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M&A activity in the analytical services sector: points to consider

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There has been remarkable consolidation in the analytical services sector in the US and elsewhere globally over the past few years. Make no mistake; the need for analytical and related testing services is growing significantly. Because of the legal and regulatory frameworks that demand such services, however, there is considerable need for attendant technical expertise to staff these laboratories, and the need for specialised expertise is also growing exponentially. This article summarises mergers and acquisitions (M&A) trends and explains why skilled help is essential to avoid liability.

Background

Regulatory testing is a growing business for a number of reasons. In the US, Congress amended the Toxic Substances Control Act (TSCA). Congress gave the US Environmental Protection Agency (EPA) new authority to compel chemical testing, making it much easier for the EPA to unilaterally order toxicity or environmental fate and related testing. The EPA utilised this authority in 2020 and mandated chemical testing for Pigment Violet 29, for example. The EPA is expected to utilise this authority more regularly, especially under the Biden administration, and ramp up industrial chemical testing considerably.

Under the TSCA, the EPA is also required to evaluate all 'active' industrial chemical substances to determine if any 'condition of use' is likely to pose an unreasonable risk to human health or the environment. The TSCA authorises the EPA to compel chemical testing to assist it in prioritising active chemicals for risk evaluation and to order testing as deemed necessary. In anticipation of chemical evaluation under the TSCA, forward-thinking chemical producers are voluntarily testing their products as a prophylactic measure to be positioned well to rejoin assertions of unreasonable risk. This practice better informs business strategies

and demonstrates product stewardship. Understanding which data is most applicable for analytical characterisation and risk evaluation and which test methods are appropriate for a given product is paramount to successful testing.

Apart from the push the TSCA has given testing, in the US, product manufacturers, especially in the consumer market, are being constantly challenged to prove the safety of their products and the chemical constituents included in them. This will not abate, especially under a Biden administration, given public health activists' new and important standing in the public health debate.

Internationally, Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)-like laws that require chemical testing have mushroomed. The South Korean Act on Registration and Evaluation, Authorisation and Restriction of Chemical Substances (K-REACH), *Kimyasalların Kaydı, Değerlendirilmesi, Güzni ve Kısıtlanması* (KKDIK) in Turkey, and Eurasia REACH in Russia are just a few of the global chemical evaluation programmes that authorise governments to compel chemical testing. The recently announced European Union (EU) Chemicals Strategy for Sustainability will jump start a new round of testing in all product areas, especially industrial chemicals and chemicals used in cosmetics and other consumer products. There is every reason to believe these programmes will continue to propagate. Whether navigating one or multiple chemical evaluation programmes simultaneously, a complex integrated testing strategy may be required.

Evolving technologies like nanotechnology, biotechnology and synthetic biology are requiring greater bandwidth in testing capacity and demanding testing sophistication, and similarly, new products emerging globally will fuel the relentless push for testing. The US, under the Biden administration, and Europe are expected to encourage green energy programmes, the very basis of which is premised on new and adaptive chemistries and products that will require and promote product testing.

The pandemic has supercharged an already hot therapeutics market and an equally hot biocides market. Even with the rapid development and approval of COVID-19 immunisations and an array of chemical disinfection and sanitiser products underway, the industry is ever-mindful that the next virus is around the corner.

These trends are growing in strength. The demand for testing capacity is impressive. It is no wonder that laboratory consolidation is on the rise with no sign of abating.

For example, Eurofins Scientific reportedly acquired 136 labs over the three-year period ending in 2019, tripling its full-time staff to over 40,000 employees. Depending on your perspective, this may seem a positive development. Offering an array of testing specialties and support services, as well as harmonised contract terms across global sites, enables laboratory conglomerates to meet the increasing testing demands and offers a more streamlined option for study sponsors. Clearly, from the M&A support and financial services market, the trend is great for business. If you are a smaller, specialty lab wishing to become part of a larger enterprise, you no doubt have been fending off suitors for a while waiting for the perfect match. If, however, you are the purchaser of specialised testing services, this trend is not necessarily a desirable one, and if you are the purchaser of testing labs, considerable care must be taken to ensure the new owner is fully aware of the need for specialised expertise in offering elite testing services without the requisite professional competence. Every effort should be made to avoid key person defections, massive layoffs and related staff disruptions.

