



ASIA PACIFIC

LIFE SCIENCES SPOTLIGHT

HARPER REVIEW DISPENSES IMPORTANT
RECOMMENDATIONS FOR THE LIFE SCIENCES
SECTOR

PHARMACEUTICAL PATENT TERM
EXTENSIONS IN AUSTRALIA

PRC ANTI-CORRUPTION REGIME 101

REVISIONS TO THE MEDICINES AUSTRALIA
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A NOTE FROM THE GUEST EDITOR

Welcome to the fifth edition of *Life Sciences Spotlight*.

At the end of 2014, DLA Piper conducted a survey asking those of you in the life sciences sector to tell us what has been occupying your time and keeping you awake at night.

We asked you what your most pressing legal issues were over the last 12 months and what your predictions of the most pressing legal issues will be in the next 12 months. Unsurprisingly, the top legal concern over the past 12 months and in the next 12 months was compliance and transparency. Ensuring compliance is not a simple task in the current regulatory environment. The sands are continually shifting – there are new regulations, changing regulations and everything in between. Overlaid with this, regulators are sharpening their focus on life sciences companies and the importance of getting it right, or not getting it wrong, has never been as critical.

Other legal issues you identified as causing you concern were varied and included biosimilars, competition issues, M&A, data privacy and product liability.

We also asked you what the most important region was from a legal perspective. Around 50 percent of you answered China. Again, no huge surprise. Having successfully navigated the financial tsunami, China's sound economic track record combined with its eye-catching market of over 1.3 billion individuals means that it is attractive destination for life sciences companies. However, all this does not come without some significant challenges. In order to be successful in China one must understand, implement, and adhere to a continuously evolving rule of law.

In this edition, we explore many of the areas of concern you identified in our recent survey. In "Unravelling the Helix", **Sammy Fang** and **Julia Gorham** will take us through a real-

world dilemma discussing the intersection of anti-bribery and anti-corruption laws and employment law in China. **Yan Zhao**, **Jason Chang**, **Bing Li**, **Bing Ryan** discuss a range of topics relevant to the PRC from its new biosimilar approval pathway to the nuances of the PRC's anti-corruption regime.

Simon Uthmeyer and **Mathew Taylor's** article focus on competition issues in Australia, in particular the long-awaited Harper Review and the recommendations relevant to life sciences companies. We also step back and look at the year that was in the context of product liability claims where **Kieran O'Brien** and **Adam Stevens** look at the Australian class actions that defined 2014.

Thank you to all of you that participated in the survey. It will help shape the way we do business and how we assist you in executing your business strategy. It will also help us shape the content of *Spotlight* over the next 12 months.

We hope you enjoy this edition of *Life Sciences Spotlight* and we encourage you to tell us what topics you like to learn more about in 2015.



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If you would like further advice, please contact us using the details above.

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UNRAVELLING THE HELIX

In each edition 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. In this edition, DLA Piper partners Sammy Fang and Julia Gorham discuss the intersection of anti-bribery and anti-corruption law and employment law in China.

FarmaPharma Pty Ltd (FP) is a foreign pharmaceutical company that has just entered the Chinese market. FP has hired a team of local sales representatives to promote its products to general practitioners in Guangzhou. Its employment contracts are drafted so that they are paid on a commission basis. In several visits to general practitioners, one of the sales representatives states that he is willing to share his commission on any orders placed by the general practitioner. This has come to the attention of a local government official and an investigation has been launched. The investigation reveals that this is a practice used by a number of FP's sales representatives. Concurrently, FP is seeking to incorporate a subsidiary company to distribute its products in China and this application has been denied presumably in the wake of the allegations.

FP wishes to terminate the sales representative(s) and is concerned that its application has been unlawfully denied. FP approaches you for advice reading its internal obligations and potential legal risks, particularly with respect to the denial of its application to incorporate a subsidiary company. FP is also looking for advice in relation to termination of the sales representative(s).



SAMMY FANG'S PERSPECTIVE

Sammy Fang's practice focuses on the Greater China market, particularly in relation to China-related disputes, regulatory compliance and investigations. Sammy has also dealt with crisis, disputes and investigations across multiple jurisdictions including Australia, Hong Kong, Indonesia, the US and China and regularly assists our securities litigation and white collar practices in the US. You can reach him at: sammy.fang@dlapiper.com



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How to navigate the regulatory environment in China

Potential violation of the anti-bribery and anti-corruption laws of China and elsewhere

The local Chinese government has launched an investigation of local FP employees bribing general practitioners in Guangzhou, China. Based on this information, the company needs to assess the potential risks that its employees have violated the Chinese anti-bribery and anti-corruption laws and regulations and the corresponding laws (the ABAC laws) in the jurisdictions where it is incorporated or conducts business. The ABAC laws in different jurisdictions are complex and diverse. Some of the most expansive and stringent ones include the *Foreign Corrupt Practices Act* of the United States (FCPA) and the *UK's Bribery Act*. Australia also has its own legislation that prohibits bribing foreign officials, whether committed in Australia or by Australians overseas.

Although the ABAC laws in different jurisdictions bear certain similarities, there are many notable differences, including:

- 1 the types of conduct prohibited and the elements that make up an offence in each jurisdiction are sometimes very different;
- 2 the focus of the law is not the same;
- 3 the penalties vary dramatically from jurisdiction to jurisdiction; and
- 4 the degree of enforcement by local regulators.
For example, in many jurisdictions, the relevant offences carry administrative rather than criminal sanctions. By contrast, individuals may be sentenced to death in some countries, such as China, for corruption offences.

Plan an internal investigation – Will it stand up to potential scrutiny?

In addition to responding to the Chinese authority's investigation, FP should also take into consideration that the investigation initiated by the Chinese governmental agency in Guangzhou could trigger attention from law enforcement authorities from other countries. These non-Chinese regulatory agencies may look into the misconduct of the FP employees in the company's Chinese operation. They are also interested in knowing how the company has itself investigated the issues, its findings and any subsequent remedial actions in correcting such misconduct, including whether FP has followed the company's policies to punish the relevant personnel and whether the company has enhanced its internal controls and business practices in further deterring and preventing such misconduct.

Moreover, FP needs strong evidence in supporting its decision of disciplining employees (such as termination) who committed misconduct. For the above mentioned reasons, a company in FP's position should retain outside counsel to conduct an internal investigation in determining whether any of its employees have violated the ABAC laws in China and in relevant jurisdictions. This investigation can be carried out in parallel to the Chinese government's investigation. In conducting the internal investigation, the company should strictly adhere to its internal procedures and properly document the investigation findings.

Before the internal investigation starts, the outside counsel retained by the company should build an investigation plan that is reasonable in scope and with robust methodology. Ultimately, a foreign regulator such as the Department of Justice in the US and the Serious Fraud Office in the UK will expect no less. This will impact on whether these regulators' decision to investigate FP's conduct if they have jurisdiction to do so. Outside counsel needs to define the scope of the investigation, identify potential targets, the company's

reporting obligations, and any specific areas of investigation beyond typical anti-bribery and anti-corruption elements (such as IP issues and industry specific compliance issues). Issues such as timing and costs of document review, how to secure witnesses, and engaging and coordinating with other legal and non-legal experts should also be taken into consideration as part of the investigation planning.

Conduct an internal investigation

Many issues come into play during an internal investigation. For example, due to the potential conflict of interest between FP and its employees, FP should advise its employees to obtain independent advice at an early stage of the investigation. It is also a good practice to engage qualified local counsel in each affected region to handle issues relating to local laws.

FP must also ensure compliance with local data privacy legislation. Although China does not have a comprehensive privacy law or data protection law, a mixture of different laws, regulations and guidelines provides protection to personal information and data privacy. Under general Chinese data privacy regulations, an employer cannot use its employees' private or personal data without notifying the employees of the purpose, scope, methods of the data collection and further obtaining consent from the employees. While collecting information from the company's email server or share drives pose minimal or low risk of exposure from a data privacy perspective, FP should set aside any personal data collected during the process and not access or use the data during the investigation. Moreover, if employees use their own computers and other electronic devices for work purposes, FP should consider potential data privacy issues before undertaking collection of these devices.

Another special consideration for FP during the internal investigation process is China's State Secrets law, under which any information or data that is considered to be state secrets cannot be accessed, reviewed, or transferred outside of China. State secrets are defined very broadly under Chinese law. Without precise definition what may constitute state secrets, it is extremely difficult, if not impossible, to determine what a state secret is in practice. A good approach is to examine the source of the information and the manner in which the information is already being monitored or protected by the authorities or the parties responsible for generating and protecting the information from disclosure.

In addition, due to the ongoing government investigation, FP should be prepared for the Chinese regulators' inserting themselves into the company's internal investigation. The Chinese government agencies often actively intervene in a company's internal investigation. Establishing early dialogue with the Chinese regulators and building relationship of trust are essential steps for FP to deal with such intervention.

Although the Chinese regulators do not recognize legal privilege and may search and seize documents and records from FP's premises or their attorneys' premises, FP should still maintain the confidentiality of all the documents relating to the internal investigation. Maintaining legal privilege is also important and relevant for FP as it needs to protect information it obtained during the investigation at its home jurisdiction. In addition, FP needs to put in place proper measures to preserve documents in preparation for local Chinese authorities' commanding the seizure of documents and records.

Implement remedial actions

Upon completing the internal investigation, FP should implement remedial actions in correcting any fraudulent practices within the company or misconduct of its employees. In doing so, FP should bear in mind the corrective actions required by the regulators in relevant jurisdictions. Such remedial actions include terminating employees who engaged in misconduct, designing specific policies and procedures to deter and prevent future violations, and enhancing legal compliance training within the company. However, the degree and extent of remedial action expected by foreign regulators may vary from regulator to regulator.

