Recently Sir Andrew Witty, CEO of GlaxoSmithKline (GSK), stated that: “It would be naïve or arrogant of us as an organisation to think that we had all the answers internally”. This is hugely relevant in the current patent cliff-dominated industry environment but how can the industry best harness outside ideas and accelerate innovation?

We are all aware that the traditional pharmaceutical business model needs to change. The model was built on major, prolonged investment in developing products that turned into huge blockbusters, from which companies could maximise returns until the patent expired and could leverage as cash cows to fuel further research. However, this era is now coming to an end: most of the blockbuster breakthroughs have been discovered and those which are already out there, such as Pfizer’s Lipitor and Sanofi’s Plavix, are now coming off patent.

Surely, one may ask, the business model now just needs a little reworking to search for ‘mini-blockbusters’ and it just requires a little more time and money, doesn’t it? Well, not exactly.

It currently costs around $1m per day to get a drug to market. This cost is so staggering because for every molecule that gets to market, 9,999 other molecules do not. In addition, of the small percentage that reach the market, only around a quarter actually become profitable and remember these successes have to fund research for all the rest. To exacerbate the return on investment equation further, due to patent expirations, and the length of time between patent and launch, those launched drugs only have a limited length of time (typically five to 10 years) to recoup their investment before generics can be sold for a fraction of the cost.

Since all low hanging ‘blockbuster’ fruit has now been gobbled up, so the 1/10,000 ratio is now likely to be much higher and subsequent returns lower. This is why many of the world’s largest pharmaceutical companies have either outsourced or completely withdrawn their R&D efforts for the most difficult disease areas such as CNS and infectious diseases where those ratios look even bleaker.

For those of us who have worked in the industry for any length of time, this information is not new (even if being reminded of it every now and again is still shocking!). So we know the innovation model has to change – but change how?
The innovation continuum
As Sir Andrew eluded, one key way to boost innovation is to look beyond your own four walls and engage with different minds outside the organisation. This involves moving beyond what we have called the traditional ‘closed model’ of healthcare innovation (See Figure 1).

Academic and pharma collaborations have been implemented for a number of years with many notable successes: Roche and Lilly are seen as leaders in this type of collaboration. According to Heather Fraser, from the IBM Institute for Business Value, who has been involved in benchmarking studies in the area, both of the companies have achieved this by “consistently excelling at the building blocks, such as project management, having explicit strategies and models for externalisation in place and seeking collaborative improvement”.

“Importantly, they have had a good understanding of the motivations of the different stakeholders,” she said. Many others could learn from their approach.

Collaboration for the greater good
The next stage along this continuum is the ‘consortia’ approach, which involves multiple parties. In healthcare this has mainly been used when the profit motive has been removed; it is collaboration for the greater good.

Paul Wyatt, head of the Drug Discovery Unit (DDU) at the College of Life Sciences, University of Dundee, who has been involved in both types of collaboration, pharma and academia and consortia, believes the benefits of tight, integrated industry and academic partnerships are clear.

“We are able to bring together a combination of skill sets and knowledge, share access to key elements such as target and disease expertise, compound libraries and safety pharmacology studies to discover and seamlessly move candidate drugs into pre-clinical and clinical development.” However, there are challenges that need to be addressed to enable success.

“The academic and biopharma worlds run research in very different ways. Their natural mindsets can be divergent, focused respectively on ‘let’s see where this project takes us?’ versus ‘how can we achieve this solution?’ Technical requirements differ too in terms of scale and consistency requirements for assays, for example. The DDU scientists with many years of biopharma experience are able to act as a bridge between those worlds.”

The College of Life Sciences has also been involved in the HIT-TB collaboration, a part of the TB Drug Accelerator programme (TBDA), the goal of which is to identify a series of small molecules with the potential for development as treatments for tuberculosis. Wyatt describes the structure of the consortium as “an incredibly exciting approach to disease research”.

