Interview: Mark Barrett – CEO; Brian Glennon – CTO, APC, Ireland

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Founded in 2011, APC has grown to be the largest process development company in Ireland. It is the largest employer of PhD Chemical Engineers nationally, is partners with the largest pharma and biotech companies globally, and over 80% of the company's revenue is export driven.

Since starting APC in 2011, what have been the milestones that you've achieved along the way that you are proudest of?

Brian Glennon (BG): The decision to form APC itself was of course the first big milestone. Mark and I both were working with the SSPC and on a lot of research that clearly had a lot of applications for the pharmaceutical industry. Ireland had a lot of great research infrastructure, academic collaborations, and we all felt we'd done a lot of great research; however, we felt that we could and should do more with it than just publish papers. In that sense the ultimate validation of your work is getting someone to pay you for it, and so we sought out to do just that, and our efforts turned out to be rather successful.

At the beginning the work we did was mostly supporting the local industry in Ireland, which is in itself substantial, but the work there was mostly focused around problem solving in a commercial manufacturing setting. The big milestone for us was when we started to work with R&D groups based outside of Ireland, often at the headquarters level, and with candidates still in phase II or III

of clinical development. In the first year, 90 percent of our work was around manufacturing support, whereas today it makes up maybe 25 percent of our activity, and almost all of our growth is coming from international clients, often at the headquarters level.

Mark Barrett (MB): I think the fact that we've been able to get companies from all over the world to work with APC, is a very big achievement and a testament to our credibility and capability. As such, securing our first US and mainland European contracts and first multi-year agreements with clients, independent of their activities here in Ireland, was a very big step for APC.

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A second milestone from my perspective was Brian and my decision that we wanted to create a globally relevant company, something that wasn't just local or about us, but involving hundreds of experts who can really have an impact on the way medicines are developed at a global level. This realization didn't happen at a single moment, but as we worked to attract the best and brightest minds we realized we could really work to become a global enterprise delivering innovation relevant at the global level, and we embraced that idea more fully with our decision to build this new facility.

Five years after launching, how does APC's range of capabilities compare to what you originally thought you'd be able to accomplish?

BG: The philosophy or purpose hasn't changed at all, as the key principle behind everything we do lies in understanding processes. This is the principle that guides our research agenda, and our work usually lies in understanding processes at the molecular and biological levels, and how processes actually function in in larger scale production systems with parameters very different than in the lab. That has all been constant to a large extent.

What has expanded is our range of specialized expertise, analytical capabilities, and technology we can employ to that end.

MB: When we started there were some areas of research we had worked with a lot and understood very well, and others that we'd seen and thought were interesting but hadn't had the time to delve into too much. The academic world is very linear in many respects, as you may only be working with a professor or two, a few post-docs, and a few PhD's, and it's difficult to collect the broader capabilities of a large multi-disciplinary group behind one goal. At APC that has been possible, and we have developed significant expertise in each segment of different processes, such that we have teams to work specifically on upstream or downstream issues in both chemical and biological

synthesis. As such, the level of detail we can get into at any stage of a bioprocess or chemical synthesis, in terms of either analysis, capabilities, and technologies, is now frankly remarkable and is constantly becoming more precise.

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Can you share with us an example or two of the projects that you've been particularly proud of and feel best demonstrate the value APC can bring to clients?

MB: There was a clinical asset in phase II for a rare disease and the company had reached a point where they could not make it any more. They came to us with an initial statement saying they needed support on the process side to understand the fundamentals of how that medicine was made. This was a rare disease where patients' lives were at risk, and our work over several months helped to underpin the sustainable supply of the medicine and bring it back into the clinic so that development could continue. As we understand, the clinical research was completed and now it has been filed with and approved by the FDA; I am certainly proud to know that the innovation and knowledge brought by APC to this project played a critical role in enabling these patients to have access to this treatment.

BG: Since we focus on the chemical and bioprocesses, we play a unique role as a partner that is largely agnostic to the drug itself, its purpose and mode of action. We've had the opportunity to work on everything from mAb's for cancer or skin diseases to HIV, diabetes, and drugs for all sorts of orphan conditions.

Our value comes in the fact that because we're involved many of these drugs are now able to be brought to market quicker, and thus patients can have access sooner, and otherwise we play an important role in ensuring a reliable and sustainable supply of these medicines for patients.

How has APC benefited from broader trends towards collaboration and outsourcing in the global pharmaceutical industry?

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MB: If you look back 20 years, the pharma and early biotech industries were built by the big companies that owned the IP, and who built massive organizations around that. Over the last two decades they have started to ask themselves if they are best positioned to carry out the different aspects of drug development, or if they should be partnering with other companies with expertise in those areas. Clinical research was the first area to see a significant amount of outsourcing, with

the first big CROs like ICON & Quintiles emerging. This added to the presence of engineering companies such as Jacobs & PM Group who designed manufacturing facilities, and today are massive.

APC is the next step of that evolution, as the areas of research we deal with were fully internalized before, and we are the first company offering the pharma industry a viable opportunity to do things in a different way. Pharmaceutical companies are now open to many different ways they can boost value to patients and shareholders, and where that was fully internalized before, today they are more open than ever to collaboration. While we are very good at what we do and offer exceptional results, this shift is bigger than APC.

