WRITTEN CASE STUDY 2

The Corporate Law Academy

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Case Study 2

Introduction

Many law firms require students to complete a written exercise at their assessment centre. These exercises are designed to test your ability to analyse information and present your findings in a clear, concise and appropriate manner.

When we review mock case studies, these are some of the most important skills we look for:

- **Understanding:** *Can you spot the key issues – have you identified what the client cares about the most? Have you answered the right questions?*
- **Quality of writing:** *Are your points clear? Are you using simple language?*
- **Relevance:** *Have you had the confidence to be selective? Can you determine what's appropriate? Do you use the right formalities?*

With that in mind, here's what we'd suggest:

- **Write using simple language**. *This is a key skill for lawyers who must break down technical legal speak in a form that clients can understand. Get straight to the point and provide clear definitive answers.*
- **Use the correct form.** *For example, in a letter, write the address at the top right hand corner and sign with your name or a name that has been given to you using the appropriate formality.*
- **Take time to plan your answer:** *It is very common to be given a large amount of information in these case studies and time is often the biggest challenge. But still, take the time to plan your answer and try to identify the most relevant points. The assessors are looking to see who can distinguish between what is useful and what is not.*
- **Have a clear structure:** *Consider using sub headings, numbered points and paragraphs so your email, memorandum or report is easy to read.*

The assessment

Our case studies are designed to help you prepare for the real written exercise. Below you will find the task and supporting documents for the second case study. You have one hour to complete the task.

To simulate a real written exercise, we recommend that you print out the materials, time yourself and hand-write your answer. Try to work in a quiet environment with no distractions. If you would like feedback, please email your answer to admin@thecorporatelawacademy.com with the subject "Written Case Study".

Finally, please note that the below case study is fictional. Names, job titles, businesses, places, events, locales, and incidents are either the products of the author's imagination or used in a fictitious manner. Any resemblance to actual persons, living or dead, or actual events is purely coincidental.

Good luck!

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Your Task

EMAIL

FROM: Max Williams
TO: [Trainee]
SUBJECT: RE: Champtons research
DATE: 05.04.2018

Hi [Trainee],

I hope you had a good week.

We are undertaking some preliminary work for our client, Champtons, and I need you to write a research report in preparation for our meeting later today.

Let me give you some background to the deal so that you're up to speed. Champtons is a multinational pharmaceutical company that's headquartered in California. You've probably heard of their most famous drug, Apaxatine, which is commonly prescribed for high cholesterol.

The problem is that their patent on Apaxatine is about to expire. That's why Champtons is looking to acquire a biotech company - so they can develop a new drug.

Champtons has lined up two potential acquisition targets, Tamgen and Alexis, and has asked us to perform some early due diligence into the two companies. In our meeting, I'd like us to be prepared to handle any questions.

Please can you draft a short report summarising which target company you think is a better fit for Champtons and why. I have attached our initial due diligence findings together with some documents sent from our information team. You may reference these documents in your report.

Please try to keep it clear and concise, I may need to refer to it in the meeting.

Thanks,

Max

Max Williams
Partner

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Document 1

Champtons – About Us, www.champtons.com/about

About Us

Established since 1986, Champtons has become a leading pharmaceutical company specialising in major clinical conditions. Innovation is at the core of our business and we are focused on developing products that have a meaningful impact on people's lives.

We push for breakthroughs in scientific research and strive to be at the forefront of evolving medicines. Today, our 100,000 employees are dedicated to finding solutions for debilitating diseases.

The Champtons model is based on four fundamental components of our business:

- A global reach with offices across the United States, Europe and Asia
- A proven track record of identifying and developing breakthrough medicine
- Our investment in proprietary technology and innovation
- Our commitment to developing transformational medicines so people can live longer and more productive lives

All of this, combined with the quality of our people across the world, places us at the forefront of change in the pharmaceutical industry today and for the future.

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How do drugs get made? The Pharma Review

Based on its dynamism and innovation, the pharmaceutical industry has become one of the most profitable trade sectors, in addition to actively moving the economy. The global pharmaceutical market is expected to reach $1.12 trillion in 2022; the increase in drug sales will be largely driven as a result of an increasing and aging population, rising income levels and the expansion of health care systems in emerging markets. In contrast, the traditional USA market had decreased its share as a result of the expansion of generics, the patent expiration of key blockbuster drugs, the impact of the latest global economic crisis and governmental restrictions.