The key elements include: the involvement of and funding from multiple organisations including pharma, charity, academic and public development agencies; and the pooling of skills and crucially a controlled ‘open innovation’ mindset that enables the sharing of promising chemical entities within the TBDA to maximise and accelerate learning. It is attractive to potential pharma partners because of a requirement for unfettered release of potentially commercially sensitive information.

The ultimate goal in this case is altruistic; as such it makes an open approach easier to contemplate and organise. However, Wyatt thinks that a similar model could be used, particularly in the early phases of drug identification, to tackle conditions such as Alzheimer’s disease where research has proved difficult.

Outside-in or inside-out?
Both academia and pharma and consortia types of collaborations are jump-points to potentially radical innovation models that would address the patent cliff and parched pipeline. The first landing area is what we call ‘outside-in and inside-out innovation’.

Outside-in innovation companies bring smaller partners into their midst and share their knowledge and resources. In the tech industry, this is called ‘incubation’. Procter & Gamble’s (P&G) Connect + Development approach is often held up as the gold standard. The company brings in external ideas from smaller companies and works with them to help the business and/or idea grow. Organisations outside P&G may even pick up on promising ideas or concepts.

This approach is not limited to consumer products either; Lilly has a programme under which it will take in external molecules for target testing, in the knowledge that it will be involved with any promising molecules as they move forward.

The flip-side approach is inside-out innovation where a company has a technology that does not fit with its strategy or portfolio, or it wants to realise the potential beyond the immediate industry. IBM does this with software products. It has an open database where concepts and technologies, which can be developed by interested external parties, are shared. Opening access to its patents allows IBM to treat IP as intellectual capital that it can invest in specific industries with the aim of improving services and reducing costs while helping innovation and growth.

The IT industry: a case study?
This is not the end of the innovation continuum, however, and to understand what the possibilities are, it is helpful to look at where other analogous industries get their innovations. The most obvious examples come from the famously innovative world of tech. Apple and Google are both impressive examples with advances in hardware and software, and yet they both

Pharmaceutical Market Europe March 2013
www.pmlive.com/pme 29
subscribe to different models of innovation.

Apple’s system for hardware innovation is remarkably similar to that of pharma companies - product-led development in a secret and closed environment. However, Apple’s App software development stems from a very different model. Apple concluded during development of the first iPhone, that it was better to draw on the resources of developers who were not employees of Apple (from multimillion dollar companies through to 14-year old kids working in their bedrooms). The result: a system where anyone could produce and make apps for Apple products, vastly increasing the company’s pool of innovation resource. However, Apple set strict controls and regulations on developers, and rigorously reviews (and often rejects) apps that are going to be released in its App Store.

“What would happen if pharma further opened up the innovation process?”

Google has a slightly different stance. Although it agrees with the Apple model of opening up software development to the world of talented companies and amateurs alike, Google believes in an open system where anyone can produce applications for its operating system, Android, without the need for an authoritarian checking system for App quality and content.

No one can argue that both parties touch on a single key to success: without opening up the innovation process and drawing on a much larger innovation base than they could have internally (Apple employs around 50,000 people but estimates that an additional 210,000 motivated people gain employment through app development alone), they could not have been as innovative as they are today. Importantly, it is not just a numbers game: this also enables them to harness external experts with different skill sets, approaches, structures and mindsets.

So could we look for an alternative to the current model in pharmaceutical research, which often incentivises against stakeholders sharing information? What would happen if pharma further opened up the innovation process? What would happen if researchers with a different mindset were utilised?

Crowdsourced innovation

There are three possible approaches to crowdsourced innovation: platform, hybrid and non-platform models.

Apple and Google use the Platform Model, which involves structuring a framework for developers to generate ideas. The key to this approach is that developers understand fully what they get out of the relationship. In addition, this model is a ‘benefit’ model for both parties, ie, be it remuneration or receiving credit, both parties must take a reward. One healthcare example of this is the company Foldit.

