



In the middle of the New York City hustle, somewhere between the smell of roasted Ghanaian coffee and the ever-present background noise, I'm sitting in a café with Lou Ambrogio*, Vice President Emeritus of Strategic Projects at Pfizer, one of the largest pharmaceutical companies in the world. We're trying to lift the curtain to peek behind the scenes of the Big Pharma industry, and Lou is the perfect gentleman to do so, with more than 33 years of experience under his belt. How has the industry transformed itself over the last few decades? What are the challenges that the industry faced? Where is it moving to now and what will we see in the future? What is there about pharma that is only known by those actively involved?



* Lou joined Pfizer in 1980 as an engineer and worked in various areas of the corporation's business. After several domestic and international assignments of increasing responsibility, he served as a VP of Engineering Operations for several years before moving to his most recent position as VP of Strategic Projects.

Industry turbulence over the last 10-20 years and Big Pharma's response

JJ: *How did the pharmaceutical industry need to reinvent itself after the patents expired? What was the impact?*

LA: The impact on the companies was significant to say the least: some have handled it well, but many have not. One of the underlying reasons was that the model of billion dollar blockbusters had worked well for Big Pharma in the past; they weren't concerned about smaller products. They also had no need to value their generic portfolio, since blockbusters generated big returns. As patents expired, however, this provided the generic companies with numerous products to bring to market and new discoveries became rarer. Big Pharma was caught by surprise – loss of exclusivity combined with a reduction in new blockbusters coming to the market - the industry was simply not equipped to compete on the new basis.

Next, we saw a cycle of takeovers and mergers which, in the long run, added little to shareholder value. Aside from lost sales, innovation suffered as the companies shifted focus to integration of new business, synergy savings and closing of sites. This cycle was repeated in some cases every 2-3 years. Innovation, which used to be the cornerstone of Big Pharma, was lost as R&D fell into turmoil.

JJ: *So what was the response of Big Pharma to the changing rules of the game? And was it a successful one?*

LA: Generally, two approaches were taken, M&A and building a generic business. M&A was a strategic decision, highly motivated by financial engineering and a desire to replace the innovative products that were lost to generics and replenish the discovery pipeline.

Instead of placing a focus on research, which is long-term and risky investment, the mindset was, "what can we acquire now to fill the gap in new products". Many companies paid above par for these options, thus harming shareholder value in the long run. Some deals had to be made, but

looking at their share price then and now, it becomes clear that it was a very short-sighted strategy. Capital allocation was not judicious, shrinking funds went to M&A rather than building the business by improving technology or investing in their own R&D (or becoming more efficient). The products that were acquired from startups often never made it out of development, thus putting increased strain on the bottom line.

As the generics business became very attractive, it proved a challenge for Big Pharma to create a generic arm within their companies. Culturally coming from their blockbuster mentality, most companies were not ready to play in the nimble and agile world of the generic business. Success has been mixed.

Current pharma challenges and trends – not obvious to an amateur observer

JJ: *Has the attitude of the Big Pharma executives changed since then? And what is on their agenda these days?*

LA: It [attitude] sure did. A few decades ago, everybody wanted to be big – and that was not necessarily the right thing to do. Nowadays, companies realize that they're much better off focusing on what they're really good at, at their "know how" – and hence the trend is to shrink and spin off non-core parts of the business (like Pfizer's divestiture off its animal business Zoetis, or Abbott spinning off Abbvie).

Pharma is very much an innovation-driven business and it's very difficult to manage innovation. But now, it seems CEOs are on the right track – the blockbuster pharma model is changing and the industry is becoming more targeted. Companies are focusing on niche solutions, customizing hard-to-make products such as injectibles, and we are already seeing positive signs from this new trend. Just look at how many companies there are on the market with specialized products targeting only one or two disease classes. Small is not only beautiful. It can also be very profitable.

JJ: So what are the ways of cultivating innovation? And how will our healthcare level benefit from it?

LA: Our healthcare level is already much better now than it was 20-40 years ago. HIV, cancer, hepatitis, hypertension and many more diseases have very effective treatments now. This all became possible with R&D and innovation.

So how do you create an environment that fosters innovation? I've seen two very effective ways. First, narrow down the research scope and opt for external collaboration. This means moving away from being big and performing R&D across many disease areas, to being focused on a few that you believe you can have success in. What did this mean for pharma companies? It meant moving away from big labs, and shrinking and creating more targeted R&D centers. Many large-scale labs were simply demolished during this process.