The pharmaceutical industry is characterized by intensive Research & Development (R&D) activities. The control of intangible assets linked to the innovation process, especially patents, is of extreme importance in this segment, since many resources are employed in the innovation process, resulting in a product development cost - from the discovery of the drug to the stage of launching the product into the market- of approximately US$ 2.6 billion. The high R&D costs are a reflection of the long period required for the development of a new compound, which may reach up to 13 years before the pharmaceutical formulation goes to market, associated with a very low success rate, with only one molecule of the 10,000 employed in the initial research stages reaching the commercial stage (Kaitin, 2010; Bunnage, 2011).

Furthermore, patent protection in the pharmaceutical industry is used as a defensive instrument, configuring a commonly applied anti-competitive practice. Some of strategies employed include so-called blocking (acquiring and not using new patents) and fencing (requesting patenting for any possible technology that can be used by a competitor) techniques, through which companies try to prevent the entry of new competitors into the market as well as to advance on their direct competitors (Salomão, 2006; Sternitzke, 2013).

It should be emphasized that according to Bartlett & Ghoshal (2000), a high innovation rate is a necessary, but not a sufficient factor for an industry to keep ahead in the pharmaceutical market. As such, other elements present in these large organizations in Europe and the USA make them achieve these expressive performances, including a positive organizational image, well defined objectives, a capacity for constant learning, leadership and creativity in marketing and sales initiatives.

The opportunities in biotech are similar to that of the pharmaceutical industry. But biotech firms tend to spend more time and money on research and development because they are still developing the initial products. Only if a product is close to approval by the FDA will a biotech firm seriously invest in marketing and development. Otherwise it's too much of a risk. Smaller biotech firms often form alliances with larger pharmaceutical companies, whether that's a merger, acquisition or loose tie-up. That's because the large companies already have the resources and global reach in place to push sales.

Compared to other industries, the biotech and pharmaceutical industry has skyrocketed in recent years. And while there are always risks, the overall mood is positive. Demand is rising thanks to an ageing population and wider access to global markets. Just don't get too attached to the status quo. These days, the market is prone to multi-billion dollar acquisitions. And as one analyst says, "Especially in Big Pharma, the idea of long term organic growth has become a myth."

PARTNERSHIPS AND STRATEGIC ALLIANCES

More pharmaceutical companies are partnering or buying biotech firms as a means to generate

growth. New development means potential access to billions in revenue and even if not, Big Pharma suffer from a massive case of FOMO - the fear of missing out. Last month, there were $11 billion of bids and deals in the biotech sector as tax reform has helped companies to pay less in tax. That's only expected to continue throughout 2018, despite some concerns of a valuation bubble.[1]

[1] Excerpts taken from Akkari, Alessandra Cristina Santos, Munhoz, Igor Polezi, Tomioka, Jorge, Santos, Neusa Maria Bastos Fernandes dos, & Santos, Roberto Fernandes dos. (2016). Pharmaceutical innovation: differences between Europe, USA and 'pharmerging' countries. Gestão & Produção, 23(2), 365-380. Epub June 14, 2016, licenced by CC BY 4.0.

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Tamgen - About Us, www.tamgen.com/about

Tamgen, Our Mission, Our Focus

Tamgen is made up of a team of former academics who specialise in the development of selective molecules for the treatment of serious medical conditions.

With offices in Germany and the UK, our mission is to combat some of the world's biggest health crises through sound industry knowledge and decades of experience.

We are focused on the development of small molecules that selectively modulate the effects of androgens and estrogens.

We are currently developing Enboral (Ostarine®; Tamgen-024), a selective oral tablet, targeted at women with high blood pressure. We are evaluating Enboral for the treatment of other serious medical conditions where building lean body mass is important.

Tamgen recently developed Capesaris® (Tamgen-758), a selective ER alpha agonist, as a hormonal therapy for men with advanced prostate cancer.

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New drug could soon defeat high blood pressure, International Business Times

Enboral, a promising new drug to treat high blood pressure in older women, is being hailed as a game-changer with "blockbuster sales potential" according to financial analysts. The drug is a pioneering oral therapy, only for women who fit a specific health profile.

Enboral works by inhibiting specific molecules that promote high blood pressure. Because of the way it binds to receptors, it will not be available to women who have already had treatment for high blood pressure.

Phase 3 trials for the drug ended last Wednesday after results showed it to be effective in lowering high blood pressure. According to Tamgen - the biotech behind Enboral - the new drug demonstrated a "favourable overall response".

Tamgen is now waiting for approval by the European Medicines Agency. An approval could be the turnaround that the company has been waiting for. The company was once hailed as the "Apple of biotech" for its series of successful drugs on the market including Abaxi, Remalyst and Olstea. It also had a deep pipeline that included products for cancer, asthma and diabetes.

But the last few years for the company has been bumpy after clinical trials for its latest drug, Capesaris, was subject to a series of public investigations by the Wall Street Journal.