Employment related considerations

While carrying out the investigation, FP may wish to suspend the employees. Under Chinese law, companies are permitted to suspend employees with full pay. If the investigation confirms the allegations, FP can further consider terminating the employees who engaged in misconduct. However, FP needs to support its termination decisions with strong evidence.

If FP unilaterally terminates its employee and cannot justify the termination under the relevant Chinese laws, or the employee is protected from termination, FP would be deemed by the courts to have committed an unlawful termination. This may entitle the employee to be reinstated and the employee may be entitled to compensation in an amount equal to the full salary from the date of wrongful termination to the date of reinstatement (or double statutory severance pay or damages if reinstatement is not possible).

We are witnessing an increasing level of assertiveness by various Chinese regulatory authorities in the past 18 months. Added to this is the continued appetite of US and UK regulators to focus more of their attention on multi-nationals with businesses in China and other parts of Asia. Companies operating in this region cannot afford to be complacent in their approach to regulatory compliance and in their handling of this type of investigations.



HARPER REVIEW DISPENSES IMPORTANT RECOMMENDATIONS FOR THE LIFE SCIENCES SECTOR

By Simon Uthmeyer and Matthew Taylor (Melbourne)

The long-awaited Harper Review final report was released on 31 March 2015. This update highlights key recommendations relevant to the life sciences sector:

ALIGN THE MISUSE OF MARKET POWER PROHIBITION

The Harper Review recommends bringing the misuse of market power prohibition into line with the other provisions in Part IV of the *Competition and Consumer Act 2010* (Cth) (CCA). If implemented, these amendments would expand the reach of section 46 and make it easier to prove a contravention, primarily because of the removal of the “take advantage” limb and the addition of an “effects” test.

The three key changes recommended by the Harper Review are:

- 1 Expanding section 46 to encompass the standard Part IV effects test (in addition to the existing purpose test). If implemented, this would make it easier to prove contraventions of section 46. The Australian Competition and Consumer Commission (ACCC) has long advocated for this change on the basis that it is difficult for the ACCC to prove the subjective purpose of an accused.
- 2 Removing the “take advantage” limb. If implemented, this would make it more difficult for a firm with market power to defend its actions. The taking advantage limb has traditionally provided comfort to firms engaging in conduct that would be a rational business strategy even for a firm without substantial market power. The Harper Review initially proposed including an express defence to this effect. The removal of this limb in favour of exclusive reliance on the standard Part IV substantial lessening of competition

test would expand the reach of the prohibition and place significant importance on the interpretation of that test. The Harper Review recommends requiring Courts to have regard to specific factors that increase or lessen competition including efficiency, innovation, product quality or price competitiveness.

- 3 Introducing the standard Part IV substantial lessening of competition test in place of the existing proscribed anti-competitive purposes. If implemented, a key issue will be whether there is sufficient certainty associated with the application of this test in the context of misuse of market power. The Harper Review recommends requiring Courts to have regard to specific factors that increase or lessen competition including efficiency, innovation, product quality or price competitiveness. In our view, the inclusion of those factors would not alter the nature of the test. Existing jurisprudence establishes that the test requires a comparison of the state of competition in the relevant market with and without the conduct, including pro-competitive and anti-competitive factors.

The Harper Review also recommends allowing the ACCC to authorise conduct which satisfies a public benefit test (which requires that public benefits outweigh public detriments, including any lessening of competition). This change would standardise section 46 with other provisions of Part IV. However, the time and cost associated with an authorisation

application means that significant forward planning and investment would be required by firms with substantial market power seeking to rely on authorisation as a basis to engage in conduct that could lessen competition.

If the recent matter of *ACCC v Pfizer* were to be decided under the new (amended) section 46, it is likely, in our view, that the Federal Court would reach the same outcome because:

- in relation to the allegation that Pfizer misused its market power, the Federal Court held that Pfizer had taken advantage of its market power but did not do so for an anticompetitive purpose;
- the ACCC did not to plead an anti-competitive effect (despite having the opportunity to do so in relation to its allegation that Pfizer engaged in exclusive dealing); and
- on the Federal Court's findings, an argument that Pfizer's conduct had, or was likely to have had, the effect of substantially lessening competition in the Australian atorvastatin market is unlikely to succeed.

REPEAL THE INTELLECTUAL PROPERTY EXCEPTION

The Panel recommends that an overarching review of Australia's intellectual property (IP) regime be undertaken, by way of a 12-month Productivity Commission inquiry. In the Panel's view, the review should address:

- competition policy issues in IP arising from new developments in technology and markets; and
- the principles underpinning the inclusion of IP provisions in international trade agreements the Panel also recommends that a separate independent review should assess governmental processes for establishing negotiating mandates to include IP provisions in such agreements.

In addition, the Panel recommends that the IP exception in section 51(3) of the CCA be repealed. This recommendation is particularly relevant to IP rights holders and any party entering into licences or assignments involving IP rights. Currently, section 51(3) of the CCA provides a limited exception, for certain types of transactions involving IP rights, from the application of Part IV of the CCA. More specifically, the IP exception covers certain conditions in licences or assignments of IP rights in respect of patents, trademarks, registered designs, copyright and circuit layouts. However, the exception is limited, in that it does not extend to the prohibitions in Part IV against resale price maintenance (section 48) and the misuse of market power (section 46). In the Panel's view, repealing the IP exception should not depend on, nor be delayed pending, the outcome of the proposed Productivity Commission inquiry.

If the latter recommendation is implemented, transactions previously protected from regulatory scrutiny by the operation of section 51(3) may give rise to material competition risks (for example, for originator manufacturers of pharmaceutical products) going forward. Importantly, however:

- the Panel recommends that IP licences and assignments should remain exempt from the cartel provisions of the CCA, consistent with the general position in respect of vertical supply arrangements;
- in the Panel's view, such vertical arrangements involving IP rights should only contravene the competition law if they have the purpose, effect, or likely effect, of substantially lessening competition; and
- competition law risks arising from the repeal of section 51(3) may be mitigated in circumstances where IP licensing or assignment arrangements produce offsetting public benefits, by applying for an exemption from the CCA through the usual notification or authorisation processes.

DEREGULATE PHARMACY OWNERSHIP AND LOCATION RULES

In the Panel's view, current restrictions on the ownership and location of pharmacies in Australia are unnecessary to ensure that pharmacies meet community expectations of safety, access and standard of care. By implication, those restrictions unduly restrict competition. The Panel recommends that such rules be repealed and replaced with regulations that effectively promote safety, access and standard of care but are less harmful to competition (and, in turn, less detrimental to the long-term interests of consumers). Likewise, we note that the recent National Commission of Audit (in its Phase One report) also recommended that pharmacy ownership and location rules be deregulated.

Importantly, due to the significant expected impact on the pharmacy sector, the Panel considers it likely that transitional arrangements will form an integral part of the reform process and contends that negotiations for the next Community Pharmacy Agreement afford the Australian Government an opportunity to implement such transitional arrangements with a view to the eventual removal of location rules.

We note that the Panel's recommended changes to the merger exemption process, the ACCC's powers, and the authorisation and notification regime may also be relevant to businesses in the life sciences sector.

If you would like to understand the potential implications of the Harper Review for your business, please do not hesitate to contact us.



AUSTRALIAN HIGH COURT CONFIRMS THAT LATE APPLICATIONS FOR PHARMACEUTICAL PATENT TERM EXTENSIONS MAY BE GRANTED IN AUSTRALIA

By Nicholas Tyacke (Sydney), Eliza Mallon and Louis Italiano (Melbourne)

Pharmaceutical patent term extension regimes are of critical importance to innovators in the pharmaceutical industry, for whom an ability to exploit a monopoly to a patented invention is often subject to lengthy delays because of the time it can take to obtain the necessary regulatory approvals to market a pharmaceutical product.

In *Alphapharm Pty Ltd v H Lundbeck A/S* [2014] HCA 42, the majority of the High Court of Australia has confirmed that where a patentee fails to apply for an extension of a pharmaceutical patent term within the prescribed timeframe of six months from either the date the patent was granted or the date of inclusion on the Australian Register of Therapeutic Goods (ARTG) because of a genuine error or omission, the Commissioner of Patents may grant the patentee an extension of time to do so.

EXTENDING THE TERM OF THE ESCITALOPRAM PATENT

Enantiomers are molecules that are non-superimposable mirror images of each other, and are designated (+) or (-) based on how they rotate polarised light. In 1997, Lundbeck successfully obtained inclusion on the ARTG of CIPRAMIL, a “racemic” mixture of the (+) and (-) enantiomers of citalopram, used to treat depression.

In September 2003, Lundbeck obtained ARTG inclusion for its related LEXAPRO product, comprised of only the (+)-citalopram (known as escitalopram). Lundbeck also held a patent directed to escitalopram (the Escitalopram Patent), which noted that escitalopram was *therapeutically more active and more than 100 times more effective* in treating depression than the racemic mixture of CIPRAMIL.

In December 2003, Lundbeck applied to extend the term of its Escitalopram Patent under s 70(1) of the *Patents Act 1990* (Cth) (Act). Section 70(1) allows a patentee to apply for an extension of term of a pharmaceutical patent by up to five years to compensate the patentee for delays in obtaining regulatory approval to market the patented product.

Importantly, s 71(2) of the Act provides that such an application under s 70(1) must be made:

- during the term of the patent (Patent Term Timeframe); and
- within the later of six months from either the date the patent was granted or the date of inclusion on the ARTG (Grant or ARTG Timeframe).

