

# LIFE SCIENCES SPOTLIGHT

CHINESE REGULATORY ENFORCEMENT ACTION  
SHOWING NO SIGNS OF SLOWING DOWN

PATENT STRATEGIES AND LOYALTY DISCOUNTS

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# A NOTE FROM THE GUEST EDITOR

## Welcome to the fourth edition of *Life Sciences Spotlight*.

Since our last edition, there has been a number of developments in the Life Sciences sector across the Asia Pacific region and we are pleased to be able to update you on these recent trends.

It is evident that the focus on compliance in the region will continue for some time unabated and changes to the regulatory landscape are continuous and increasing. Those in the industry who have responsibility for legal and compliance have an ever increasing burden in this respect. Not only are the goal posts continually shifting but there are many, many more hurdles that need to be cleared. In short, ensuring compliance is getting much more difficult.

In this edition, **Andrew Ball** and **Elizabeth Ticehurst** discuss from an employment perspective, how best to achieve compliance from employees in Australia. **Scott Thiel** explains the new rules governing the collection, use and security of consumer personal information in China. This is a significant development given that the new rules significantly expand privacy protection for consumers in China. These changes follow a wave of privacy reform across the region. Given that Life Sciences companies routinely collect and handle personal data, these rules present significant changes for the industry.

In addition to increasing and changing regulation, regulators are keenly pursuing enforcement. In this issue, **Sammy Fang** and **Sally Zhang** consider the new wave of regulatory enforcement action by government authorities in China and ways to implement a proactive and effective regulatory and compliance program. In addition, **Simon Uthmeyer** discusses the ACCC's recent action against Pfizer which has caught everyone's attention in Australia. One has to ask, is this the first of a new wave of enforcement against patentee's in Australia, similar to those in the United States and Europe?

Whilst the outlook for life sciences companies presents a number of challenges across the region, particularly in relation to compliance, it is clear that from the volume of recent

transactions that there is an emerging trend in M&A activity. This activity is likely to provide opportunities for companies from some period of time.

In contrast to the increasing burden in relation to regulatory compliance, recent amendments to requirements relating to merger and acquisitions activities in a number of jurisdictions bring some welcome relief. In China, the new simplified merger regime will provide a fast track process for a broad range of transactions. **Jingwen Zhu** discusses this new regime which will potentially speed up the process for 60 percent of transactions (according to MOFCOM). Further, in this edition, **Masahiko Ishida** discusses changes to the law in Japan, which once effective may simplify the licence requirements for medical device manufacturers in the context of an acquisition.

Since the last edition, we have welcomed a number of new lawyers at DLA Piper who advise life sciences companies. In this edition, we introduce you to **David Ryan**, a partner in our Corporate practice in Sydney. Over the next few editions, I will enjoy introducing you to other members of our Life Sciences team.

We hope that you continue to enjoy *Life Sciences Spotlight*, and that you learn something new every issue. We are always open to your thoughts and suggestions.



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# UNRAVELLING THE HELIX

In each issue of *Life Sciences Spotlight*, partners in the DLA Piper Life Sciences team will assist in unravelling the legal aspects of a real-world Life Sciences dilemma using a hypothetical fact situation. In this issue, Dr Simone Mitchell and Melinda Upton discuss the notification obligations which rest with life sciences companies regarding reporting of counterfeit medicines, and consider what mechanisms can be put in place to prevent the importation of counterfeit medicines onto the Australian market.

*FarmaPharma Pty Ltd (FP) is the sponsor of ProductX, a prescription hormone replacement therapy pharmaceutical. FP's Customer Care Complaint Centre receives a call from an individual using ProductX who is claiming that since first using the product, she has experienced alarming side effects. The side effects are not listed as potential side effects in the Consumer Medicine Information for ProductX. FP obtains a sample of the product for testing and on initial visual inspection it appears that the pharmaceutical may be counterfeit.*

*FP comes to you for advice regarding its legislative reporting obligations and what measures it can put into place to minimise future importation of counterfeit products.*



## DR SIMONE MITCHELL'S PERSPECTIVE

Dr Simone Mitchell is a partner in the Life Sciences sector and Intellectual Property and Technology practice, based in Sydney. Her experience encompasses advising on regulatory issues including registration, pricing and Pharmaceutical Benefits Scheme reimbursement matters as well as representing Life Sciences companies in patent disputes. Simone has a degree in veterinary science and is a registered veterinary surgeon. You can reach her at [simone.mitchell@dlapiper.com](mailto:simone.mitchell@dlapiper.com).

### What are FP's reporting obligations?

The Therapeutic Goods Administration (TGA) relies on industry, the public and healthcare professionals to report problems with medicines or medical devices. It is the TGA's role to then investigate reports received by it to determine any necessary regulatory action.

The *Therapeutic Goods Act 1989 (Cth)* (the Act) specifies circumstances in which a sponsor of a registered or listed medicine must give information to the TGA as soon as it becomes aware of such information. These circumstances include where the sponsor becomes aware of information that indicates that the quality, safety or efficacy of the registered or listed medicine is unacceptable.

The Act specifies that sponsors of therapeutic goods must comply with any reporting requirements that are prescribed by the TGA. The *Australian Requirements and Recommendations for Pharmacovigilance Responsibilities of Sponsors of Medicines* (Requirements) sets out the mandatory reporting requirements for sponsors in relation to adverse reactions to medicines and significant safety issues, as well as guidance on pharmacovigilance systems. Sponsors are required to report serious adverse reactions and significant safety issues associated with a suspected or confirmed quality defect of a medicine for which they are the

sponsor, including when the product is suspected or confirmed to be an adulterated or counterfeit medicine. These reports must be made within certain timeframes as set out in the Requirements.

Following the report of the alarming side-effects, FP, as the sponsor of Product X, must ensure that it complies with the reporting obligations mentioned above and that it does so in accordance with the timeframes for serious adverse reactions (as opposed to the reporting timeframes for significant safety issues).

Importantly, FP must report the adverse reaction and suspicions of a counterfeit product to the TGA as soon as possible and in any event, no later than fifteen calendar days from call to the Customer Care Complaint Centre. The clock starts on the day that the 'minimum data elements' are received by any personnel of FP, including sales representatives, or the person responsible for pharmacovigilance or persons working for or with this person. These four minimum data elements are:

- an identifiable patient;
- one or more identifiable reporters, i.e. physician, pharmacist, other healthcare professional, consumer, non-healthcare professional or lawyer;

- one or more suspected reaction(s); and
- one or more suspected medicine(s).

FP must also ensure that it complies with the record keeping requirements contained in the Act which stipulate that it retain reports of adverse reactions or similar experiences with the use or administration of its registered and listed products for a period of not less than 18 months from the day the TGA is notified of the report.

Although it is not prescribed by legislation, FP should also ensure that it has an effective system of pharmacovigilance in place so that appropriate action can be taken, when necessary, and to assure responsibility for its products. At a minimum, this should include:

- a designated person in Australia responsible for pharmacovigilance;
- establishment of a system which ensures that information about all suspected adverse reactions are reported to the correct personnel within FP;
- clear written standard operating procedures; and
- training of staff directly performing pharmacovigilance activities.



### MELINDA UPTON'S PERSPECTIVE

Melinda is a partner in the Life Sciences sector and is the Head of the Intellectual Property & Technology Australia practice. Melinda

is a leading practitioner with extensive experience across all aspects of brand protection, exploitation and enforcement. She has acted for domestic and global clients across a range of industries, including the Life Sciences sector. Her work includes advising clients on branding and rebranding strategies and maximising their intellectual property portfolios including creating and subsequently protecting portfolios.