The second key element is collaboration. Luckily, we see more and more of this these days. Collaboration entails finding a true synergy between the parties – and this is something Big Pharma should have done years ago, rather than placing a heavy focus on M&A. Collaborations that we see today include joining forces in discovery (R&D), marketing to spread the risk and, for example, partnering with universities as a way to be closer to the forefront of innovation. Many companies understand this and have joint projects with universities in Boston, West Coast, UK, etc., and are actually collocating their staff.

JJ: Looking behind the scenes from a geographical point of view, what other trends do you see around the world?

LA: Well, if we look at Asia – both production and innovation has already arrived there. Since drugs react differently in Asian bodies, companies need to do clinical studies in Asia as well. If we're talking about China specifically, all the Big Pharma companies have partnerships there. It's a strategic decision to both trigger innovation and get governmental access to the market, to



be able to sell the product in the largest market. India has long been viewed as a low-cost production location but its reputation has suffered due to many quality issues, which have led to import bans for products. Patent laws in India are still a challenge and an impediment for Big Pharma to sell innovative products there.

In the emerging markets you need to build a plant locally to receive green light from the government to sell your products. So what most of the pharma companies do is build a plant with packaging lines or something low-tech, in order to be able to import products, negotiate better prices with the government and gain a foothold into the region.

Preferential pricing is not only limited to emerging markets. It is also part of daily routine in the EU. Compared to the US, where prices are set by the companies, the EU and some other countries with social healthcare systems (like NHS in the UK) have governments buying the drugs directly from the companies. Interestingly, if one EU country gets a good deal with the pharma company – all member countries can benefit from it. This was the case when France negotiated a good price for a hepatitis C drug from Gilead. It is interesting to see that, in the US, it is the PMOs who are driving a hard bargain on pricing with pharma and not necessarily Medicare or the Veterans Administration.

So, whereas pharma still locate production into regions for taxation or financial reasons, now they are also doing to get access to the market. Of course taxation has been very much in the news over the last few months, with many USA companies looking to do inversion deals, to lower their tax rate. The jury is still out on this trend, some companies have embraced and others rejected it. Whether or not it will dilute the focus is yet to be seen.

JJ: Do companies still have a lot of banal issues or improvement opportunities in their plants, such as Lean, or are they all Toyota-like by now?

LA: The pharma industry is still on its learning curve in terms of Lean. Some companies are better, some - way behind. Pfizer had a good Lean base, but it is still not where it should be. An excuse that is often used is that pharma is a regulated industry and not a widget maker so many aspects of Lean do not apply.

Many pharma companies have established Continuous Improvement or Lean departments. However, the role seems to have evolved into a tactical versus strategic function. My view is that internal staff are better at identifying the key issues and using external resources such as Tefen to develop the opportunities and manage the execution. I've seen many opportunities left on the table due to lack of staff or changing priorities. There is a belief that it's more cost effective to execute with in-house staff. A mix of in-house with external is likely to be the optimal solution.

JJ: Thinking ahead, what other opportunities are there out there for the pharma industry?

LA: There are still a lot. Innovation is amongst the most important ones. Outsourcing the right things is the next one. A current trend is to outsource many of the non-core functions, such as Production, Lab Maintenance and MRO Procurement.

Restructuring the overall network continues to be a big opportunity for the pharma industry. M&A has resulted in overcapacity in the manufacturing networks of most companies. Re-organizing the supply organization by technology instead of geography has the greater potential in many cases.

There are also many Lean initiatives that will keep improving productivity and efficiency. These include end-to-end time studies, cycle time and capacity modeling, and building a Value Stream

(process-centric) organizations. The key here is to avoid organizational silos – true improvement will encompass an end-to-end process.

JJ: So how does Tefen compare to other companies that you have worked with in the past?

LA: I believe that being as close to the shop floor as possible as a consultancy is key to bringing real value to the client. Tefen has exactly that operational knowledge, bringing a competitive advantage to its clients and refreshing their competitive landscape. Compared to other companies, Tefen has a strong industrial engineering background and the company is driven by data and processes. That's what gives them a true understanding of the pharma reality and its assumptions - drilling down to the details. Yet, they are also very realistic in recommendations and don't overpromise – I like that they provide clients with a menu of opportunities and corresponding benefit ranges. I've always liked working with Tefen people, who have plenty of energy and drive, because it's people that make a difference at the end of the day in the consulting business.

Interviewed by Jelena Joffe, Project Manager and Life Sciences lead at Tefen USA, New York.