BG: The next decade will certainly bring huge shifts in (bio)pharma innovation, development and manufacturing. We can imagine whole ranges of new therapy types, new therapeutic areas, the rise of RNA technologies, gene therapy and more. However, regardless of what the drugs are they will still have to be made, and as such there should still be some basic processing principles that remain relevant. For us, and Ireland to an extent, the challenge is not what the innovative drugs will look like, but can we still make them. Already we see huge changes in how drugs will be manufactured beginning to take place with the increasing use of disposable technologies and process intensification, and perhaps we will see a move away from massive billion dollar facilities and towards smaller more mobile platforms and flexible supply chains.

I would also point out that the big pharma companies have increasingly seen the value of institutional knowledge, and while they can do certain tasks well themselves, they also know that it is beneficial to bring in partners that can help them do the same task better and more efficiently. At the same time, the industry is under pressure from regulators who are constantly increasing demands on manufacturers as the number of operating steps in GMP sequences is increasing. As such, there is an increasing demand for information and it needs to be developed and presented in a strategic, consistent way such that some synergies and economies of scale are realized, so from that perspective its almost inevitable that there will be some outsourcing and standardization to some point.

At the opening ceremony for APC's facility the Taoiseach said "this new research center is a vote of confidence in Ireland and enhances our reputation as a leading location for pharmaceutical research and development." What would you highlight as the main reasons and accomplishments APC has made on the global stage that have helped to showcase what Ireland is capable of?

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MB: APC is very unique in the sense that we're working with the biggest pharmaceutical companies in the world, and many of them have referenced the fact that they don't have any existing partners in this innovation space. To an extent APC is a global company, 30 or 40 percent of our staff is non-Irish, and we could be based anywhere, but there are many benefits to being in Ireland. First of all, following Brexit Ireland will be the only native English speaking population in the EU. Location wise, we're also lucky enough to be in a position where we can speak to the west coast of the US and Australia in the same day.

Ireland has been known as a manufacturing hub, and is still usually associated with manufacturing even though we now have great academic institutes, academic consortia, and companies like APC that are global leaders in pharmaceutical innovation. Certainly any contact we have as APC with global pharma headquarters and presence we build in the media will go towards eroding that perception, and building a new one associated with our technical expertise, knowledge, and capabilities in the pharmaceutical space. It's a place where special things can happen.

BG: Early on, we were very excited to visit Boston where there are all these startups around MIT and Harvard, or around UCLA and Berkley in California, and seeing these types of clients recognize our capabilities and expertise was an important validation of our value proposition for us. Projects and work in Ireland was far less exciting for us in many ways.

What we did not realize at the time as much is just how unique Ireland was as an incubator for a company like ours, and as a breeding ground for talent in the biopharma space. Ireland is the seventh largest pharmaceutical manufacturing country in the world, but per capita or per square kilometer we're far and away the most intensive manufacturer of pharmaceuticals in the world. This means that from our offices here we can be at any pharma manufacturing site in the country in two and a half hours, and from another perspective both Mark and I had extensive experience working with and in the pharmaceutical industry itself, in manufacturing plants, even though we were both essentially academics. So our relationship with the rest of the Irish pharma sector has been a virtuous circle; we've benefited from Ireland's experience and the strong manufacturing industry here, and equally Ireland is now benefiting from our activity at the international level.

MB: We were naive to much of that when we started. We knew there were a lot of pharma companies here, but never realized the importance of connecting our research to manufacturing

plants and how unique that was. When we went to the US we realized very quickly that many of these companies hadn't been in a manufacturing site before. Now in Ireland we have an environment with a huge number of pharma companies, great support for research from industry and government, and a lot of skilled engineers and scientists. Moreover, Ireland also has a very rich pharmaceutical ecosystem that is excellently supported by the IDA fighting for FDI on one side, and Enterprise Ireland supporting and nurturing companies based in Ireland and helping them collaborate with the university ecosystem. Between these two organizations exists an umbrella of academic and public institutes like the SSPC, NIBRT, NICB, and others, and a very natural collaborative environment has emerged between them all; APC has been lucky enough to fit in amongst these organizations as well, and from a certain point of view, today we're just one piece of that very rich ecosystem.

To wrap up, what metrics will you use to measure the success of APC and your own efforts?

> Our work and efforts are helping manufacturers to transition to more advanced or next-generation techniques

MB: To me there are two factors; the quality and innovative features of our research. That's something we're focusing on internally, our current quarterly focus. We're proud of that and the people that work here have a technical vision of what APC can do as a company and we've set that bar very high.

Another is related to the new therapeutic areas. The complexity of these medicines is extreme, the processes by which they are made are very different from those in the past. Our work and efforts are helping manufacturers to transition to more advanced or next-generation techniques, and I'm very proud of the impact we're having in that regard.

BG: I second what Mark has said, and I'd also add that I get a lot of satisfaction seeing the people that have chosen to join this voyage with us. To see the team of people, the talent we can attract, and looking back to when we had three people versus now, that's the most satisfying part. People have chosen to join us from across Ireland and around the world, and to me that shows we're really doing something important.

At the same time, the academic in me is very proud to be serving as an outlet or career pathway for a lot of excellent researchers coming from academia who don't have many other opportunities comparable to APC. As such we're now the largest employer of PhD's in Ireland, and the largest employer of graduates from the SSPC, which is one of the top five or six research groups in basic

and platform level pharmaceutical science at the global level.

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