#### **What strategies can FP put into place to minimise the risk of further counterfeit products from being imported?**

FP must ensure that it actively supports public authorities' efforts to guarantee the highest standards of product quality

and safety and to prevent the importation of further counterfeit medicines into the Australian market. This includes:

- working closely with local Australian authorities to deliver information and educational programs to create awareness of counterfeit medicines and their risk to patient health and safety;
- consistent monitoring of its supply chain and proactive implementation of innovative solutions to prevent counterfeiting and falsification (this may include implementation of a data matrix identification system or a system of coding and identification);
- in-house initiatives to increase awareness, education and communication amongst internal and external stakeholders;
- regular checks and monitoring of internet sites selling medicines online;
- coordination at local and global levels of the organisation to ensure dedicated and consistent implementation of anti-counterfeiting strategies; and
- cooperation with local and international authorities from police, customs, health agencies and health care professionals to promote vigilance and create awareness.

FP's approach to combating counterfeiting must involve a wide range of initiatives, including those mentioned above, which utilise different objectives in support of its common goal.

#### **How important is Australian Customs in preventing importation?**

Cooperation with Australian Customs is integral to FP's efforts and strategy to combat counterfeiting of its medicines. Customs should be provided with all the tools necessary to spot counterfeit medicines and FP should ensure that it provides the appropriate training and personnel to assist Customs in this process.

On 15 April 2013, some important changes came into force regarding the Australian Customs seizure provisions in the *Trade Marks Act 1995* (Cth) and the *Copyright Act 1968* (Cth). These changes

are favourable to rights owners such as FP and will form an integral part of FP's enforcement strategy.

In order to obtain the benefit of these favourable amendments, FP should ensure that it lodges a trade mark Notice of Objection and a copyright Notice of Objection with Customs which list all of the trade mark and copyright material for which protection is sought. This will then allow Customs to seize imported shipments of medicines such as ProductX that are suspected of infringing FP's copyright or registered trade marks. As part of the scheme for dealing with goods seized:

- the imported goods will be forfeited to Customs unless the importer files a claim for them within a designated claim period. The importer will be required to include sufficient information to identify itself to Customs, including an address for service;
- FP will have access to additional information about the importer of the seized goods from Customs. This includes the name and address of the consignor or supplier, personal information that could help identify the exporter and identifying information about the importer contained in the lodged claim form. This will assist FP to identify the ultimate supplier of the counterfeit goods; and
- FP will be able to remove samples of the seized goods for further analysis if they provide certain undertakings to Customs, rather than just relying on photographs to determine whether the goods are counterfeit or genuine.

The positive changes brought about by these amendments to the Australian Customs seizure provisions are an important and cost-effective mechanism for FP to prevent counterfeit goods from entering Australia.

A layered anti-counterfeiting strategy which includes collaboration with local Authorities such as Customs will be integral to FP's future success in combating the importation of counterfeit medicines.



# THE CHINA REGULATORY SERIES – THE LATEST MARKET DEVELOPMENTS IN 2014

## CHINESE REGULATORY ENFORCEMENT ACTION SHOWING NO SIGNS OF SLOWING DOWN

By Sally Zhang (Beijing) and Sammy Fang (Beijing)

2014 has heralded another wave of regulatory enforcement action by government authorities in China. At the official level, the central government is showing no signs that its campaign to tackle corruption is coming to an end. Since the end of 2013, a number of high ranking government officials and officials of major state-owned enterprises (SOE) have been detained for investigation by the Communist Party's central disciplinary committee.

Regulatory investigations (ranging from commercial bribery, anti-trust, and product liability investigations) targeting both multinational and domestic companies, together with major policy initiatives by Chinese regulators continue to make the headlines, and to name a few, these include:

- In May 2014, the National Health and Family Planning Commission (NHFPC) published “The Notice of Conducting Further Investigation into the Common Practices in Medical and Health Industries” to emphasize its “zero tolerance” attitude towards improper and non-compliant practices in the medical and health industries. In reinforcing the “Nine Prohibitions” issued by NHFPC back in December 2013, the NHFPC has now come out to highlight that future investigations against such improper practices (such as bribery and kickbacks, commissions on drug prescription, collection of prescription information for commercial purposes etc.) will be one of its top priorities going forward.
- Earlier this year, the head of China's Supreme People's Procuratorate reported the prosecutors' offices' 2013 national anti-corruption and anti-bribery campaigns in his work report to China's third session of 12th National People's Congress (one of the key legislative assembly meetings in China). The report noted that 4,549 public officials were investigated and punished in connection with commercial bribery in 2013, and there was also a dramatic increase in the number of investigations targeting the offering of bribes (as opposed to the prosecutor offices' past practice of focusing on the recipients of bribes).
- The focus of anti-bribery investigations by various government agencies against international players in the pharmaceuticals industry have since last year been expanded to include investigations against domestic pharmaceutical companies.
- In the first five months of 2014, it has been reported that over 50 management level employees of domestic companies have been arrested or investigated for bribery related offences, with 11 of them from the energy sector.

- In the past six months, there have been various media reports in the Chinese media of anti-trust investigations against companies in the technology, pharmaceuticals, and automobiles industries being carried out by the Chinese regulators, the National Development and Reform Commission and the State Administration of Industry and Commerce (AIC).

## THE BUTTERFLY EFFECT: WHAT'S NEXT?

The government enforcement action described above indicates that the authorities are no longer limiting their focus on multinational companies operating in China. Domestic companies, particularly those operating in sensitive industries such as energy, telecommunications, food and healthcare, are also potential targets. There are presently no shortage of rumors in the Chinese market and the local media as to who will be the next likely target and what these actions will lead to.

The trend appears that the authorities are looking to address a number of public concerns that have been bubbling under the surface for some time. These include food safety, access to healthcare, and generally the high cost of healthcare and housing. In doing so, China's new leadership continues to demonstrate that they are prepared to take down any "tigers" or "flies" in pursuit of their stated objectives of addressing these public concerns. Many of these "tigers" include SOEs which enjoy dominant market positions in industries such as energy, telecommunications, electricity, and aviation.

Internally, many companies are also starting to experience the adverse impacts of some of these enforcement activities from their employees. These include the impact on staff morale as company management are trying to navigate through a climate of uncertainty and fear of not knowing what the end game for the government will be. There are also reported increases in the level of employment disputes and whistle-blowing activities as employees are concerned whether or not their own conduct at work may become the subject of regulatory or internal investigations.

Various local branches of the NHFPC have also made public announcements that they are prepared to put any parties (which include healthcare professionals, hospitals, and any company supplying drugs or medical devices to hospitals) who have committed anti-bribery violations on their "commercial bribery negative records" list, which will be circulated on their websites. Any party put on such a list will potentially have their licenses revoked and barred from bidding for public healthcare related tenders.

## SOME TAKE-WAY POINTS

From a regulatory and compliance perspective, companies operating in China, either international or domestic, should not simply rely on event-based crisis management as the main response to the current wave of government enforcement action. An effective regulatory and compliance program with proactive and preventive measures localized for the China market will be a must. The fast evolving regulatory climate in China dictates that regular reviews and updates are needed to prevent potential risks from materialising into a crisis.