According to Reuters, Enboral could potentially generate €90m in annual sales.

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Can Tamgen get back on its feet?, The Financial Mail

Tamgen is back on the market with a new drug, four years since its peanut-allergy-treatment was canned by the European Medicines Agency.

Last week, Enboral completed its Phase 3 clinical trials and the drug is now under review by the EMA. But this isn't the first time a drug from Tamgen has shown promise. During the 2000s, Tamgen was the poster-child for a new wave of biotech success, having secured a large round of investment funding, which led to the development of a number of successful drugs.

In 2012, Capesaris was set to be on the same path. That is, until an investigation by the Wall Street Journal would reveal that patients were recruited without proper consent.

It's lucky that happened. In clinical studies evaluated by the EMA and advisory committee, Capesaris had showed "serious adverse events or adverse events leading to discontinuation" of the drug, wrote Jeff P. Sanders, deputy director of the EMA's division of the Human Medicines Research and Development Support.

He wrote that there was memory impairment in a greater incidence of patients with Capesaris than in comparison-group patients, which were "characterised as serious" in the eight patients reporting this reaction. Also, there were more liver problems with Capesaris, with 13.5% of patients suffering them, compared with 1.8% on placebo.

Members of the expert panel also expressed the concern that the studies so far hadn't gone on for long enough and that patients had not given adequate informed consent.

The new drug Enboral looks promising, although the burden of proof will be on Tamgen to demonstrate its clinical trial procedures were fully compliant. The question is whether Tamgen will be able to shake off its tarnished reputation.

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Peuters News Report

German drug maker Tamgen recorded a 2.4 percent rise in first-quarter revenue, outpacing market expectations for early 2018. Revenue rose to €194m following a new marketing drive to sell its anti-diabetic medication Remalyst.

Shares of the company also rose 4.6 percent to $152.22 as investors anticipate its latest drug Enboral. It is a potential hit for Tamgen, but the company does face possible competition. The fast-growing Biotel is also developing a drug to lower high blood pressure.

Tamgen recorded a net loss in profit for the first-quarter of 2018 compared with the same quarter of last year. Sources have said this is a one-off cost to settle claims that arose in relation to its previous drug Capesaris.

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Alexis - About Us, www.alexis.com/about

Alexis Sciences is a U.S. biotech company that discovers and develops medicines with a goal of improving real world outcomes for patients. We specialise in brain development and restoration with a focus on the central nervous system.

Our first approved drug, Loxetine, is commercially available in Europe, Latin America, the Middle East and Asia-Pacific for the improvement of sleep efficiency in insomniacs. Its novel form of action penetrates the blood-brain barrier and influences the sleep-wake cycle.

Alexis Sciences has a promising pipeline of drugs for the treatment of neuro-degenerative diseases.

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Is it time for Teva?, Biotech Daily

Teva Pharmaceutical has raised its offer for young start-up Alexis, according to Bloomberg's sources. The price isn't known but it's said to be a large increase on the bid that Alexis previously rejected. In the process, Teva has also taken a look at Alexis's financial information, sources say, so it appears Alexis may be changing its mind, granting Teva the opportunity to conduct due diligence.

Teva has been trying to take over Alexis ever since their exclusive alliance to co-commercialise insomnia drug Loxetine ended in 2016, according to a source at the company.

Last year, CEO John Bresch revealed to Biotech Daily that the company would be open to a merger. "There absolutely could be assets out there that complement our niche in the neuroscience space", he said.

"But we will resist any attempts by a large rival to swallow us up. We want a merger of equals."

It's no wonder that Alexis is fighting off this takeover. Teva would not settle for a merger.

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Positive results for anti-insomnia drug maker

US biotech start-up Alexis has revealed encouraging sales numbers in relation to its over-the-counter insomnia drug Loxetine. The company reported that the drug continued its “strong sales growth” in the first quarter of 2018, reaching $12 million in revenue sales – a 26% increase on last year.

“These figures demonstrate that Alexis will more than double its 2017 sales by the end of the 2018 fiscal year”, according to Brian Scott, CEO of Alexis. Loxetine has achieved strong market traction in the US and Canada, and the company is now expanding into Europe.

A recent study also suggests that Loxetine may have a role in regulating REM sleep, a signal that the drug may have wider applications, such as patients suffering from sleep apnea.

This is good news, but it does little to reassure shareholders that Alexis has a diversified pipeline. Many have raised concerns that the company is too dependent on Loxetine sales. As CEO of Biotel says: “Alexis hit the jackpot when it came out with Loxetine but it hasn’t made much attempt to reduce its dependence on the drug. What happens when sales slow? Who will want to buy its shares then?”.