Believing its application satisfied the above requirements of s 71(2), Lundbeck filed an application under s 70(1) three months after the inclusion of LEXAPRO on the ARTG. However, in 2009 the Full Federal Court held that Lundbeck's application to extend the term of its Escitalopram Patent should have been based upon the inclusion of CIPRAMIL on the ARTG because the racemic mixture of CIPRAMIL "contained" the pharmaceutical substance disclosed in the Escitalopram Patent. As a result, Lundbeck's application under s 70(1) was deemed not to have been made within the Grant or ARTG Timeframe.

Following the Full Court's decision but before the 20 year term of its Escitalopram Patent was due to expire, Lundbeck made a second application under s 70(1) to extend the term of its Escitalopram Patent based on the inclusion of CIPRAMIL on the ARTG. As its application could not satisfy the Grant or ARTG Timeframe requirement of s 71(2), Lundbeck made a concurrent application for an extension of the Grant or ARTG Timeframe under s 223(2)(a) of the Act.

Section 223(2)(a) of the Act confers the Commissioner of Patents with a general remedial power to extend the time for doing a 'relevant act' that was not done in time because of an error or omission by the person concerned or his or her agent or attorney. The Commissioner considered that Lundbeck's genuine misunderstanding of the law led to its failure to apply for an extension of the term of the Escitalopram Patent within the Grant or ARTG Timeframe, and that such an error warranted the exercise of discretion under s 223(2)(a) to grant Lundbeck an extension of time to apply to extend the term of the patent.

Alphapharm, who had begun marketing a generic version of escitalopram, appealed the Commissioner's decision to the Administrative Appeals Decision and subsequently the Full Federal Court, both of which upheld the Commissioner's decision. Alphapharm subsequently appealed the Full Federal Court's decision to the High Court.

THE QUESTION BEFORE THE HIGH COURT

The central question before the High Court was whether s 223(2) of the Act conferred the power upon the Commissioner to extend the time within which Lundbeck could apply under s 70(1) of the Act to extend the term of its Escitalopram Patent, having regard to the statutory limitations applicable to the provision.

Certain "prescribed actions" are unable to be extended under s 223(2) of the Act. In particular, under reg 22.11(4)(b) of the *Patents Regulations 1991 (Cth)* one such "prescribed action" is the "filing, during the term of a standard patent under s 71(2) of the Act, an application under s 70(1)".

Alphapharm argued that reg 22.11(4)(b) operated to limit the Commissioner's power to grant an extension of time in relation to both the Patent Term Timeframe and Grant or ARTG Timeframe requirements of s 71(2), because the filing of an extension of term application was the very "action" for which an extension could not be granted.

Lundbeck, however, contended that the express reference to "the term of a standard patent" in reg 22.11(4)(b) rendered the provision operable only to prohibit extensions of time in relation to the Patent Term Timeframe requirement.

THE HIGH COURT'S DECISION

The majority of the High Court considered the legislative history and context of the extension of patent term regime in Australia, noting that its purposes were to balance the competing interests of:

- a patentee whose ability to exploit his or her monopoly had been delayed by the regulatory process; and
- the public interest in the unrestricted use of an invention after the expiration of a patent term.

Their Honours noted that there was nothing in any of the extrinsic materials, or in the long policy debates on simplifying extensions of term that suggested any rationale for excluding the Grant or ARTG Timeframe requirement from the general remedial power to extend time under s 223(2)(a).

The majority considered text of reg 22.11(4)(b) as a whole, including its syntax and immediate context, concluding that Alphapharm's arguments provided an "incomplete and inadequate foundation" for construing the provision that was inconsistent with the objects of the extension of term regime. The majority therefore held that the only time requirement that was excluded from the general remedial power to extend time in s 223(2)(a) was the Patent Term Timeframe requirement.

IMPLICATIONS OF THE DECISION

The High Court's decision confirms that where a patentee fails to apply for an extension of a pharmaceutical patent term within the Grant or ARTG Timeframe because of a genuine error or omission, the Commissioner may grant the patentee an extension of time to do so. The decision is consistent with the Australian Patent Office's longstanding practices, and will reassure innovators that Australia has an effective pharmaceutical patent term extension regime with adequate protections to ensure patentee rights are not prejudiced by genuine errors or omissions or delays in obtaining regulatory approval.



PRC ANTI-CORRUPTION REGIME 101

By Sammy Fang (Hong Kong)

While most compliance officers are familiar with the *United States (US) Foreign Corrupt Practices Act* and *United Kingdom (UK) Bribery Act*, the Chinese anti-bribery and anti-corruption (ABAC) regime has received less attention than its overseas counterparts. We briefly outline below China's ABAC regime and some of its nuances.

The PRC ABAC regime is governed by a collection of laws and regulations, mainly the Criminal Law, Anti-Unfair Competition Law, the Interim Provisions on Prohibiting Commercial Bribery, as well as other rules and regulations issued by the State Council and other government authorities. Bribery offenses generally fall under two categories: “official bribery” and “commercial bribery”.

CRIMINAL LAW BRIBERY TO STATE WORK PERSONNEL

The offender, either a corporation and/or an individual, commits an official bribery offense, if the offender offers property to a “State Work Personnel” (SWP) in return for an improper benefit. There are four elements that must be satisfied:

1. An offer of property to a SWP;
2. In return for a benefit, or for the assistance to obtain a benefit;
3. The amount involved meets the required threshold or certain requisite conditions if the amount involved is below such threshold; and
4. There is corrupt intent to bribe the SWP.

The current threshold for corporate offenders is CNY 200,000 (approximately USD 32,000) or CNY 10,000 (approximately USD 1,600) for individual offenders. Penalties range from temporary criminal detention up to life imprisonment as well as confiscation of illegal gains.

COMMERCIAL BRIBERY

Similar PRC Criminal Law provisions exist for offenders who bribe non-SWPs in pure commercial bribery offenses, although the elements are slightly different and the monetary thresholds are higher. However, even the PRC Criminal Law thresholds are not met, there is also an administrative offense which targets commercial bribery at an administrative level.

The Anti-Unfair Competition Law prohibits companies from offering cash and/or property through improper means for the purpose of selling and/or purchasing goods.

The Administration for Industry and Commerce (AIC) is in charge of handling administrative commercial bribery matters and has broad discretionary powers to investigate and penalize in connection with such offenses. Penalties include fines, confiscation of any illegal gains, and revocation of the company's business license.

FREQUENTLY ASKED QUESTIONS

What is State Work Personnel according to PRC Criminal Law?

In the PRC, there is no specific definition of what a “government official” is. Instead, the PRC has a legal concept of State Work Personnel or “SWP” who consist of: (1) people who perform public services in the legislative, administrative, or judicial agencies or the military; (2) people who perform public services in state owned enterprises (“SOEs”), institutions, or civil organizations; (3) people assigned by the government, SOEs or institutions to non-state-owned enterprises, institutions, or civil organizations to perform public services (such as a deputy general manager of a Sino-foreign joint venture company who has been sent to the joint venture by the Chinese party which is an SOE); and (4) people who perform public services according to law. For example, positions such as “directors, managers, supervisors and cashiers” of state-owned companies who are in a position to manage or supervise the state’s assets would likely be considered as “performing a public service.” In contrast, employees whose functions do not reflect authorities’ duties and power and are related to labor and technical skills (such as salespersons and ticket office clerks) would likely not be considered “a person performing a public service.”

How do I prepare for unannounced visits by a local Chinese bureau?

In the past two years, we have seen an increase in unannounced visits by PRC government authorities. PRC law has no mandatory requirement that government officials must give notice prior to visiting a business premise. Aside from calling your lawyer immediately, you may consider adopting a

“dawn raid protocol” to properly implement and train your employees to respond in an orderly and effective manner:

- Train employees to remain calm and treat the officers with courtesy and respect.
- Have a procedure in place to contact relevant individuals and develop a crisis management team.
- Implement procedures to properly identify the government officer, search warrant and/or authorization documents to ensure the matter is handled properly.
- Educate leadership on the basics of evidence preservation, proper documentation, confidentiality, making copies of seized materials, and how to communicate with the officers.

What is a current area of interest in China? What do I need to be particularly aware of?

In Q4 2014, we have seen a lot of issues with the Chinese media and journalists. The Chinese government has been cracking down on local television networks, magazines, newspapers, as well as online media. Certain journalists in state-owned media outlets have been alleged to have received bribes and/or for money in exchange to publish favorable news articles, quash stories, and/or otherwise obstruct the normal reporting of the news. If you have significant marketing and public relations departments which require large budgets for hosting, entertaining, and/or giving gifts to local Chinese journalists, and/or third-party agencies who do the same, keep abreast of these latest developments and review your company’s current practices.





JUST WHAT THE DOCTOR ORDERED

REVISIONS TO THE MEDICINES AUSTRALIA CODE OF CONDUCT

By Dr. Simone Mitchell, Matthew Evans and Valiant Warzecha (Sydney)

On 24 April 2015, the Australian Consumer and Competition Commission (ACCC) granted authorisation for Edition 18 of the Medicines Australia Code of Conduct (Code). This edition of the Code significantly strengthens the current reporting requirements and comes with the condition that before 1 October 2016 the Code will be further amended to include a requirement that member companies will need to ensure that a transfer of value or benefit will be able to be individually reported.