Some of the areas worth paying attention to include:

- Periodic review or audit of sales and marketing practices;
- Review of interactions between employees, the company's third party agents or consultants and government officials and State-owned enterprises;
- Check and assess the current procedures for the handling of whistle-blower complaints;
- Whether present compliance training materials and efforts are sufficient;
- Whether current document management and retention policies are sufficient and well communicated to employees;
- Whether there are protocols for responding to potential regulatory investigations by local authorities such as the National Development and Reform Commission (NDRC), AIC and Public Security Bureau;
- Whether employees are sufficiently trained to respond to raid scenarios; and
- Whether there are there sufficient protections under internal policies and the relevant employment contract provisions to defend the company from potential employee claims, even if the termination is based on compliance violations committed by the employee.



# PATENT STRATEGIES AND LOYALTY DISCOUNTS MEET COMPETITION LAW: ACCC V PFIZER

By Simon Uthmeyer (Melbourne) and Sophia Grace (Melbourne)

The Australian Competition and Consumer Commission's (ACCC) proceedings against Pfizer Australia Pty Ltd (Pfizer) bring into the spotlight strategies pharmaceutical companies may employ to seek to extend the benefits of patents that are soon to expire. While pharmaceutical companies are naturally keen to retain market share following the expiry of their patents, some strategies they use to do so can fall foul of competition law.

Whilst the ACCC has not initiated any proceedings for any pay for delay settlements reached between patent holders and generics, as has occurred in the US and the EU, the Pfizer case demonstrates that the ACCC is looking at the conduct of the patent holders in the Australian market and issuing proceedings where appropriate. Unlike 'pay for delay' proceedings for which there has been very little jurisprudence anywhere in the world the ACCC's allegations are based on the long standing prohibitions in the *Competition and Consumer Act 2010* (CCA) against misuse of market power and exclusive dealing. Accordingly, the ACCC does not have to pave the way with new precedent in its proceedings against Pfizer.

## ACCC'S ALLEGATIONS

The ACCC's allegations concern misuse of market power and exclusive dealing in breach of the CCA. The ACCC asserts that before and after the expiry of its atorvastatin patent for Lipitor, Pfizer engaged in conduct to prevent or deter generic versions of atorvastatin from entering the market, and to substantially lessen competition.

Atorvastatin is used primarily for lowering blood cholesterol and aiding the prevention of cardiovascular disease. For several years Lipitor was the highest selling prescription medicine under the Pharmaceutical Benefits Scheme. The ACCC's press release notes that "[p]rior to the loss of patent protection in May 2012, Lipitor was prescribed to over one million Australians, with annual sales exceeding \$700 million."

According to the ACCC, in early 2012 Pfizer offered large discounts and the payment of rebates previously accrued on sales of Lipitor on the condition that pharmacies acquire a minimum volume of Pfizer's generic atorvastatin product for periods of up to 12 months. Pfizer first made the offers prior to its loss of patent protection for the atorvastatin molecule. At that time other suppliers of generic medicines were prevented from making competing offers to supply generic atorvastatin products to pharmacies.

The ACCC alleges that:

- Pfizer misused its market power in breach of s46 of the CCA. Pfizer used its market power to prevent or deter suppliers of generic atorvastatin from competing in the atorvastatin market; and
- Pfizer engaged in exclusive dealing with a purpose of substantially lessening competition in breach of s47 of the CCA. Pfizer supplied the discounts and rebates on condition that the pharmacies acquire not more than 25% of their generic atorvastatin requirements from other suppliers for a particular period of time.

Pfizer denies these allegations.

## OTHER STRATEGIES TO RETAIN MARKET SHARE ON EXPIRATION OF PATENTS

The strategy alleged against Pfizer is just one strategy a pharmaceutical company might employ to seek to extend the benefits of patents that are soon to expire. Other strategies companies might use to extend the market share or royalties received from a patent include:

- "Pay for delay" – where the original patent holder pays for the delay of entry of competing generic drugs;
- Buying out competitors;
- Introducing follow-on patented products (for example on new pharmaceutical mixtures or related technologies);
- Engaging in conduct which frustrates competitors.



In September last year we updated you on “pay for delay” cases before the US Supreme Court and the Director General (DG) of competition in the European Union (EU). Those cases concerned settlements of patent litigation where the original patent holder paid for the delay of entry of competing generic drugs. We noted that the US Supreme Court and the DG of competition in the EU had confirmed that reverse payments in patent settlements are subject to competition law and are potentially anticompetitive. We observed that if the Australian Federal Court were to follow those two decisions than a reverse payment could constitute a criminal cartel under the CCA. However, there has yet to be any proceedings issued by the ACCC alleging “pay for delay” settlements are anticompetitive.

Thwarting or delaying the entry of competing generic drugs can be worth a lot to the original patent holder. This is because it can facilitate the continued exploitation of the patent’s monopoly. In our September update we noted that the EC has estimated that prices can be 90 percent higher without generic drug entry and hence why the ACCC and even the Commonwealth Government appears to be focusing on strategies pharmaceutical companies might employ to seek to extend the benefits of patents that are soon to expire.

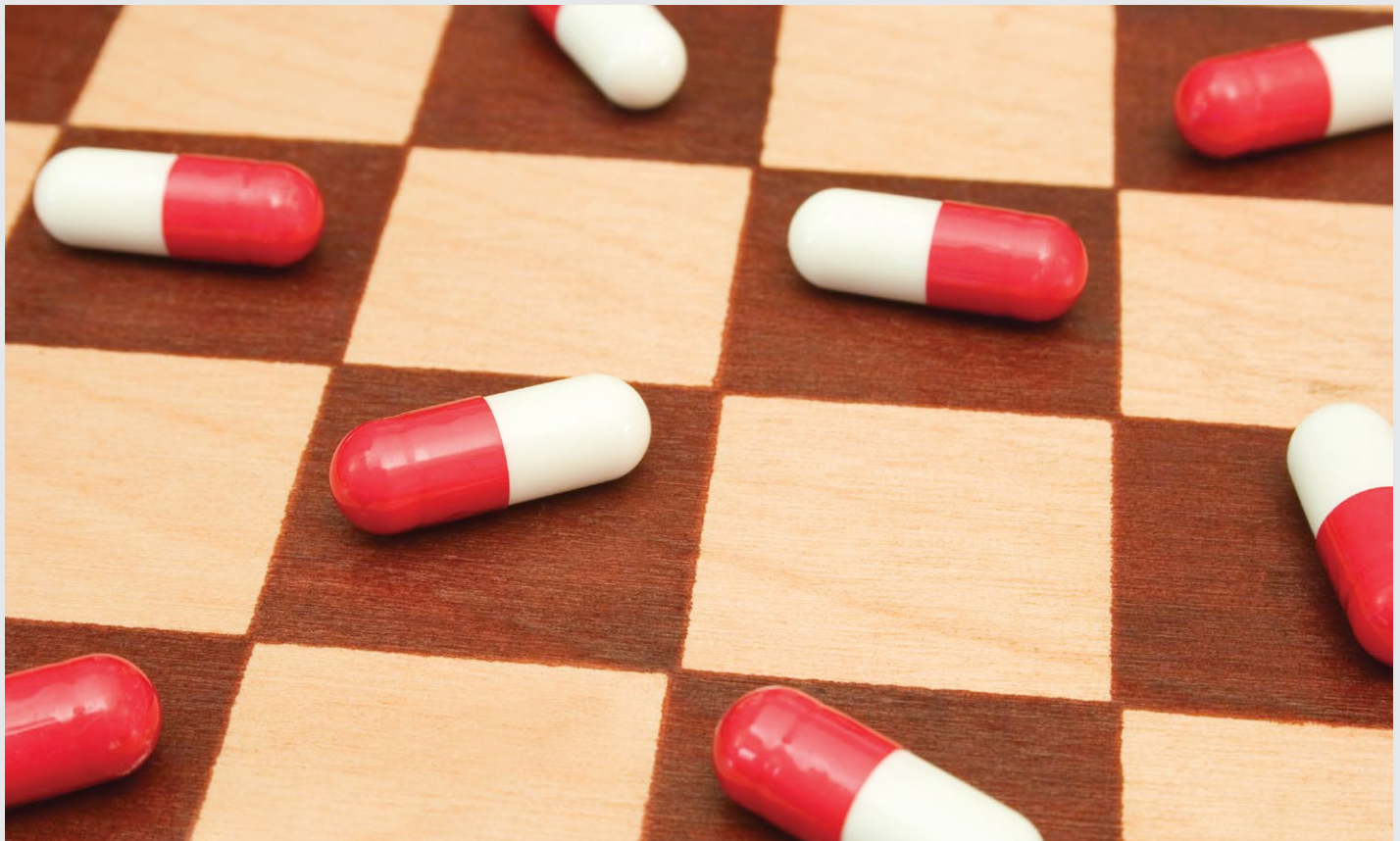
The ACCC v Pfizer case shows that the ACCC is willing to take action where the ACCC considers strategies are anticompetitive.

