilities assuming production at sufficiently high utilization.

That said, it is important to construct a facility that aligns with a vaccine's demand. The 300M facility in the above example would be more expensive to construct and operate on an absolute basis (as opposed to per-dose basis), so if demand is only 50M doses per year, the per-dose cost for this facility would be significantly more than an otherwise equivalent facility designed for 50M doses per year (Scenario 3). This effect is demonstrated in the table below:

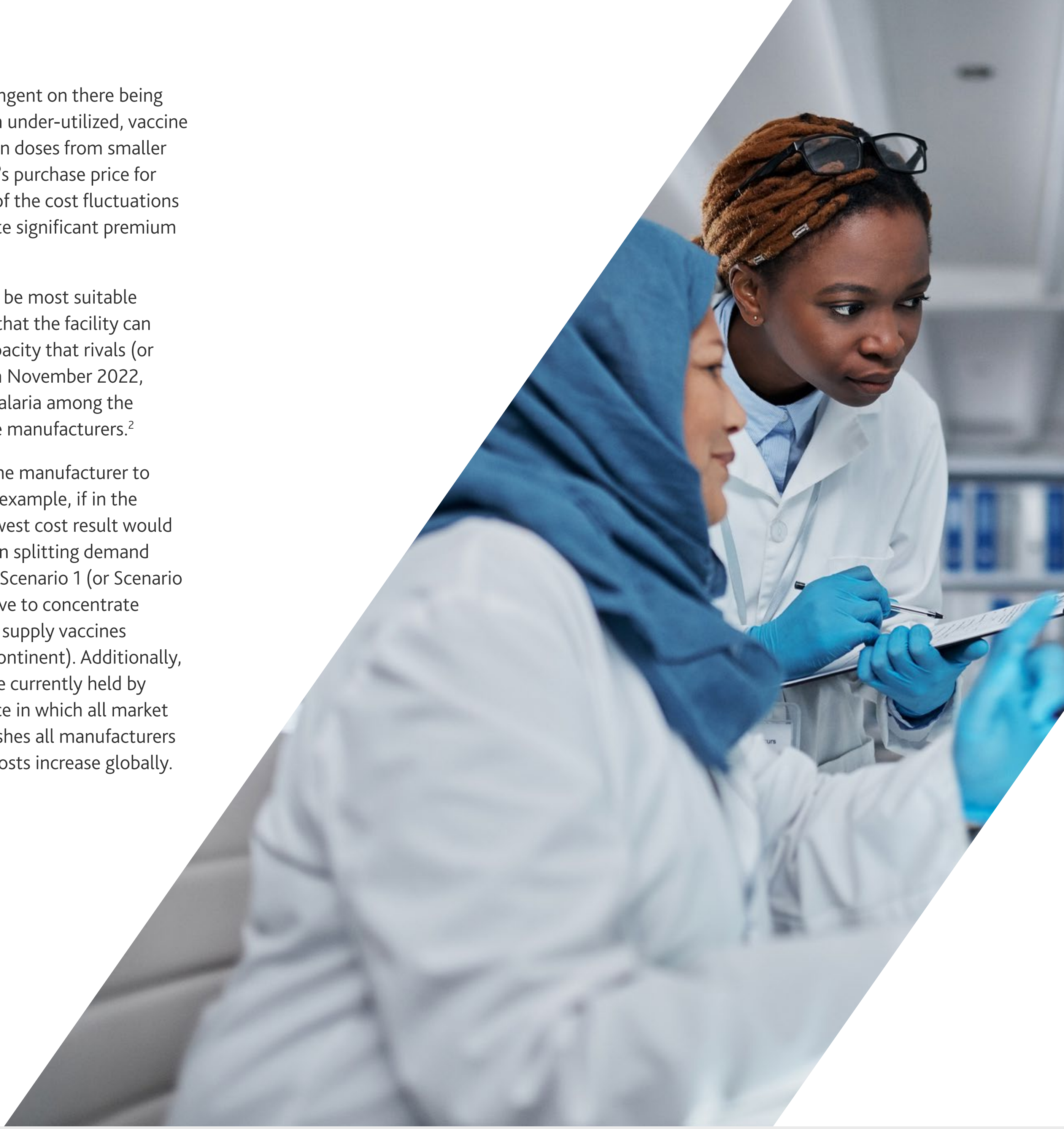
OTHERWISE EQUIVALENT FACILITIES AT 50M AND 300M DOSE/YEAR CAPACITIES

	SCENARIO 1	SCENARIO 2	SCENARIO 3
Facility Capacity	50M	300M	300M
Annual Depreciation	$3.0M	$5.0M	$5.0M
Production Volume	40M	240M	40M
Facility Utilization	80%	80%	13%
Depreciation Cost Per Dose ($)	$0.08	$0.02	$0.13

As shown, the potential savings from a larger facility is contingent on there being sufficient demand such that the facility is well utilized. When under-utilized, vaccine doses from a large production facility can be more costly than doses from smaller but highly utilized facility. As a point of comparison, UNICEF's purchase price for measles was under $0.50/dose in 2022[1], so the magnitude of the cost fluctuations between the three scenarios presented has potential to create significant premium on a relative basis.