By way of background, the Code prescribes the standards for ethical marketing and promotion of prescription pharmaceutical products in Australia, acting to compliment legislative requirements found in the *Therapeutic Goods Act 1989* (Cth) (TGA) and the *Therapeutic Goods Regulations 1990* (Cth). It includes provisions which govern standards for appropriate advertising, the behaviour of pharmaceutical representatives and relationships with healthcare professionals (HCPs). It is revised on a triennial basis to ensure that it is a reflection of current community and professional standards and given that it concerns anti-competitive practices, it must be authorised by the ACCC.

The most notable amendment to Edition 18 of the Code is the new and expanded transparency regime, which includes more rigorous disclosure requirements. The ACCC has previously made a number of strong statements as to the level of transparency they expect in future editions of the Code to impose, so it did not come as a surprise that the revisions made to edition 18 of the Code focused on moving towards increased transparency, particularly in relation to benefits provided by companies to HCPs. Further, it was not an unexpected turn of events when the ACCC refused to grant approval to the new edition of the Code unless certain amendments were made to further increase

transparency. After a number of months of uncertainty, the ACCC has approved the new edition of the Code subject to an important condition. That condition is discussed further below.

Pursuant to edition 18 of the Code, all “transfers of value” from pharmaceutical companies to individual HCPs will need to be reported. “Transfers of value” is defined as a transfer of anything that would have a value to the recipient from the perspective of general community standards and value. It would include such things as speaking fees, advisory board fees, or sponsorships to attend a conference. Under the new reporting regime, a report for a ‘transfer’ must indicate the HCP’s name, a description of the service or event and an itemised account of the payment and/or value of the “transfer.” However, where a HCP refuses to give consent to the disclosure then the individual payment can be reported in aggregate.

In their draft determination handed down on 17 October 2014, the ACCC were critical of the ability to circumvent the disclosure requirements by only reporting the aggregate value of the transfer if consent was not given by the HCP. Accordingly, the ACCC has imposed a condition that before providing a benefit to a HCP, a member company will need to ensure that the benefit will be able to be individually reported. The condition is not effective immediately, rather requiring Medicines Australia to amend the Code before 1 October 2016 to mandate the reporting of all transfers of value.

The new edition of the Code also includes a number of other significant amendments in relation to the provision of benefits to HCPs, including a maximum cap of \$120 on the cost for meals and beverages (excluding GST and gratuities) provided by a company to a HCP within Australia. Given the introduction of this maximum limit, the new transparency model does not require reporting of food and beverages provided to HCPs.

From a practical perspective, the new disclosure regime may reduce the readiness of HCPs to accept ‘transfers of value’ (and arguably achieve the purpose behind the transparency provision). However, the more pressing concerns are the legal ramifications of mandatory disclosure. The regime is likely to present substantial data privacy issues for companies, particularly given the HCP data will be made publicly available. This will certainly be an issue that companies will need to look at closely to ensure compliance with *Australia’s Privacy Act*.





A MYRIAD OF PROBLEMS AND OPPORTUNITIES – A COMPARISON OF THE PATENTABILITY OF ISOLATED NUCLEIC ACID IN THE UNITED STATES AND AUSTRALIA

By Dr. Lisa Haile (San Diego), Nicholas Tyacke (Sydney), Eliza Mallon and Louis Italiano (Melbourne)

Due to the inherent nature of the technologies that underpin it, the biotechnology industry has faced challenges worldwide in relation to precisely what constitutes “patentable subject matter.” In particular, patents directed to genetic material have been the subject of significant public discourse and legal challenge. These challenges have led to a divergence of laws governing the patentability of genetic material between jurisdictions.

As will be seen from the analysis below, the divergence in laws relating to the patentability of genetic material between the US and other jurisdictions, such as Australia, has resulted in a heightened level of industry uncertainty and instability in the US, especially in the molecular diagnostics area.

A COMPARISON OF THE LAW OF SUBJECT MATTER ELIGIBILITY IN THE US AND AUSTRALIA

The threshold question of subject matter eligibility in the US is based on Section 101 of Title 35 of the US Code, as interpreted by the Federal Courts, which states in applicable part that:

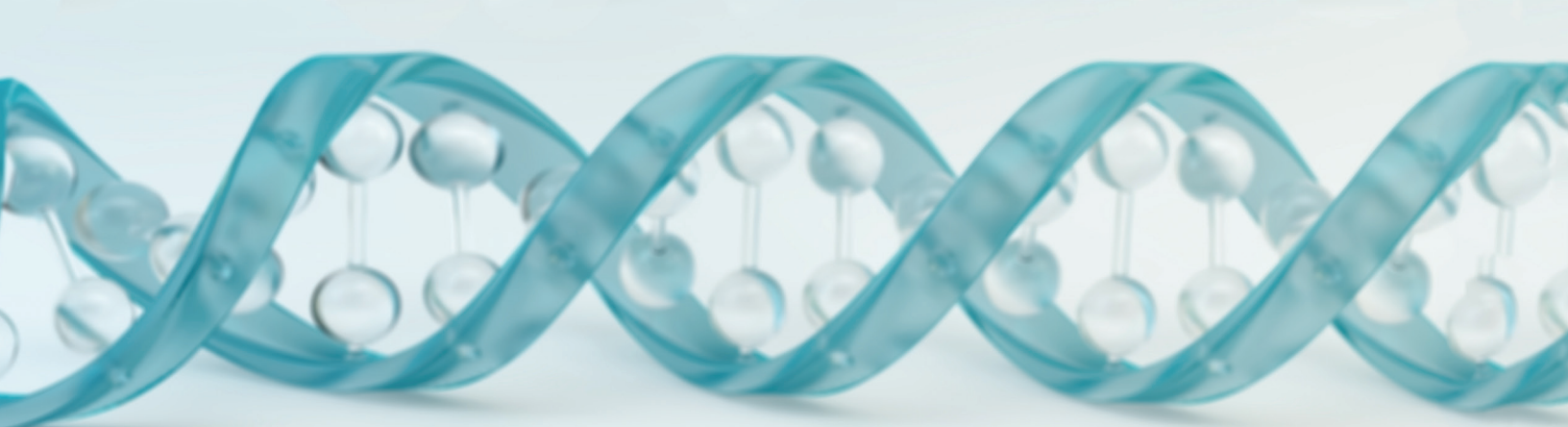
Whoever invents or discovers any new and useful process, machine, manufacture or composition of matter ... may obtain a patent ...

At least up until recent Supreme Court cases, as long as the subject matter sought to be patented fell within one of the four statutory classes AND involved human intervention, it was patent eligible (as per *Diamond v Chakrabarty*, 447 U.S. 303, 1980, at 308-309).

On the other hand, in order for an invention to be of patentable subject matter in Australia, it must be a “manner of manufacture” (s18(1)(a) *Patents Act 1990* (Cth)).

The guiding test for whether an invention is a “manner of manufacture” and therefore patentable subject matter in Australia was established by the High Court of Australia (Australia’s highest court) in *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252 (NRDC). In NRDC, the High Court ultimately held that a product that amounts to an “artificially created state of affairs” (i.e. something which, but for human intervention, would not exist) which also has economic significance will constitute a “manner of manufacture”. The NRDC case remains the leading case on subject matter eligibility in Australia, having been consistently applied to rapidly evolving technologies from information technology to biotechnology for over 50 years.

These respective principles were applied by the United States Supreme Court in *Association for Molecular Pathology v Myriad Genetics, Inc*, 596 US 12-398 (2013) and the Full Court of the Australian Federal Court in *D’Arcy v Myriad Genetics Inc* [2014] FCAFC 115, in which the courts addressed whether claims directed to isolated genetic material constitute patentable subject matter in their respective jurisdictions.



THE MYRIAD BRCA GENE PATENTS IN SUIT

Nine composition claims from three patents were at issue in *Association for Molecular Pathology v Myriad Genetics, Inc*, 596 US 12-398 (2013), being:

- claims 1, 2, 5, 6, and 7 of US Patent No 5,747,282 (all to “isolated DNA”);
- claim 1 of US Patent No 5,693,473 (to “isolated DNA”); and
- claims 1, 6, and 7 of US Patent No 5,837,492 (all to “an isolated DNA molecule”).

The Australian Full Federal Court decision of *D’Arcy v Myriad Genetics Inc* [2014] FCAFC 115 focussed on claim 1 of Australian Patent No 686004 (to an “isolated nucleic acid”).

(individually and collectively “the Myriad Patents”).

Each of the Myriad Patents is described in its corresponding specification as “*methods and materials used to isolate and detect a human breast and ovarian cancer predisposing gene [BRCA1 for all patents except for 5,837,492 which was for the BRCA2 gene], some mutant alleles of which cause susceptibility to cancer, in particular, breast and ovarian cancer.*”

It is important to note that in the US and Australian decisions that considered the Myriad Patents discussed below, only the threshold subject matter eligibility test for patentability was considered (that is, other requirements such as novelty and non-obviousness/inventive step of the claimed invention were not considered).

THE US MYRIAD DECISIONS

The US Myriad case began in the Southern District Court of New York, which held that Myriad’s claims to isolated DNA were invalid because the DNA was a product of nature and therefore not patentable subject matter.

Myriad appealed the District Court’s decision to the United States Court of Appeals for the Federal Circuit (Federal Circuit) in *The Association for Molecular Pathology & Ors v United States Patent and Trademark Office and Myriad Genetics Inc* 653 F3d 1329 (2011), with the majority in that case overturning the District Court’s decision, holding the claims to be directed to patentable subject matter. Each of the judges of the Federal Circuit placed separate emphases on the differences between naturally occurring and isolated DNA. Whereas Judge Lourie focused on differences in physical size and covalent bonding between naturally occurring DNA and isolated gene sequences, Judge Moore placed greater emphasis on the fact that DNA does not occur in nature in an

isolated form, and that it had long been the US Patent Office’s practice to grant patents for isolated DNA molecules on this basis. Judge Bryson, dissenting, considered that the variations in covalent chemistry between naturally occurring and isolated DNA were not material as the functional coding sequence and therefore informational content of the molecule remained identical.