## USE OF LOYALTY DISCOUNTS AND REQUIREMENTS CONTRACTS

The case will highlight the operation of the exclusive dealing and misuse of market power provisions of the CCA in the context of strategies used to extend the life of a patent. The Court’s decision will likely also give some insight into how the use of loyalty discounts and requirements contracts, generally, might contravene those provisions.

Loyalty discount arrangements are pricing structures where the seller offers lower prices in return for a buyer’s commitment to source a large share (or all) of its requirements from the seller. Requirement contracts are agreements where the seller agrees to supply as much of the good or service required by the buyer in return for the buyer promising that it will obtain its goods or services exclusively (or nearly exclusively) from the seller.

Such arrangements can be pro-competitive. For example, they can incentivise distributors to promote the brand and thereby promote competition between sellers of different brands. However, they can also be anticompetitive where, for example they restrict competition from actual or potential competitors and substantially lessen competition. They can therefore be caught under the exclusive dealing and/or the misuse of market power provisions of the CCA as is alleged in the case of Pfizer.



The use of discounts on the bundled supply of medical products was considered in the high profile case of *ACCC v Baxter Healthcare Pty Ltd (No 2) (2008) 170 FCR 16*. Baxter manufactured and supplied medical fluids to State Purchasing Authorities for use in hospitals. Baxter was effectively the sole supplier of sterile fluids. However, Baxter faced competition in the supply of peritoneal dialysis (PD) fluids. Baxter responded to tenders from various State Purchasing Authorities by offering inflated prices for products sold individually, but heavily discounted prices for sterile fluids sold as a bundle with PD fluids on an exclusive basis under long term contracts. The Court found that Baxter had contravened each of the provisions of the CCA alleged against Pfizer, being the misuse of market power and exclusive dealing provisions.

It will be interesting to see what the Court says about Pfizer's conduct.

### **GOVERNMENT TO KEEP A CLOSE EYE ON PFIZER CASE**

Minister for Small Business Bruce Billson stated that the Federal Government will keep a close eye on the ACCC's case against Pfizer for its alleged misuse of market power ahead of an independent "root and branch" review of competition law. Minister Billson stated:

*As part of the "root and branch" review of competition law the independent panel will look at claims that the misuse of market power provision isn't living up to the expectations that the law makers had at the time of its introduction.*

*Removing impediments to fair competition rewards responsive businesses that create new innovative products and allows the economy to grow while driving down the cost of living.*

*As a Government we have made it clear we want competition based on merit not on muscle and competition law and policy settings that ensure that efficient business, big and small can prosper.*

### **"ROOT AND BRANCH" COMPETITION POLICY REVIEW**

The *ACCC v Pfizer* case might also be relevant to the Competition Policy Review the Government is undertaking. The Competition Policy Review involves a comprehensive review of Australia's competition laws. While the case will likely be heard before the findings of the Review Panel are handed down, issues encountered by the ACCC in running the case against Pfizer, particularly in respect of the misuse of market power provision, will likely inform any submissions it makes to the Review Panel.

The workability of the misuse of market power provision (s46 of the CCA) is likely to be one of the issues considered in the review. Misuse of market power cases are difficult to prove and there has been a call to amend it so that it captures additional conduct. For example, the Competition Policy Review Issues Paper, 14 April 2014 at [5.9] notes that there has been considerable debate over whether the "focus on the 'purpose' of the conduct in the misuse of market power provisions sufficiently captures conduct considered to adversely affect competition and the competitive process, and whether there should not also be a focus on prohibiting the anti-competitive 'effect' of the conduct situation."

The Review Panel are currently considering submissions on its Issues Paper which were due on 10 June 2014. The Review Panel is currently planning to release its Draft Report at the end of September after which there will be a further public consultation process.

### **WHAT NEXT?**

The *ACCC v Pfizer* case has been tentatively listed for hearing commencing on 29 September this year. We will keep you posted.



# LEGAL UPDATES – DATA PRIVACY PROTECTION IN NEW PRC CONSUMER RIGHTS LAW EFFECTIVE FROM 15 MARCH 2014

By Scott Thiel (Hong Kong)

The newly revised Consumer Rights and Interests Protection Law of the People's Republic of China (the New Law), which became effective on 15 March 2014, is the first revision of China's Consumer Rights Law since 1993. Among the additions are rules governing the collection, use and security of consumer personal information.

Articles 14 and 29 of the New Law contain the specific privacy obligations. Article 14 states that consumers shall have the "right to have personal information protected in accordance with the law" when purchasing and using merchandise or services, and Article 29 requires the following measures be taken when businesses collect or use consumer personal information obtained either online or offline:

- (a) purpose, method, scope and rules of collection and use of personal information shall be explicitly stated and consented to by consumers;
- (b) business operators shall keep the personal information confidential and not disclose, sell or illegally provide the personal information to others;
- (c) business operators shall also take technical or necessary measures to ensure information security and to prevent information disclosure or loss, and take immediate remedial measures when such disclosure or loss has happened or likely to happen; and
- (d) sending commercial information to consumers is prohibited where the consumer has not consented or requested it, or where the consumer has expressly indicated that he/she does not want to receive such information.

Although Article 29 requires the business operator to notify consumers of the information set out in (a) above and to obtain the consumer's consent, Article 29 does not specify the format of such notification and consent. Neither does

Article 29 stipulate whether the notification has to be given orally or in writing or whether opt-in, opt-out, oral or written consent is required.

Despite this, compliance with Article 29 of the new Consumer Rights Law is strongly recommended. The life science sector should take all necessary steps to make sure that they collect and use consumer information in accordance with the requirements under Article 29. The life science sector, especially the consumer-facing pharmaceutical companies and medical professionals, should notify and obtain consumers' consent when they collect personal information directly from consumers. Where they acquire personal information from third parties and do not have direct relationship with the consumers to whom the personal information relates, they should make sure that the relevant consumers are duly notified of and consented to the transfer, and the purpose and scope of use of their personal information. A practical solution is to impose appropriate contractual undertakings on the third parties as part of the engagement.