What can go wrong?

This discussion focuses on pre-clinical industrial chemical testing as opposed to outsourced testing by big pharma in the drug or medical device testing area. Many of the same issues are likely applicable across both sectors, however.

Testing services are always highly scripted. Contract research organisations (CRO) have, over the years, developed contracts that define the rights, duties and obligations of the CRO and the study sponsor. While performance issues are a matter of contract interpretation, the remedy is unlikely to provide much satisfaction. When testing goes bad, for whatever reason, the consequences of technically flawed, non-compliant or inadequate data can be costly well beyond the contract value of the agreement. This is true for several reasons.

First, in the industrial chemicals market, the availability of reliable and relevant data is typically the factual predicate to market entry. The lack of such data can delay or preclude market entry as a legal matter or prevent product launch based on a company's internal metric for commercialisation. Every day of delay reflects missed revenue. Selecting the best CRO for a required study is a complicated calculus including many factors like lab capacity, technical competencies, compliance with quality standards and cost. Reduced lab capacity, juxtaposed with more stringent deadlines imposed by regulators, is a growing issue, much to the frustration of the regulated community. Even if a lab has capacity, there is no guarantee the technical capabilities and quality systems of the lab will align with the testing needs. The lab needs to be very clear about what its staff can and should undertake, and the sponsor needs to be equally clear-eyed about its needs and the timetable for completion. Contract breach could cost the sponsor a product line or similar commercial disaster, inviting significant damages for which the lab could be liable.

Layered on this fundamental reality is the fact that testing strategies are evolving at a different pace around the globe. In the US, the government's policy for industrial chemical testing disfavours animal testing and encourages testing alternatives that involve *in vitro* methods or advanced computer-modelling techniques, known as *in silico* models, or bridging other existing data. This evolution is essential, but is fraught with scientific and, thus, commercial uncertainty, the nemesis of the business community. Implementing the wrong study design could limit the utility of the data and may contradict jurisdictional mandates to avoid unnecessary testing on animals.

Second, companies have a hard time distancing themselves from 'bad' data. If a CRO completes a study and the results are unfavourable, because the lab erred or because the result was entirely unexpected, the results often must be disclosed to the government and are generally publicly available. Under many international chemical programmes, the government holds test results that reflect an 'adverse' human health or environmental effect to a higher disclosure standard and data owners are required to promptly report the results to the government, consistent with regulatory requirements intended to invite close government scrutiny. Technical errors, deviations and deficiencies should be documented during study conduct and, in turn, disclosed when submitting these data for government review, but inferences adverse to the study sponsor, the CRO, and the product being tested will inevitably follow. These reputational injuries are hard to quantify but are quite costly. Even if the bad data is the result of lab incompetence or error, both the lab and data owner could be responsible for the consequential implications of that error.

Bottom line

Many things can go wrong when testing a chemical; getting it right is far more complicated than most people think. Some believe the intense consolidation in the testing community reflects a misguided notion that chemical testing is just like any other fee for service transaction. When lab owners and their financial supporters neglect to ensure the professional capacities reflected on staff are calibrated to provide the requisite skills needed to design and undertake testing that is accurate and compliant with all the standards to which the CRO is held, lawsuits happen and professional reputations are questioned.

The testing surge will continue. So will the need for carefully curated technical staff to ensure the right testing is done well, on time and on budget. For those of us who work with CROs, there is growing concern that the intense consolidation underway sometimes comes at the expense of quality and sufficient attention to technical detail and core competencies. Chemical testing is demanding, and getting it right requires a well-developed CRO infrastructure and a highly skilled team of professionals. While achieving this result is daunting from a time-to-market and financial investment perspective, the upside is as considerable as is the price of failure to achieve as much. ■