A further appeal to the US Supreme Court in *Association for Molecular Pathology v Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013) resulted in the Court ruling in a unanimous 9-0 decision that:

a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but that cDNA is patent eligible because it is not naturally occurring. Id. at 2111... To be sure, [Myriad] found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention. Id. at 2117.

In the US, the Myriad case has unfortunately been extended beyond the patentability of genes and the decision seems to have created a roadblock to the patentability of other naturally occurring biologics. For example, the USPTO has begun to examine patent claims for other biologics such as proteins, stem cells, and other compositions under the Myriad test and has been consistently rejecting such claims. In many instances, unless a DNA or protein sequence is claimed in combination with a detectable label, or linked to a solid support, for example, the subject matter test of section 101 has been used to reject the claims as lacking patentable subject matter under Myriad.

THE AUSTRALIAN MYRIAD DECISIONS

***Cancer Voices Australia and D’Arcy v Myriad Genetics Inc* [2013] FCA 65**

***D’Arcy v Myriad Genetics Inc* [2014] FCAFC 115**

The applicant/s in each case argued that the invention defined in claim 1 did not involve an artificially created state of affairs, asserting that there was no material difference between the claimed isolated nucleic acid and the corresponding nucleic acid in its natural state within the cells of the human body.

The patentee, Myriad, on the other hand, contended that the claim was valid because it claimed a product which consists of an artificially created state of affairs providing a new and useful effect of economic significance. In doing so, Myriad relied on evidence said to establish that isolated nucleic acid differs chemically, structurally and functionally from nucleic acid found inside a human cell.



The economic significance part of the NRDC test was not put in issue by the applicant who conceded that the isolation of the nucleic acid leads to an economically useful result – in this case, the treatment of breast and ovarian cancer.

Neither the Federal Court of Australia nor the Full Federal Court (FFC) agreed with the applicant that the isolated nucleic acid was not patentable subject matter. The FFC in particular held that “*the isolated nucleic acid, including cDNA, has resulted in an artificially created state of affairs for economic benefit*”¹ and that therefore the claimed product is patentable subject matter. Such a test is clearly broader than that applied in the US, which prohibits a patent from being granted on something that is naturally occurring, and this in part explains the difference between the outcomes of the two cases.

The FFC preferred the approach taken by Judges Lourie and Moore of the Federal Circuit who focussed on the difference between the isolated and naturally occurring DNA. Accordingly, the FFC stated that “*the analysis should focus on differences in structure and function [of the isolated molecule] effected by the intervention of man and not the similarities*” (at [155]). Further, the FFC noted that, contrary to positions of the US Supreme Court and Judge Bryson’s dissenting judgment in the Federal Circuit decision, the subject matter of the claims in the Myriad patent was “*a compound; a nucleic acid. It is not a claim to information*” (at [210]; see also [212]).

On 13 February 2015, the High Court granted D’Arcy Special Leave to Appeal the unanimous 5 judge FFC decision. This indicates that the High Court considers the patentability of isolated genetic material a legal issue of such importance that it requires addressing by Australia’s highest court. However, it should be noted that this does not necessarily mean that the High Court intends to reverse the FFC. Rather, it may indicate that the High Court wishes to issue a decision on behalf of Australia’s highest court that removes any doubt that isolated genetic material is patentable subject matter, just as it did in *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd & Ors* [2013] HCA 50, when it affirmed the lower courts’ decisions, and upheld longstanding precedent, that methods of medical treatment are patentable subject matter.

In the meantime, isolated genetic material remains patentable subject matter in Australia.

USPTO GUIDANCE AND RECENT AMBRY DECISIONS – UNCERTAINTY REMAINS

USPTO GUIDANCE

In December 2014, the USPTO issued an interim guidance notice concerning the examination of claims for subject matter eligibility (the Interim Guidance). The Interim Guidance superseded earlier guidelines that were issued by the USPTO in March 2014, and implemented a new procedure for determining the subject matter eligibility of claims under 35 U.S.C. § 101 in view of the Supreme Court’s decisions in *Association for Molecular Pathology v Myriad Genetics, Inc.* (2013) and *Mayo Collaborative Services v Prometheus Laboratories, Inc.* (2012).

Under the Interim Guidance, USPTO examiners are instructed to undertake a two-step analysis for determining subject matter eligibility under 35 U.S.C. § 101: firstly, considering whether a claimed invention is (1) “*directed to one of four statutory categories*” (i.e. a process, machine, manufacture, or composition of matter); and secondly, determining whether the claimed invention is “*wholly directed to subject matter encompassing a judicially recognised exception.*” In determining whether a claimed invention is a “*judicially recognised exception*”, examiners are directed to consider the analysis as set out in *Mayo*, being: (1) whether the claims at issue are directed to a judicially recognised exception (i.e. a product of nature, a natural phenomenon, or an abstract idea); and (2), whether any element, or combination of elements, in the claims renders them “*significantly more than the judicial exception.*”

The Interim Guidance has confined the scope of patent ineligible subject matter as compared to the previous guidelines issued by the USPTO in March 2014, clarifying that “*the application of the overall analysis is based on the claims directed to judicial exceptions... rather than claims merely involving an exception*”. Furthermore, whereas the former guidelines emphasised the importance of the existence of “*structural*” differences between a natural product and a claimed invention, the Interim Guidance has clarified that “*changes in functional characteristics and other non-structural properties can evidence markedly different characteristics.*”

¹ *D’Arcy v Myriad Genetics Inc* [2014] FCAFC 115 at 218.



While the Interim Guidance provides welcome clarification to US patent applicants in the biotechnology industry, isolated naturally-occurring material remains patentable ineligible subject matter in the US. By contrast, the Australian Patent Office continues to grant patents over isolated genes with known functions, as long as such patents do not fail for lack of novelty or inventive step.

THE AMBRY DECISIONS

Following the Supreme Court's decision in *Myriad*, a number of Myriad's competitors, including Ambry Genetics Corp. (Ambry), announced that they intended to begin marketing their own versions of Myriad Genetics' BRCA gene diagnostic test. Myriad subsequently instigated proceedings against those parties in the District Court for the District of Utah, alleging that such tests would infringe various claims in its patents that had not been struck down by the Supreme Court's decision, being:

- **Primer Claims** directed to single-stranded DNA primers that are used in the polymerase chain reaction process for replicating BRCA1 and BRCA2 genes; and
- **Method Claims** directed to techniques for screening BRCA genes for mutations by comparing patient sequences with ordinary "wild-type" sequences.

In March 2014, Judge Shelby denied a Motion for a Preliminary Injunction that Myriad had filed against Ambry, holding that Ambry had indeed "raised a substantial question of invalidity" under 35 U.S.C. § 101. Judge Shelby found that the Primer Claims may not constitute patentable subject matter because they may fall within the ambit of the Supreme Court's rejection of claims to mere isolated DNA in *Myriad*, and that the Method Claims may be rejected in the light of the Supreme Court's decision rejecting claims directed to a diagnostic method involving the observation of a natural correlation in *Mayo Collaborative Services v Prometheus Laboratories Inc* 132 S Ct 1289 (2012).

Myriad appealed to the Federal Circuit, where it argued that primers are essentially the same as cDNA, which the Supreme Court explicitly found to be patent eligible. Ambry argued, however, that a primer is essentially just isolated DNA, which the Supreme Court held to be not patent eligible. With regard to the Method Claims, Myriad argued that the methods are applications of the discovery of the BRCA gene sequences, which the Supreme Court has held are patent-eligible, not the gene sequences themselves.

In December 2014, the Federal Circuit affirmed the District Court's decision, determining that both the Primer and Method Claims were directed to patent-ineligible subject matter in violation of 35 U.S.C. § 101. The Federal Circuit found that the Primer Claims were not directed to patent-eligible subject matter because the primer sequences to which the claims were directed, were identical to the BRCA sequence directly opposite to the strand to which they were designed to bind, and structurally identical to the ends of DNA strands found in nature. The Federal Circuit therefore held that the Primer Claims were not distinguishable from the isolated DNA found to be patent-ineligible in *Myriad*.

Citing the Supreme Court's decision in *Alice Corp. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014) (*Alice*), the Federal Circuit held that the Method Claims were not directed to patent-eligible subject matter on the basis that they merely recited an abstract idea of comparing BRCA sequences and determining the existence of alterations. The Federal Circuit further held that because such sequence comparison techniques were well-understood, routine and conventional techniques used by scientists, the Method Claims contained no inventive concept capable of rendering the subject matter of the claim patent-eligible (as per *Alice* at 2355).

CONCLUSION

Isolated nucleic acid sequences are patentable in many jurisdictions, including Australia, Canada, China, Europe, Japan, Russia and South Korea. For now, the US has segregated itself and is clearly not harmonising its law with the rest of the world.

It is clear that the biotech industry in the US requires certainty following the uncertainty introduced by the *Myriad* and *Ambry* decisions. Without such certainty, pharmaceutical and biotechnology companies are unlikely to be incentivised to continue to research and develop new and useful diagnostic or therapeutic products from subject matter that is of biological origin.

On the other hand, the Australia Patent Office and judiciary's preparedness to leave any such specific subject matter exclusions to the legislature provides for a more certain non-retroactive environment, conducive to research and development, and investment, in the Australian biotechnology industry. Appropriate patent protection as well as certainty is particularly pertinent in the biotechnology industry if the advancement of medicine is not to be impeded.