This is a significant development as the PRC does not have a comprehensive data protection law, with general data privacy protection in China regulated largely by the Decision of the National People's Congress Standing Committee on Strengthening Internet Information Protection (the Decision) and the National Standard on Information Security Technology – Guideline for Personal Information Protection Within Information System for Public and Commercial Services (the Guideline)

along with other protection provisions across various laws and regulations, which mainly focus on personal information that is in electronic form provided by internet users. Now, privacy protection has been expanded to consumer information in all forms. The life science sector, which necessarily handles personal data on routine basis, should be aware of this significant change and review their practices in order to comply with the New Law.

The addition of data privacy protection to the Consumer Rights Law reflects a general trend towards a more sophisticated data privacy regime in China. PRC government authorities are becoming more interested in data privacy and more willing to take steps toward enforcing private sector personal information protection. This change is evidenced by the penalty provisions in the New Law, which stipulates that a breach of Article 29 may now result in adverse consequences for the business operator, such as confiscation of illegal earnings in conjunction with a fine between twice and ten times the value of the illegal earnings. Where there are no illegal earnings, a fine of no greater than RMB 500,000 may be imposed.

While we expect authorities would, in the normal course of practice, issue warnings before bringing enforcement actions, businesses that collect or use consumer information should consider strategies to be able to comply with this New Law commencing from 15 March 2014.



# ENFORCING COMPLIANCE

## HOW TO ENSURE THAT EMPLOYEES IN AUSTRALIA COMPLY WITH REGULATORY CODES

By Andrew Ball, (Sydney) and Elizabeth Ticehurst, (Sydney)

Pharmaceutical companies are subject to a range of regulatory restrictions that limit how prescription medicines can be marketed and promoted. Breach of these restrictions can leave the company exposed to monetary penalties, sanctions and adverse publicity, but companies are often caught short when an employee commits a compliance breach and may not be sufficiently prepared to take action to address the breach. This article highlights some examples of how breaches can occur, and suggests ways in which companies can enforce employee compliance.

### Scenario 1

*XYZ Pharmaceutical Pty. Ltd. (the Company) arranges a one-day educational conference for healthcare professionals, to provide training in several of its products. After the conference a sales employee, acting without the knowledge or approval of his manager, takes several healthcare professionals to an expensive restaurant, and then a night on the town, all expensed to his company credit card.*

*Section 9.1 of the Medicines Australia Code of Conduct (Code) requires that pharmaceutical company interactions with healthcare professionals have the primary objective of enhancing medical knowledge and improving the quality use of medicines in Australia. The provision of a meal and 'a night on the town' absent any educational content would constitute a breach the Code. As a result, the Company could be subject to sanctions for breach of the Code due to the employee's actions.*

Employers should take care to:

- Draft policies that require employees to comply with regulatory codes and guidelines.
- Ensure employees are adequately trained in their obligations under applicable codes and guidelines.
- Be consistent in their treatment of employees that breach regulatory codes and guidelines.

## Discussion of Issues

### Can XYZ Pharmaceutical dismiss the employee?

If the company wishes to dismiss the employee immediately, it will generally need to show that it has a valid reason for dismissal. A valid reason will generally exist where the employee has breached a significant or material company policy, or a term of the employment contract. However, often employment contracts do not specifically refer to the regulations, codes and guidelines that apply to the company's business. If the company's policies also do not require the employee to comply with applicable regulations, codes and guidelines, the company may find it difficult to point to a specific breach of policy by the employee. In that case, there may not be a valid reason for dismissal, and the employee could bring an unfair dismissal claim against the company for termination of employment (provided that the employee has unfair dismissal rights under the *Fair Work Act 2009*).

The best way to enforce compliance and ensure that the company can take action against employees that fail to comply, is to include in the company's policies a specific requirement that employees comply with all applicable regulations, guidelines and codes of conduct that apply to the company's business. A good policy should ideally also provide a list of these documents, so that employees are fully aware of them.

**Case Reference:** In *Linfox Australia Pty Ltd v Glen Stutsel* [2012] FWAFB 7097 an employee was found to have been unfairly dismissed, despite writing offensive comments about his supervisors on his Facebook page. One of the reasons for the dismissal being found "harsh, unjust and unreasonable" in the circumstances was that the company did not have a social media policy that specifically prohibited these actions.

### Scenario 2

When an XYZ Pharmaceutical manager questions the employee about the events at the conference, the employee denies that he has done anything improper, and says that the medical professionals are personal acquaintances. The manager produces the XYZ Pharmaceutical's Employee Handbook, which requires all employees to comply with applicable regulations, guidelines and codes of conduct. However, the employee insists that he does not know what is required under the Code, and should not be held responsible for an "innocent" breach.

### Discussion of Issues

Even if the company's policies require employees to comply with applicable regulatory requirements relating to the Company's business, it may be unreasonable to expect that employees are familiar with all requirements they are expected to comply with. If the employee has not been provided with training and guidance about the applicable regulatory requirements, and the Company dismisses him for a compliance breach, the employee could still bring an unfair dismissal claim on the basis that the dismissal is "harsh, unjust or unreasonable" in the circumstances.

### Scenario 3

The employee reveals that he was not alone in providing entertainment to the healthcare professionals at the conference. Two other employees also attended the dinner and the after-dinner festivities. After investigating, the company decides to dismiss the first employee for serious misconduct, and give final written warnings to the remaining two employees. The first employee protests that this is not fair, and that he should also be given a final written warning instead of being dismissed.

### Discussion of Issues

Treating the employees differently may be risky unless there is a good reason for deciding on different punishments. The company's treatment of other employees who have engaged in the same or similar conduct may be relevant in deciding whether a dismissal is "unfair, unjust or unreasonable".

**Case Reference:** In the case of *National Jet Systems Pty Ltd v Mollinger* 18 March 1999, Print R3130, the first officer of an aircraft was dismissed after an incident where the flaps of the aircraft were retracted too soon following takeoff. The Captain on the same aircraft was not terminated notwithstanding that he also bore responsibility for the incident.

The Australian Industrial Relations Commission decided that there was no proper basis for distinguishing between the two individuals and consequently the termination of the first officer was harsh, unjust or unreasonable.



# CHINA'S SIMPLIFIED MERGER REVIEW IS EFFECTIVE

By Jingwen Zhu (Hong Kong)

China's simplified merger review regime is now effective. China's merger review regulator, the Antimonopoly Bureau at the Ministry of Commerce (MOFCOM), has published criteria for a simplified merger review, *the Interim Rules on Application Criteria of a Simplified Review*, which came into effect on 12 February 2014. Tentative procedural guidelines have been published on 21 April 2014 and became immediately effective.

Similar to the European Union's "Short Form CO", under the new regime, transactions that possess certain criteria will qualify for so called "fast track" or simplified reviews. It is hoped that the new regime significantly decreases the average MOFCOM review time of 64 days.