In 2011, after scientists failed repeatedly to piece together the structure of a protein-cutting enzyme from an AIDS-like virus, they called in gamers and challenged them to produce an accurate model of the enzyme. They did it in only three weeks, even though this problem had stumped scientists for more than a decade. The gamers achieved their discovery by playing Fold.it, an online game that allows players to collaborate and compete in predicting the structure of protein molecules. Was it a PhD student from MIT who was the best at this protein folding game, as the designers expected? No, it was a female administrator with no formal scientific training, highlighting the sheer untapped potential of this type of crowdsourcing.

The Hybrid Model involves a semi-structured, reward-based approach to solving problems. An example of this model is InnoCentive; a website that acts as a broker between ‘solution seekers’ and ‘problem solvers’. Companies with a problem (which range across disciplines including health, social, societal and technological) post details on the website, with a monetary prize. It has more than 270,000 registered solvers from nearly 200 countries and some notable breakthroughs in its portfolio. Current healthcare projects range from a point-of-care test for plasma clotting factors to how to make diabetic cookies taste good.

The final option is the Non-Platform Model. This is a truly open model, without clearly defined rewards for participants. A fantastic example came from researcher and academic Jay Bradner and his team in Boston. Instead of patenting a promising cancer molecule they had discovered, they published it, including how to produce it. The result is that the JQ1 molecule has since been analysed and tested by hundreds of researchers across the world who have found promise across several cancers using hundreds of animal models, thus innovating far more quickly and across a greater number of diseases than any single team could.

What does crowdsourced innovation mean for pharma?

These three models explain how pharma could radically change its innovation model. Now, of course we are not suggesting that if pharma found a promising molecule, like Bradner et al in Boston, it should then publish instead of patent it. Instead, why not publish the 9,999 less promising molecules that are sitting on the shelf never to be looked at again, or at least a subset of them? Just think about the sheer amount of public domain data this would create, and therefore how quickly innovation would rise on the back of it. The pipelines would
Certainly not look so dry after such a deluge.

But then, what pharma company would ever want to share data on molecules like that in the knowledge that competitors might gain? That would be some seriously naïve business practice, wouldn’t it? Not if all pharma companies bought in to the idea, the net result of which would be thousands of molecules being released into the public domain where they would all gain more possible leads than they lost.

“If fully open crowdsourced innovation actually happened, everyone would gain”

If this were the case, through the successful development of those molecules by independent scientists, academics and amateurs, and subsequent product in-licensing opportunities alone, pharma would make more commercial return than they could possibly make sitting on old molecules.

Alternatively, if you are the innovative company that pioneered such an approach, there is no doubt that you would gain a loyal following of partners and researchers – just as Apple has – and with the right risk, reward and licence model this could be commercially attractive for all partners.

If fully open crowdsourced innovation actually happened, everyone would gain – pharma, academia, science, healthcare and patients. It is in fact, difficult to lose in this scenario!

New innovation isn’t an option; it’s a necessity

Perhaps the most important element of all is that the healthcare environment is changing in a way that encourages and may even demand this change in innovation and collaboration.

As we move increasingly to a world focused on outcome and not product, pharma will need to develop a ‘package of care’ that moves beyond the pill. This could include diagnostics, delivery and monitoring systems, and behavioural and educational support.

In fact, in order to differentiate from competitors, including increasing generic market erosion, this package of care could be a fundamental requirement to demonstrate value to payers, clinicians and patients alike. It is unlikely, however, that one pharma company would have the capability to deliver such an all-encompassing package of care alone (and after discussing the innovation explosion caused by crowdsourcing, why would they want to?), but there is no reason why they couldn’t create the collaboration framework needed to deliver a whole new innovation model.

But we are an industry which has always been, and will always be, slow to make such changes aren’t we? This new model of innovation is all just fantasy isn’t it? It’s a nice idea, but it couldn’t actually happen, could it? Maybe, just maybe …

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Figure 1: Healthcare Innovation Continuum