THE PHARMACEUTICAL BLACKLIST IN CHINA: A LOOK BACK AFTER ONE YEAR

By Sammy Fang (Hong Kong) and Jason Chang (Beijing)

In 2007, the Ministry of Health (now merged within the National Health and Family Planning Commission or “NHFPC”) began documenting pharmaceutical companies that have committed commercial bribery offenses and “blacklisting” them so that their products are barred from entering public medical and/or healthcare institutions. Based on the “Measures of Recording Commercial Bribery of Pharmaceutical Companies” promulgated in 2007 (2007 Recording Measures), a total of 58 companies had been blacklisted. At the end of 2013, the 2007 Recording Measures were updated.

2013 RECORDING MEASURES

On December 25, 2013, the NHFPC promulgated the “Measures of Recording Commercial Bribery of Pharmaceutical Companies” (2013 Recording Measures). After this national-level measure was released, provincial authorities and local governments issued implementation opinions to carry out the 2013 Recording Measures. Pursuant to the 2013 Recording Measures, any pharmaceutical enterprise and its agents who have committed commercial bribery may be put on a “blacklist” issued by the provincial authorities. There are five situations in which a company may be placed on the “blacklist”:

- 1 If the company is deemed as having committed commercial bribery by the People’s courts, even if no criminal penalty is actually imposed by the court.
- 2 If the procuratorate’s decision of non-prosecution is because of minor criminal violations.
- 3 If the company investigated by the disciplinary inspection department because of alleged commercial bribery.
- 4 If there are imposed administrative penalties by the Ministry of Finance, State Administration for Industry and Commerce, China Food and Drug Administration and local equivalents, etc.
- 5 Other situations regulated by laws, regulations, and measures.

“Blacklisted” companies may face numerous consequences. Their products (whether drugs and/or medical devices) could be barred from entering the relevant province’s public medical institutions or the province’s medical healthcare institutions receiving public funds for a period up to two years (essentially all public hospitals in that province.) They could face reductions in scores when submitting their bids for procurement. If the company commits commercial bribery a second time within five years, its products can be barred for a period of up to two years across the country from entering all public medical institutions or medical healthcare institutions receiving public funds.



DIFFERENCES BETWEEN 2007 AND 2013 RECORDING MEASURES

The 2013 Recording Measures preserved a substantial part of the 2007 Recording Measures. We interpret the 2013 Recording Measures as amending and strengthening the 2007 Recording Measures. Specifically, the 2013 Recording Measures added the following:

- National blacklist, in addition to provincial list.
- If two violations occur within five years, increased penalties including eligibility to enter national blacklist.
- Procedural requirement for anti-corruption clauses in contracts.
- Requirement for public medical and health institutions in other provinces to give less consideration for two years for bids tendered by provincial blacklisted companies.

TWO COMPANIES CURRENTLY BLACKLISTED BASED ON 2013 RECORDING MEASURES

As of April 2015, the blacklist terms for all companies previously “blacklisted” under the 2007 Recording Measures have expired and there are no companies known to us that are currently blacklisted under the 2007 Recording Measures. However, we have identified two companies that are currently blacklisted based on the 2013 Recording Measures:

On October 16, 2014, Chongqing Weixin Medical Supplies Co., Ltd. (Weixin) was put on a provincial blacklist for a duration of two years. It is the first company to be blacklisted

based upon the 2013 Recording Measures. Weixin is a private company registered in the Chongqing Municipality and specialized in selling medical equipment. It was alleged that its General Manager provided the former head of the Equipment Division of Chongqing No. 13 Hospital with “favor fees” amounting to CNY 135,000 (approximately USD 21,787) during a procurement project. According to Article 4.2 of the 2013 Recording Measures and Article 173 of PRC Criminal Procedure Law, Chongqing Health and Family Planning Commission decided to put Weixin on the provincial blacklist even though the bribery offense appeared to the authorities to be relatively minor and the People’s Procuratorate had decided not to prosecute Weixin nor its General Manager.

On February 16, 2015, Hainan Baozhiyuan Medical Technology Co., Ltd. (Baozhiyuan) was put on a provincial blacklist for a duration of two years. Baozhiyuan is a private company registered in the Hainan Province. It was alleged that the company paid kickbacks to the medical personnel of 12 hospitals based on a percentage of sales. These payments amounted to commercial bribery. The Industrial & Commercial Administration Bureau of Hainan Province imposed an administrative penalty on the company which includes the confiscation of the company’s illegal income amounting to CNY 302,621 (approximately USD 48,839) and a fine of CNY 100,000 (approximately USD 16,139). The Hainan Health and Family Planning Commission accordingly put Baozhiyuan on the provincial blacklist.

AUSTRALIAN EMPLOYEE SHARE SCHEMES

By Brett Feltham (Sydney) and James Newnham (Melbourne)

SO IN BROAD TERMS WHAT DO THE CHANGES AFFECT?

As part of its Industry Innovation and Competitiveness Agenda, the Australian Government committed to changing the tax treatment of employee share schemes (ESS) that were introduced by the former Government in 2009. In January 2015, the Australian Government released exposure draft legislation, and following a period of consultation with key stakeholders, draft legislation was introduced into the Australian parliament on 25 March 2015.

Once that draft legislation is passed into law, the ESS tax rules implemented in 2009 will be reversed (at least in part), and a new ESS tax regime will come into effect for ESS grants made on and from 1 July 2015. The current tax rules will continue to apply to grants made before 1 July 2015.

Late last year, the Australian Securities and Investments Commission (ASIC) also released new ESS relief in the form of two new class orders: ASIC Class Order 14/1'000 for listed entities; and ASIC Class Order 14/1'001 for unlisted entities. These new class orders provide relief to companies from disclosure (prospectus), licensing and hawking requirements under the Corporations Act 2001 (Cth) for offers of securities made under employee incentive schemes, and provide more broader relief, in terms of incentives and types of participants covered, than was previously available.

One issue with the current tax rules is that to defer income tax on an ESS discount, the offer to an employee needs to include a “real risk of forfeiture”. This means that in order not to give an employee an “up-front” tax bill, their equity interests needed to be “at risk” of being forfeited, if certain circumstances arise. The most common condition of forfeiture is where the employee leaves employment pre-vesting and this would mean that they forfeit their interests. This can make it very hard for employers to incentivise employees where the employee may have the choice between paying tax up-front, or deferring tax, but practically attributing nominal or nil value to their ESS equity, due to the risk of forfeiture.

The process by which options are valued can also create the situation where “out of the money” options (i.e. where the exercise price is more than the share market value) will still have a positive market value for tax purposes, generally due to the period that the option can be exercised. This creates an unusually unfair outcome as the employee can be taxed when an option vests, even if the option is “out of the money”, and even in circumstances where the option may not be exercised and the employee may never realise any value in the future. Not surprisingly, this saw a movement away from issuing options to Australian employees.

SO WHAT ARE THE PROPOSED TAX CHANGES FOR ALL COMPANIES ISSUING OPTIONS?

Under the proposed tax changes, employees who receive options (or rights to acquire shares) will generally only be subject to income tax on any discount once the option has been exercised by the employee (provided the option itself cannot be traded) and there are no disposal restrictions on the resulting shares. This position is broadly consistent with the treatment of ESS in other countries. That tax deferral may now also extend for up to 15 years.

Tax deferral may also be available in some circumstances even when there is no risk of forfeiture of an ESS interest, but that ESS interest is restricted from being immediately disposed of by the employee. In order to meet this test the scheme documents are required to state that the ESS is subject to specific provisions of Australian tax legislation. This amendment may allow companies to introduce new plans or reintroduce old plans, such as salary and bonus sacrifice plans, where the employee considers that they have already “earned” the award and as a result an employee would not wish to participate where there was a risk of the employee forfeiting the shares granted to them.

ISSUE TO BE AWARE OF!

Unfortunately, the cessation of employment as an earlier taxing point will remain, keeping Australia out of step with most of the developed world. Where an employee ceases employment but continues to hold their options/rights (perhaps because they are a “good leaver”), then they will still be required to pay tax at the time of cessation while not having yet (and maybe never having) realised any value. As a way of partially addressing this issue, if an employee chooses not to exercise those options in the future or allows those options to lapse, the employee will be able to obtain a refund of the income tax they have already paid.

The general eligibility conditions for employees to be able to receive tax deferral will also be relaxed, so that employees who do not own more than a ten percent shareholding in their employer or who do not control more than ten percent of the voting rights in their employer, can access that deferral (an increase from the previous five percent limits). These limits are obviously more relevant for smaller companies operating in the sector.

Capital gains tax (CGT) will remain payable on the sale of shares granted or which are received on exercise of an award, and where the shares are held for more than twelve months and certain other requirements are met, the 50 percent CGT discount will continue to apply to any capital gain. However, for options/rights, any increase in value between vesting and exercise of those options/rights will be subject to income tax and not CGT (and any increase during that period will not attract the 50 percent CGT relief).

ISSUE TO BE AWARE OF!

For those companies who do not meet the start-up criteria (see below), employees may still not be able to readily transfer or sell their shares in any event. This could be the case where private companies restrict the ability of employees to transfer shares outside of a quarantined group of 'related' people and entities, and even for listed companies whose shares are thinly traded. For employees of those companies, they can still be left in the position where they are required to pay tax in circumstances where they may not be able to easily realise any benefit. Expert assistance should always be sought in these circumstances.

WHAT ARE THE PROPOSED TAX CHANGES FOR START-UP COMPANIES?