## CRITERIA

Under the new regime, a transaction will qualify for a simplified review if it is a "notable exception", that is, it meets one of the six criteria below:

1. In a concentration between competitors, the combined market share of all participating undertakings is less than 15 percent
2. In a concentration between undertakings in related upstream and downstream markets, the market share of the undertakings in both upstream and downstream markets is less than 25 percent
3. In a concentration which is neither between competitors nor between undertakings in vertically related markets, the market share of each undertaking is less than 25 percent in the markets related to the transaction
4. Undertakings set up as a joint venture outside China and the joint venture does not engage in commercial activities in China
5. Undertakings acquire shares or assets of an overseas company which does not engage in commercial activities in China or
6. In a joint venture where two or more undertakings have joint control, one or more undertakings among them acquire sole control after the proposed concentration

As you can see, the threshold for horizontal transactions is set at 15 percent and for vertical transactions at 25 percent, the same as the old European simplified merger review rules. However, on 1 January 2014, the European Commission raised these thresholds to 20 percent and 30 percent respectively.

Consequently, the same transactions in both China and EU may qualify for a simplified review in Europe but still have to go through the standard review in China.

A substantial portion of Chinese merger notification have traditionally been the joint venture notification. Many of them have no link to China and, as such, do not cause any lessening of competition in the Chinese market. A simplified review will greatly reduce the notification burden associated with such transactions. However, guidance is needed as to what constitute “commercial activities”. Will the presence of a representative office disqualify the joint venture for a simplified review?

## EXCEPTIONS

There are exceptional scenarios where a simplified review will not apply such as where:

- a) an entity acquires sole control of a joint venture over which it already has joint control, and it competes with the joint venture in the same relevant market;
- b) the relevant market is difficult to define; or
- c) the concentration may cause a detrimental effect on market entry, technological progress, consumers and other related parties, or on national economic development.

A simplified merger review based on market share thresholds requires a clear definition of the relevant market and MOFCOM’s acceptance of such definition. In practice, this is not always straightforward. Parties involved in a transaction and their legal counsel should assess the risk that MOFCOM may hold a different view regarding the definition of the market, which may result in a protracted process to determine whether the case qualifies for a simplified review procedure.

Whether the transaction will cause a detrimental effect on market entry, technological progress, consumers or other related parties, or more broadly on national economic development, requires a comprehensive competition analysis. It may be difficult to draw firm conclusions on these matters prior to determining which review procedure to utilise.

The exceptions listed above are non-exhaustive, and MOFCOM is afforded the discretion to not apply a simplified review procedure to concentrations which may cause anti-competitive effects on the market.

## OUTLOOK

A simplified merger review regime has been discussed in China for a number of years. Hundreds of notifications reviewed by MOFCOM in recent years provide an empirical basis for a simplified review regime.

A public notice/disclosure of 10 days is currently in place. That is, when a simplified application is officially accepted by MOFCOM, basic information will be disclosed on MOFCOM’s website for public comment. The merger should be approved quickly after the 10 day period, if there are no comments leading to the discovery of substantial competition issues. This will significantly accelerate the speed of MOFCOM’s review in the future.

With MOFCOM taking steps to implement the simplified review regime and stepping up its enforcement on fail-to-file transactions, companies will not be able to use MOFCOM’s protracted review in unproblematic cases as an excuse for not making the notification.





# AUSTRALIAN NEW ZEALAND THERAPEUTIC PRODUCTS AGENCY WILL WE EVER GET THERE?

By Leah O'Brien (Sydney)

In 2003, the Australian and New Zealand governments signed a treaty aimed at establishing a joint regulatory agency for therapeutic products. While discussions originally took place over four years, the parties agreed to cease those discussions in 2007. At that time, the parties left the pathway for joint regulation open by agreeing their talks could recommence at any agreed time. In 2011, each of the governments signed a statement of intent, reaffirming their commitment to a joint regulatory agency. The statement of intent committed to a three stage approach with a goal to progressively reach joint regulation by 2016.

The joint agency, referred to as the Australia New Zealand Therapeutic Products Agency, or ANZTPA, is a work in progress. In late 2013, the Therapeutic Goods Administration (TGA) (Australia's regulatory authority) and Medsafe (New Zealand's regulatory authority) completed a number of "Business-2-Business" cooperation and sharing projects designed to improve access to information across Australia and New Zealand, setting the path for harmonisation work (see box).

In 2014, harmonisation begun by adjusting paediatric dosages of paracetamol and ibuprofen to ensure consistency across the countries in February. This was followed by the publication of a common list of colouring substances allowed for use in medicines for oral and topical use, agreed in March. The harmonisation is intended to increase regulatory alignment between the TGA and Medsafe in preparation for the transition to the ANZTPA. These small steps lead the way for greater change.

If completed consultation with the industry is an appropriate indicator of the parties next steps, we expect that future harmonisation projects will be announced in the coming year. We will continue to monitor developments and, where possible, keep you updated on future opportunities for stakeholder consultation.

According to the Australian New Zealand Therapeutic Products Agency (ANZTPA) website, harmonisation will occur in the following areas:

- *Medicines (prescription and non-prescription)*
  - *OTC medicines (integrated pre-market business processes)*
  - *Prescription medicines (orphan drugs policy)*
  - *Prescription medicines (pre-market processes)*
  - *Prescription medicines (Product & Consumer Medicine Information)*
- *Medicines ingredients*
  - *Medicines ingredients (colours) (completed)*
  - *Medicines ingredients (proprietary ingredients)*
  - *Medicines ingredients (terminology)*
- *Safety*
  - *Medicines safety (label warning statements)*
  - *Medicines safety (paediatric doses for paracetamol & ibuprofen) (completed)*
  - *Therapeutic products common recall code*
- *Medical devices*
  - *Medical devices (manufacturers' evidence of conformity)*
  - *Medical devices (product overlaps in the NZ and Australian markets)*
- *Biological and blood products*
  - *Biologicals & fresh blood and blood components (analysis of NZ sector)*
  - *Biologicals & fresh blood and blood components (GMP codes & standards)*



# M&A'S, MANUFACTURING AND DISTRIBUTING MEDICAL DEVICES IN JAPAN

By Masahiko Ishida (Tokyo)

Like other jurisdictions, Japan regulates the manufacture and distribution of medical devices in order to ensure patient safety. In the context of structuring an acquisition of a medical device company, an acquirer should consider the regulations that apply to:

- (i) the medical device manufacturer target company; and
- (ii) the medical device products made by the target company

In this article, we briefly summarize how an acquisition or merger may effect existing licenses for the manufacturing and distribution of medical devices.

The Japanese government recently passed an amendment to the Pharmaceutical Affairs Law and the regulations applicable to the manufacture and distribution of medical devices. These changes will likely become effective from November.

Under the current Pharmaceutical Affairs Law, Medical Device Manufactures (MDMs), Medical Device Marketing Authorization Holders (MAHs) and Medical Device Sellers or Rental Service Providers (MDS/RSPs) must obtain the prior approval from the Ministry of Health, Labor and Welfare (Ministry) before commencing business operations. However, under the amended law, the regulation for MDMs will be simplified, in that a MDM only has to register specified information with the Ministry to conduct its business and

MDM will no longer be required to obtain prior approval from the Ministry. As a result, the time and cost of registering a MDM's business will be reduced.