To best realize economies of scale, African production would be most suitable for vaccines with current unmet (or available) demand such that the facility can consistently achieve high utilization while producing at a capacity that rivals (or exceeds) that of existing competitors. In a paper published in November 2022, Gavi identified cholera, measles-rubella, yellow fever, and malaria among the diseases with clear market health need for additional vaccine manufacturers.[2]

Further, over-diversification of suppliers will not allow any one manufacturer to capture sufficient demand to realize economies of scale. For example, if in the above table there is initially 250M of unmet demand, the lowest cost result would be concentrating demand to align with Scenario 2 rather than splitting demand between multiple manufacturers that would then align with Scenario 1 (or Scenario 3). To mitigate potential cost premia, it might be cost effective to concentrate manufacturing capabilities in fewer manufacturers that each supply vaccines beyond their national borders (e.g., regionally, through the continent). Additionally, if new market entrants capture too much of the market share currently held by existing vaccine manufacturers, it could create a circumstance in which all market participants forgo economies of scale (i.e., if competition pushes all manufacturers represented by Scenario 2 towards Scenario 3) and vaccine costs increase globally.



1 https://www.unicef.org/supply/media/6986/file/Measles-vaccines-prices-30092021.pdf
2 Expanding sustainable vaccine manufacturing in Africa: Priorities for Support. Gavi: The Vaccine Alliance. November 2022.

DEVELOP LOCAL LABOR CAPABILITIES

Vaccines differ in their labor intensity, but for certain vaccines the cost of labor can be a significant driver of costs. Labor costs in Africa vary widely but in certain cases, African manufacturing has the advantage of lower cost labor compared with incumbent manufacturers. However, the benefits of this are only realized if the facility can be staffed predominately with local labor. If a facility is forced to rely on expat labor (i.e., importing employees from other regions) it is likely that these labor costs will be significantly more expensive given that expat labor would need to be sourced from a separate, likely costlier, market, and require a relocation premium.

A feasible solution for regions where qualified local staff is limited could be a hybrid approach in which the facility is staffed with a mix of local and expat labor that increasingly shifts towards more local labor as capabilities are developed. Under such an approach, a facility in a region with low labor costs could eventually realize a savings from relatively lower annual labor costs compared to competitors once the facility is able to be staffed with a largely local workforce and avoid the cost premia associated with a staffing model reliant on expat labor.

TARGET REGIONS WITHOUT PRACTICAL CONSTRAINTS

Supply chain and infrastructure constraints should be considered. These can impact the procurement prices of input materials, transportation of those materials, as well as utilities (water, electricity, natural gas, etc.). The impact of these constraints can also be magnified if they require the manufacturer to incur incremental costs (e.g., material importation tariffs) or a process change. For example, without reliable access to potable water a manufacturer may need to use disposable (rather than stainless steel) equipment or incur significant costs to generate high-quality water required to clean the equipment. For certain vaccines, disposable processes cannot be operated at the same scales as stainless processes and thus would require duplication of smaller-scale lines to achieve the same capacity (i.e., scaling out vs. scaling up), leading to higher fixed costs. As such, when comparing manufacturing costs across regions, it is important to consider not just differences in cost inputs but also whether practical considerations would lead to new cost categories or even wholesale process changes.