As part of the changes, the Australian Government has proposed specific tax concessions where a "start-up company" meets specific criteria. When those criteria are met, the discount on an ESS interest issued by these companies is not included in an employee's assessable income. The intention behind these proposals is that start-ups are able to offer employees more attractive remuneration packages to attract more and better talent.

WHAT IS A START-UP?

The term start-up is not itself defined and the rules are not limited to a particular type of business.

The **main qualification requirements for a company** to be an eligible start-up company are:

- the company must not be listed;
- the company and all group companies must be less than ten years old;
- the aggregated turnover of the group must not exceed AU\$50 million (aggregated turnover including connected entities and foreign entities connected to the group);
- for **shares** – the discount on the ESS interest must be less than 15 percent of the market value;
- for **options and rights** – they must have an exercise price that is equal to or greater than the current market value of an ordinary share (i.e. issued at market value or out of the money);
- an employee must be required to hold their shares, options or rights for the "minimum holding period". The minimum holding period is the same period which currently applies (and will continue to apply) for \$1,000 tax exempt schemes – the shares, options or rights must be held for three years or until the employee ceases employment. The Tax Commissioner may exercise his or her discretion to reduce this period (and as a result for the concession to continue to apply) in situations where all relevant employees are required to dispose of their options, rights or shares prior to the end of that period (such as on a trade sale or IPO) and where there was an original genuine intention for the minimum holding period to have been met; and
- for **shares** (but not options or rights) – the scheme must be available to at least 75 percent of the permanent employees with at least three years' service; and
- an employee must not hold more than 10 percent of the shares in the company (including the shares that could be acquired by exercising options/rights held by that employee).

In applying the listing, the 10-years and aggregate turnover threshold limits, investments by eligible venture capital and early stage venture capital funds can be ignored. This will mean that assets and investments of those kinds of partnerships and funds will not affect an investee start-up company's ability to access the start-up concessions.

As part of the consultative process, the Australian Government acknowledged that there were strong calls for the start-up company concessions to be extended to cover biotech and other companies (including those incorporated for more than 10 years), but no extension of the concession was made to meet those calls.

The requirement that only a “small discount” apply to the options/rights or shares means that eligible start-up companies wishing to issue options which are immediately “in the money,” performance units or rights (which are akin to an option with a zero exercise price or ZEPOs), or shares at a significant discount to employees, will not be able to take advantage of the proposed tax concession. The Australian Government’s position is that this requirement is necessary to ensure that the concession is appropriately targeted, is not subject to potential abuse through inappropriate salary packaging, and is fiscally sustainable.

Generally where a share is sold, it must have been held for more than 12 months in order for an employee to be eligible to receive the 50 percent CGT relief. The draft legislation makes clear that the 50 percent CGT relief will be available to an employee where they have received options or rights subject to the start-up concession and they have held the options/rights and shares collectively for at least 12 months, even where the shares they received on exercise have been sold by them within 12 months of exercise of their options/rights.

The restrictions in terms of ownership and discount value are not helpful. Often start-ups seek to supplement cash remuneration by offering executives an ESS interest as a way to attract and retain talented individuals. These parts of the rules, in effect, restrict the amount of salary that can be supplemented in this way. In addition, the limitation on the discount will require companies to value the shares of the company to ensure the discount limit is not exceeded (which may increase compliance costs).

WHAT ISSUES DO THE NEW ASIC CLASS ORDERS ADDRESS?

ASIC now provides more standard relief for companies than it has previously (although available relief continues to be more restricted for unlisted companies than that available for listed companies).

The new class orders also address a number of issues previously experienced by companies when seeking standard relief. Some of the key improvements include:

- widening the range of financial products that are eligible for relief, particularly in relation to offers made by listed entities;
- extending the types of participants that can be potentially covered;
- reducing the administrative burden of complying with class order requirements, including those specific to trust structures and the regulatory notification requirements; and
- increasing the cap on the number of shares that may be offered from five percent to 20 percent for unlisted entities in recognition of the greater need for such entities to use these schemes to incentive and retain employees.

However, some issues do remain, including:

- some incentive schemes will remain excluded from coverage (such as schemes that offer phantom/shadow shares or certain derivative instruments) and specific relief will still need to be sought;

- some contribution plans will remain excluded from coverage (including where contributions can be used to acquire options or “incentive rights”); and
- in relation to loan funded share schemes, coverage is restricted to where interest-free loans are used.

WHAT DO THESE CHANGES MEAN FOR COMPANIES AND PARTICIPATING EMPLOYEES?

The proposed tax reforms are a welcome development, as they will provide some measure of control to an employee as to when their options are taxable (when the options are actually exercised) and reduce the risk of an employee being taxed on options received at a time when they have not actually realised any value. Those employees will now potentially be able to fund their tax bill by selling some of the shares they receive on exercise. Clearly a common sense result.

However, these tax reforms do not appear to go far enough in meeting all of the challenges faced under the current tax regime and to allow Australia to effectively compete with other jurisdictions in relation to attracting and retaining talented employees.

The relief available under the new ASIC class orders should assist companies to continue to offer, and in some cases expand to offering, Australian based employees (and others) participation in ESS.

Companies will need to seek expert guidance on whether any of their current schemes and/or practices need to be modified in order to meet the new ASIC class order requirements and to operate as intended under the proposed tax changes.



CHINA'S FIRST REGULATORY FRAMEWORK FOR BIOSIMILAR APPROVAL

By Yan Zhao and Bing Li (Shanghai)

It is evident that biologic drugs are playing an increasingly important role in the global medicinal market. However, the Economic Institute of the China Food and Drug Administration (CFDA) has predicted a large number of these biologic drugs will lose their patent protection in the next five years and, as a result, biosimilars are expected to increase market share rapidly, in the same manner as we have seen in the block buster small molecule patent cliff of the last few years.

There exists a constant debate as to the best way to boost the biological drug and biosimilar market in China. In contrast to small molecule drugs, biologic antibody drugs account for a only a small proportion of the available and approved drugs in China largely because of their higher price and the lower reimbursement price in the internal health insurance system. In addition, under current practice, approval of biosimilar drugs follows the same process as those required of new drugs, which is time consuming and expensive.

On 4 March 2015, the CFDA released a Guidance on the Development and Evaluation of Biosimilars (For Trial Implementation) which for the first time proposes a regulatory framework for the abbreviated approval of biosimilar drugs. The Guidance has been welcomed by industry and

proposes a framework which could allow for biosimilars to undertake an abbreviated approval process. The Guidance sets out a step by step process in order for the CFDA to determine whether a candidate biological product is biosimilar to its reference product approved in the Chinese market.

Under the Guidance, the CFDA sets out three types of comparability testing that may be required in order to evaluate biosimilarity, namely:

1. Pharmaceutical data, including the structure, purity, biological activity, stability, cell substrate, dosage, and package material study data;
2. Nonclinical evaluations data, including the pharmacokinetic (PK) and pharmacodynamics (PD), immunogenicity, and toxic data; and
3. Clinical pharmacology data, including the human PK and PD studies, clinical immunogenicity testing, and clinical safety data.

The Guidance proposes that this data should be collected in a step by step manner. Where no or little difference in comparability testing is demonstrated this could allow subsequent comparability tests to be skipped.

Whether a product is determined as being not different, slightly different or uncertain will be decided by the results of each of the studies, and in turn the results will determine to what extent further studies, if any, are required. A biosimilar which is assessed as ideal need not undertake some of the comparative studies, while those biosimilars where differences to the comparator biological are identified will be required to undertake studies which will investigated the biosimilar further.

Although the Guidance sets out detailed scientific considerations of the studies required, it fails to specifically define the degree of similarity necessary in order for subsequent comparability steps to be skipped. Despite the lack of clarity in this respect, the industry has welcomed the Guidance as an abbreviated approval process for biosimilars will certainly increase the accessibility of biosimilars and reduce the cost of bringing biosimilars to market.

The CFDA will adjust the Guidance according to the situations and the problems encountered during the stage of trial implementation. We will keep you updated on the progress of the Guidance, particularly in respect of whether the CFDA introduces a defined similarity standard.



REGISTRATION OF AGRICULTURAL AND VETERINARY PRODUCTS IN AUSTRALIA CHANGES TO USE OF REFERENCE PRODUCT INFORMATION

By Katherine Armytage and Brodie Williams (Canberra)

Companies seeking to register a new pesticide or veterinary product in Australia should note the new guidelines published by the Australian Pesticides and Veterinary Medicines Authority (APVMA) which relates to the access and use of information held by the APVMA. This is particularly the case if they wish to rely on an already registered product as a “reference product” in order to satisfy the application criteria.

All agricultural products and veterinary medicines must be registered in Australia by the APVMA. As part of the application process, applicants are required to provide information to satisfy the APVMA that the statutory criteria has been met (including the safety criteria, the efficacy criteria and the trade criteria). Much of the information provided by applicants will have various statutory protections against further use and/or release by the APVMA, including information which falls within the definition of “confidential commercial information” (CCI).

The APVMA has recently published new guidelines about how it will identify, use and disclose information held by it, including information that may be CCI.

The changes to the APVMA’s practice impact upon new applications which seek to satisfy the statutory safety, efficacy or trade criteria by relying on that product being similar, closely similar or the same as an already registered or approved product (reference product).