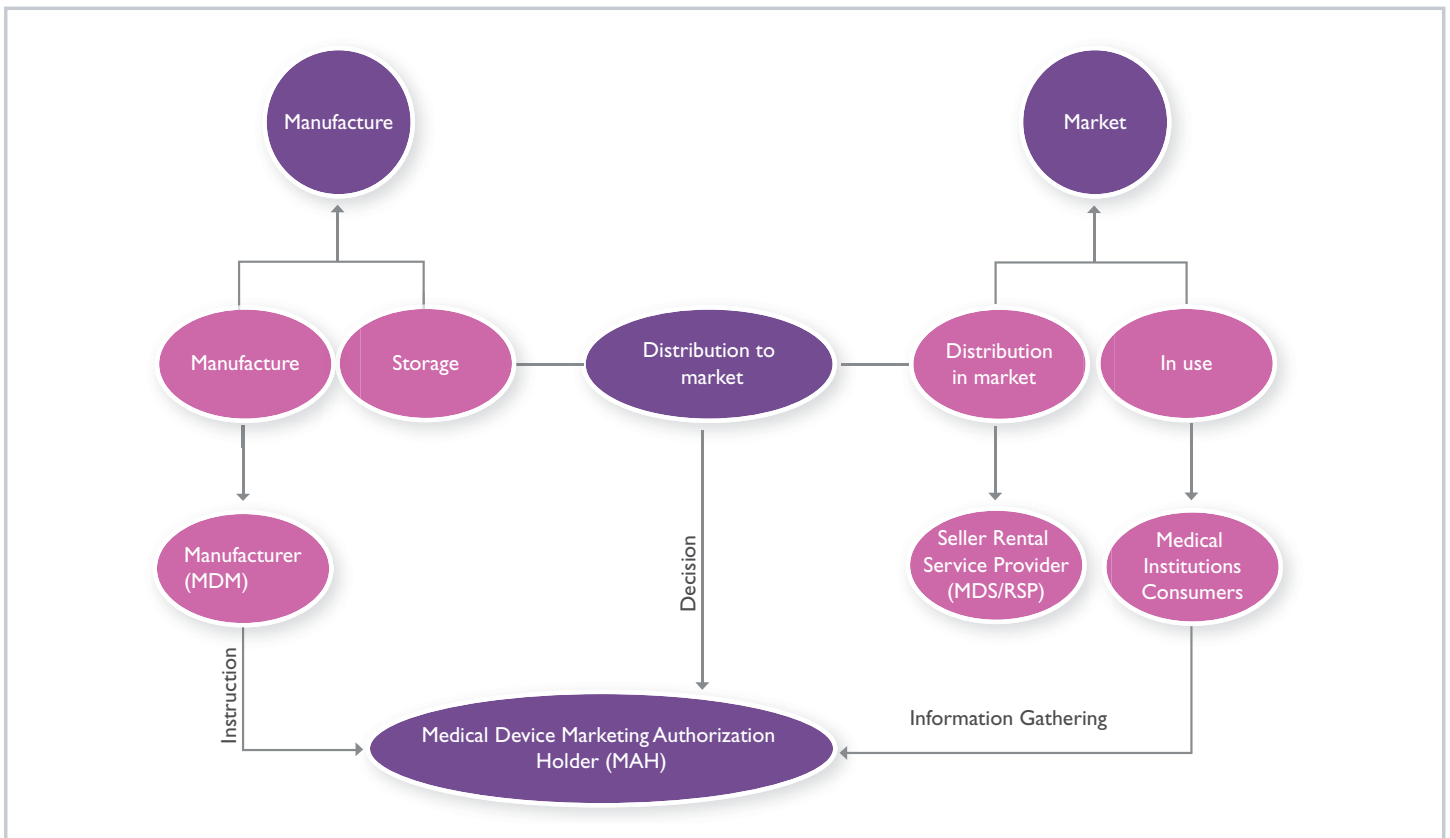
While this will assist in simplifying one aspect of the process, there are a number of factors to consider before and individual or company chooses to enter the medical device sector or even acquire another company's business or product.

### ROLES OF THE PARTIES

In Japan the roles of the parties involved in the medical device industry are broadly divided into three groups, each with a separate licensing requirement:

- (1) MDM is a manufacturer which manufactures specified medical devices.
- (2) MAH is a primary distributor and is responsible for effectiveness, safety and quality of the medical device.
- (3) MDS/RSP is a party which sells or leases (rents) specified medical devices.

The following chart illustrates the typical roles of each of the licensed parties in the medical device industry in Japan.



## MEDICAL DEVICE REGULATIONS

In order to sell particular medical devices, a MAH must comply with the notification and/or registration requirements for each device set down by the Ministry. Medical devices are classified into four categories (Class I to Class IV) based on the potential risk the medical device could cause harm to the patient. The table below provides examples of medical devices in each Class and the necessary action a MAH must take to sell medical devices of each Class.

Class	Examples	Action
Class I (lowest risk)	Surgical knife, tweezers	Notification to the Ministry
Class II (2nd lowest risk)	Hearing aid, thermometer	Obtaining certification from a registered third-party certifier*
Class III (2nd highest risk)	Contact lens, automated external defibrillator (AED)	Obtaining prior approval from the Ministry
Class 4 (highest risk)	Artificial cardiac pacemaker	Obtaining prior approval from Ministry

\*Prior approval from the Ministry is required for certain Class II medical devices.

## MERGER AND ACQUISITION STRUCTURES AND THEIR IMPACT IN THE MEDICAL DEVICE SECTOR

The manner through which a merger or acquisition takes effect may have an impact on existing licenses issued by the Ministry that permit a company to engage in the manufacture, marketing or distribution of medical devices in Japan (**Medical Device Company License**) and the approvals issued in relation to the medical device products (**Product License**).

There are four M&A structures commonly used in Japan:

- (1) share purchase;
- (2) merger;
- (3) company split; and
- (4) business transfer.

The summary below details how a Medical Device Company License and Product License may be affected by each of the M&A structures.

For the purposes of the summary, “Company A” is a Japanese medical device target company (with a Medical Device Company License for itself and Medical Device Licenses for its products) and “Company B” is a Japanese company that will acquire Company A.

### (1) Share Purchase

A share purchase acquisition under Japanese law does not have any unique features compared to those in most other jurisdictions.

In a share purchase transaction, the Medical Device Company License and the Product License held by Company A will not be affected by Company B’s acquisition of Company A’s shares. Therefore, even after the change of control of Company A, Company A will not have to obtain new licenses and Company B, as parent company of Company A, will not be required to obtain any licenses in connection with the acquisition.

### (2) Merger

There are two types of mergers available under Japanese law.

#### (a) Merger by Absorption

A merger by absorption involves two or more companies where one or more companies merge into (and are “absorbed” by) the surviving company.



Companies absorbed by the surviving company cease to exist legally on the effective date of the merger. The medical device regulatory position depends on whether or not the license holder is the surviving company.

If Company A is the surviving company after the merger between Company A and Company B, the Medical Device Company License and Product License held by Company A will continue to be effective after the merger.

If Company B is the surviving company after the merger between Company A and Company B, Company B cannot succeed to Company A's Medical Device Company License and therefore Company B must obtain a new Medical Device Company License for itself. With regard to the Product Licenses, if Company B makes filings with the relevant regulators prior to the merger, the Product Licenses that Company A obtained will survive the merger. However, Company B cannot hold the Product Licenses unless it obtains the relevant Medical Device Company License *prior* to the effective date of the merger. Company B must also make new notification filings after the merger for the different types of Product Licenses.

#### (b) Merger by Incorporation

Merger by incorporation is where two or more companies merge into a newly incorporated company where only the newly incorporated company survives and the other companies cease to exist legally on the effective date of the merger.