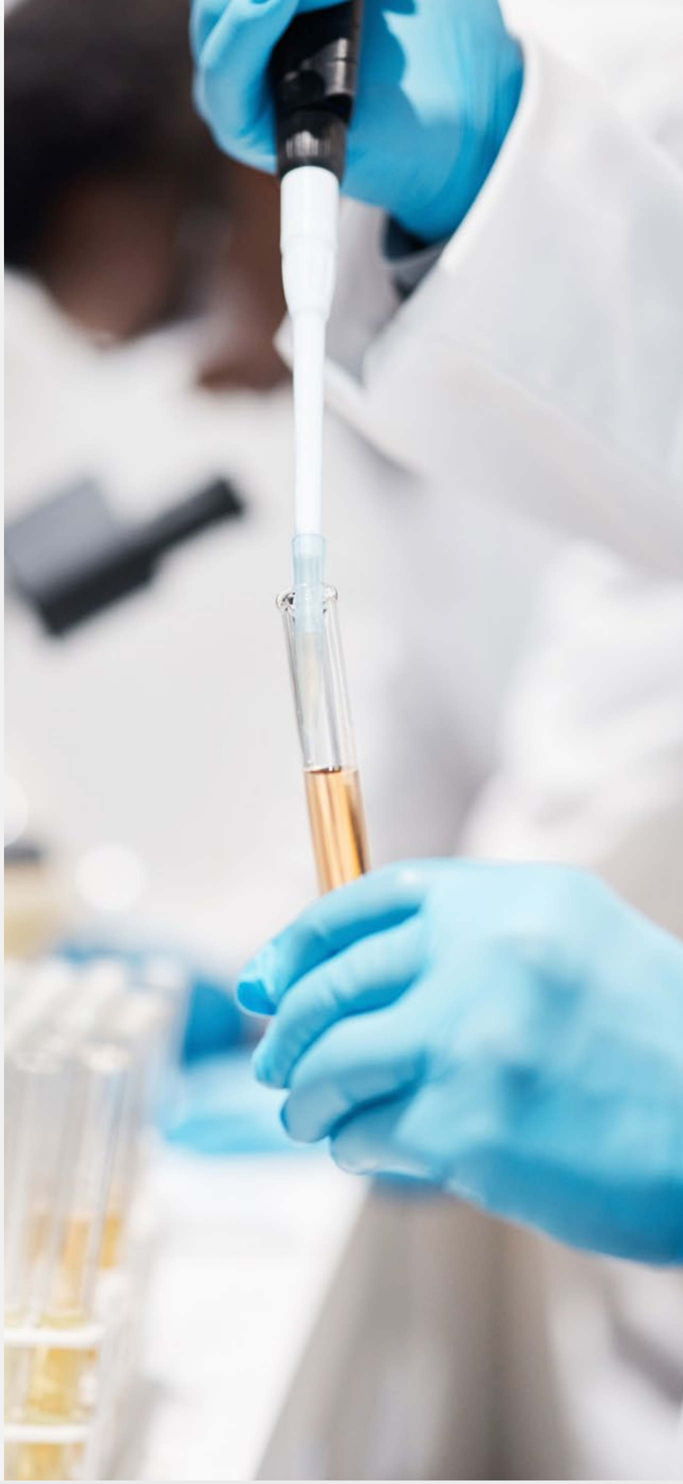
Harness Manufacturing Advances to Capture Economies of Technology

Advances in manufacturing technology can offer the opportunity for comparative cost savings due to higher-yielding processes, smaller footprints, or greater automation. Leveraging cost saving technology is a potential means of offsetting premia (e.g., caused by differences in scale, expat labor) compared with low-cost incumbent manufacturers that use established technology. The example in the table below presents the results of two cost models for the same vaccine but where one assumes a larger scale with traditional technology and the other assumes a smaller scale with novel technology that is more productive (e.g., reducing raw materials per dose), more automated (e.g., reducing labor and overhead per dose), and smaller in footprint (e.g., reducing depreciation):

NEW TECHNOLOGY CAN OFFSET COST ADVANTAGES FROM ECONOMIES OF SCALE

	HIGHER SCALE - EXISTING TECHNOLOGY		SMALLER SCALE - NOVEL TECHNOLOGY	
Volume	**300M**		**50M**	
	Total Cost	**Cost per Dose**	**Total Cost**	**Cost per Dose**
Raw Materials and Consumables	52.5M	$0.18	4.8M	$0.10
Labor	6.6M	$0.02	2.3M	$0.05
Depreciation	2.2M	$0.01	1.3M	$0.03
Overhead	2.7M	$0.01	2.3M	$0.05
Total	64.0M	$0.21	10.7M	$0.21

As shown above, the novel technology can offset the benefit of economies of scale realized by the facility with the existing technology.



Conclusions

Developing commercially viable vaccine manufacturing capabilities in Africa is not without its challenges, but there are steps that can be taken to avoid pitfalls and achieve cost competitiveness. The following should be considered:

- Production at similar high utilization of large-scale facilities will be necessary for cost competitiveness, even if that means limiting the scope of Africa manufacturing to vaccines where sufficient demand exists and concentrating manufacturing.

- Lower-cost labor, which may exist in certain jurisdictions in Africa, can reduce production costs, but it will require predominantly employing a trained local workforce at least in the long-term.

- New technologies can reduce production costs compared to existing technology being used by mature commercial manufacturers and can help mitigate other premia from production in Africa.

- There may be practical constraints to establishing manufacturing capabilities in certain regions in Africa (e.g., unreliable utilities, lack of clean water, tariffs/taxes) that should be considered when selecting facility locations.

With these steps taken, sustainably priced local manufacturing capabilities in Africa can be a reality.

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