In case of the merger by incorporation – where both Company A and Company B merge into a new company (**Newco**) and cease to exist as legal entities after merging into the Newco – the Newco cannot succeed to the Medical Device Company License that Company A held before the merger. With regard to the Product Licenses, if the Newco makes filings with the relevant regulators prior to the merger, the Product Licenses that Company A obtained will survive the merger into the Newco. However, the Newco cannot hold the Product Licenses unless it obtains the relevant Medical Device Company License prior to the effective date of the merger. The Newco must also make new notification filings after the merger for the different types of Product Licenses.

### (3) Company Split

The Company split is one of the acquisition structures available under Japanese law. The basic concept of the company split is that the assets and liabilities constituting a particular business will be transferred to an acquirer in whole or in part. The acquirer may be a newly incorporated entity under the company split procedures (New Incorporation Type Company Split) or it may be an existing company which receives the business assets and liabilities in accordance with the proceedings (Absorption Type Company Split).

The medical device regulatory position in relation to a Company Split is the same as the position that arises as a result of a Business Transfer and is detailed below.

### (4) Business Transfer

In a business transfer, the seller of the target business sells the individual assets and liabilities constituting the business to a purchaser pursuant to an asset transfer agreement. The purchaser will assume only those rights and obligations provided in the asset transfer agreement.

Both a company split and business transfer would involve the transfer of the medical device businesses from Company A to Company B (assuming an Absorption Type Company Split in case of the company split). However, the Medical Device Company License held by Company A cannot be transferred to Company B. The Medical Device Licenses can be transferred to Company B provided that Company B make the required advance notice filings with the regulators. However, in order for Company B to hold such Medical Device Licenses it must obtain a Medical Device Company License *before* the effective date of transfer of the Medical Device Licenses.

In order to ensure a smooth transition following M&A activity involving a medical device company in Japan, it is important to anticipate the Ministry's requirements, particularly if prior approval or new licenses are required to facilitate business operations.

# UPDATE ON RECENT DECISIONS

By Jaimie Wolbers (Sydney) and Jessie Buchan (Sydney)

## ***Collin v Aspen Pharmacare Australia***

In early December 2013, Justice Davies delivered judgment in *Collin v Aspen Pharmacare Australia* [2013] FCA 1336 approving the proposed settlement scheme in the representative proceeding as is required under the *Federal Court Act 1979* (Cth). The matter had been listed for trial in September 2014.

The matter was brought by Mr Collin on behalf of himself and individuals who had been prescribed certain dopamine agonists. Dopamine agonists are often used in the treatment of conditions like Parkinson's Disease or Restless Leg Syndrome. The applicant group, which was ultimately comprised of 32 members, alleged that the respondents had failed to warn, or failed to adequately warn, consumers about potential side effects of the medication which were claimed to cause obsessive or compulsive behaviours. The respondents denied these allegations and defended the claim.

In forming the view that the proposed settlement was fair and reasonable having regard to the claims made on behalf of the group members who would be bound by the settlement, Justice Davies placed great reliance on the confidential opinions of the applicant group's senior and junior counsel. While the terms of the settlement are confidential, her Honour noted that consistent methodology was proposed to assess each group member's loss and damage, and that the distribution scheme made provision for the settlement sums to be paid to group members pro rata to the loss and damage suffered by them.

The issue of the applicant group's costs, which are to be borne by the respondents on a solicitor-client basis under the settlement were also

considered by Justice Davies. Her Honour took into account the opinion of an independent costs assessor who expressed the view that fees and disbursements had been properly incurred, that no significant costs or disbursements had been incurred unnecessarily or inappropriately and that the costs assessed were fair, reasonable and appropriate in the circumstances. Justice Davies was thus able to conclude that both the settlement sum and costs aspects of the proposed settlement scheme were fair and reasonable and she made the necessary orders to give effect to the proposed settlement scheme.

## ***Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd***

The High Court judgment in *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd & Ors* [2013] HCA 50 was delivered in early December 2013. This judgment is the first occasion where the High Court has considered whether methods of medical treatment of the human body are patentable inventions within the meaning of s 18(1) of the *Patents Act 1990* (Cth).

The majority of the High Court (French CJ, Crennan, Kiefel and Gageler JJ, Hayne J dissenting) concluded that "methods of medical treatment of human beings, including surgery and the administration of therapeutic drugs, can be the subject of patents." This is consistent with the approach that has been taken by the Full Federal Court in a number of recent cases.

This decision provides important guidance on contributory (or indirect) infringement in the context of patents which claim methods of medical treatment.

If you are interested in reading more about this decision, please see our Life Sciences Alert, *High Court concludes that methods of medical treatment are patentable* available on the DLA Piper website.

## ***Novartis successfully defends "VOLTAREN" trade mark in "VOLTAGEN" opposition***

Novartis AG has been successful in its opposition to registration of the "VOLTAGEN" trade mark by Alpha Helix Inc, which sought to register the trade mark in relation to dietary and nutritional supplements for boosting pre-workout energy in class 5.

In making out its case under s 60 of the Trade Marks Act 1995 (Cth), Novartis AG argued that Voltaren was used by athletes and any persons engaging in physical activity to 'boost performance', therefore if a similar mark, 'VOLTAGEN', was used in connection with goods used for boosting or improving performance in exercise, confusion is likely to occur. The Delegate agreed, and was satisfied that:

- given the significant reputation of the VOLTAREN trade mark in the Australian marketplace; and
- the degree of similarity between the respective trade marks,
- use of VOLTAGEN would be likely to cause confusion, as consumers are likely to believe 'Voltagen' is a related product from the maker of the VOLTAREN topical rub.

Having found in favour of Novartis AG on the basis of section 60, it was not necessary for the Delegate to consider the other grounds pressed in the opposition and registration was refused.

# Q&A

WITH  
DAVID RYAN



David Ryan is a Partner in the firm's Life Sciences sector and Corporate practice.

## What are your key areas of practice?

I specialise in domestic and cross-border M&A transactions, capital raisings and corporate governance in the technology, life sciences, property and mining sectors. I also advise listed company boards in a range of sectors on corporate governance and securities law matters.

My experience spans everything from complex cross-border takeovers and schemes of arrangement transactions to local asset acquisitions and disposals.

On an international scale, I advised Mitsubishi on its joint takeover bid with Rio Tinto for Coal & Allied and Kirin when it took over Lion Nathan. Domestically, I've acted for Qantas, BHP Billiton, Downer EDI, Ramsay Health Care, Lipa Pharmaceuticals and Novogen in the last few years.

## In your experience, what do you consider are the two biggest issues/challenges currently faced by life sciences companies in Australia?

Life sciences businesses are heavily reliant on investment capital to support R&D programs, which can be costly and time consuming as well as speculative. The Australian capital markets do not always recognise the potential for life sciences companies, particularly early in their development. This makes it harder for them to raise capital. High costs are also an issue for business in Australia at the moment.

## What are the most notable cases or matters that you have worked on?

As an M&A specialist, my practice is very transaction driven. I have advised many companies in the sector over the years including:

- Advising Ramsay Health Care in relation to its acquisition of Affinity Healthcare (\$1.8 billion).
- Advising Lipa Pharmaceuticals in relation to its sale via scheme of arrangement to CK Life Sciences (HK\$609 million).
- Acting for Ramsay Health Care on its takeover of Alpha Health Care (\$50 million).

## What is your favourite thing to do outside work?

Well, my wife and family come first, but outside of that it's all about Motorsport. I love Formula 1 and I race competitively myself. I'm currently competing in the Australian GT3 Cup Challenge series in a Porsche 911 GT3 Cup Car.



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