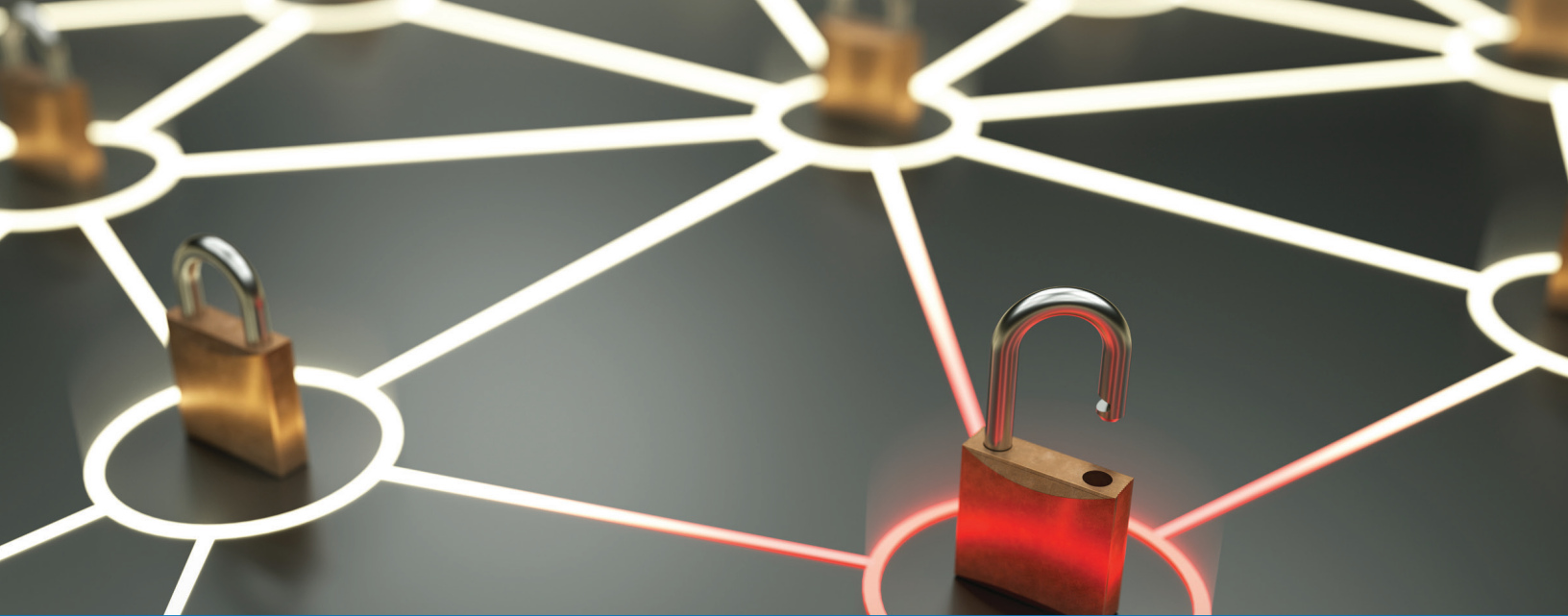
Applicants seeking to nominate a reference product, and rely on material related to that reference product, in order to register a new product must now either:

- obtain and provide to the APVMA consent from the holder of the registration or approval for the reference product (or the party which “owns” the relevant information, such as the manufacturer); or
- provide all information necessary to establish that the relevant aspects of their product are similar, closely similar or the same as the nominated reference product (for example, by providing further copies of the reference product material properly obtained from the owner of the material, or by providing new, independently sourced material); or

- provide evidence to the APVMA which demonstrates the material held by the APVMA about the reference product is not CCI (for example, because it is available in the public domain).

The form of consent will be important. Companies seeking consent should ensure that it is in writing, identifies the information in question and expressly allows the APVMA to access, use and disclose that information. On the other hand, companies who receive a request to provide their consent should ensure that it specifies any limitations that apply to the consent (for example, the consent may only allow the use and disclosure of the information to the APVMA to the extent that it is necessary to determine the application in question or may allow use by the APVMA but prevent disclosure of the material to the applicant).

Applicants should refer to the guidance available on the APVMA’s website to ensure they are in line with the updated requirements and review the changes before lodging any application which seeks to rely on material related to a nominated reference product. [Click here](#) for further details.



CONFIDENTIAL INFORMATION IN AUSTRALIA – PROTECTING YOUR MOST VALUABLE ASSET

By Andrew Ball and Stacey Holloway (Sydney)

So how can employers in the life sciences industry ensure that their most valuable asset is properly protected?

Employers who suspect a breach or imminent breach should:

- ✓ **Act quickly** – Confidentiality can be lost at a click of a button, so the longer the delay, the greater the chance of the business losing its competitive advantage. Courts do not look kindly on employers who drag their heels and then seek draconian injunctive relief.
- ✓ **Seek undertakings from the employee** – (and possibly the potential employer). Remind them of the employee’s contractual obligations, and seek to obtain promises not to breach them (or induce breaches of them). Many companies require individuals to sign undertakings on exit confirming that they have returned all company property, have not removed or copied any confidential information, and will not breach their restraints. A breach of an undertaking is an easier basis on which to seek an injunction and/or damages.
- ✓ **Gather evidence** – The most common stumbling block for employers seeking injunctive relief is a lack of evidence. Companies should not under-estimate the time that it takes to have a laptop forensically examined, or to review thousands of emails for the “smoking gun.” But an injunction is a draconian remedy so, without hard evidence, Courts are unlikely to grant it.

In an industry which relies so heavily on intelligence, innovation and ideas, employees are integral to success. But in a digital age where information can be copied, stored and passed on more easily than ever, they also have potential to be its biggest threat.

All employers should be alive to the need to protect their confidential information. But in the Life Sciences industry, in an increasingly competitive marketplace where information is particularly sensitive and valuable, this issue should be at the very top of employers’ agendas. Once lost, confidentiality is almost impossible to regain, so prevention really is the key.

So how can employers in the Life Sciences industry in Australia ensure that their most valuable asset is properly protected?

BASIC LEGAL PROTECTIONS

Competitive behaviour

In Australia, employees owe a duty of good faith to their employer. This means that competing with their employer during working hours or misusing company property for their own gain is off limits, as is soliciting clients and customers (or damaging the employer's client relationships) for their own purposes.

The common law protection, however, is not as wide-ranging as it first appears. For example, preparing for competition outside of working hours or poaching clients on behalf of a new employer may not be prohibited after the employment ends. And what constitutes competitive behaviour or "poaching" will be left to a Court to decide. So it is strongly advisable for employers to set clear boundaries of acceptable behaviour themselves.

Confidential information

During employment, confidential information cannot be used for any purpose other than as directed by the employer. And after termination protection of "trade secrets" continues indefinitely. So employees who work in critical areas and who hold information about secret formulas or patented products are prevented from sharing that information with anyone at any time. Although what constitutes a "trade secret" under the common law will not be as wide as many employers would like.

In most cases, unless employers are dealing with secret formulas or an employee who has deliberately copied and removed documents containing confidential information, they will find the common law of limited use.

Information about market strategies, products in development, client lists, pricing models, know how, and employee remuneration and

incentive packages are all examples of information which employers would view as confidential, but which the common law is unlikely to protect, especially after termination.

Intellectual property

Employees in the Life Sciences sector are more likely than most to create intellectual property (IP) during the course of their employment. Generally, IP belongs to the employer if it was created during normal working hours and within the scope of the employee's normal duties. But if IP is created outside of those boundaries, then there is a very real risk that it would belong to the employee. In an industry where that IP can be worth millions and employees are being rewarded handsomely to create it, employers need to ensure that they have full and unencumbered ownership of all IP rights immediately – and this requires contractual provisions.

Contractors

Contractors are not bound by the same duty of good faith as employees, nor are they bound by the common law duty of confidentiality. They will generally own all IP that they create, whether or not it is within the scope of their engagement and/or during their contracted hours. So it is vital that companies build appropriate express protections into their consultancy agreements.

CONTRACTUAL PROTECTIONS

So, while the common law in Australia does provide some degree of protection for employers, the boundaries of implied terms are open to challenge. Clear and express contractual clauses are strongly recommended to properly protect businesses from unfair competition – particularly in the Life Sciences industry where these issues potentially have such significant value.

Employers should consider having the following in their employment contracts:

- A general contractual obligation to act at all times in the best interests of the company and to comply with all lawful and reasonable directions and all non-contractual policies.
- An absolute prohibition on competition or "moonlighting" during the term of employment.
- A confidentiality clause which defines in detail that information which the employer considers to be confidential, and prohibits the employee from disclosing or using that information both during employment and indefinitely after termination. This can also require employees to use best endeavours to actively prevent the misuse of confidential information.
- An IP clause which assigns all IP created to the company to the extent permissible by law, or gives the company the right to use that IP on a royalty-free basis if assignment is not permissible (for example, in relation to moral rights which cannot be assigned).
- A garden leave clause. This provides significantly greater protection than any post-termination restraints since Courts are much more willing to enforce the employer's rights while the employee remains on payroll.
- Post-termination restraints, which can seek to prevent competition, poaching of employees, and the solicitation of and dealing with clients, customers and suppliers. Post-termination restraints will only be enforceable if they go no further than is reasonably necessary to protect the legitimate interests of the company (which includes trade secrets, confidential information, and client and supplier connections). Restraints need to be carefully considered and tailored to

each employee in order to stand the best possible chance of being enforceable, and employers should also note that laws differ between States and Territories so legal advice is recommended.

Similar provisions are also needed for contracts with contractors and agencies.

OTHER WAYS TO PROTECT YOUR CONFIDENTIAL INFORMATION

Non-contractual policies

Non-contractual policies can be used to convey to employees what information the business regards as confidential, and can be updated as necessary to keep pace with the law and new technologies.

Policies should be reviewed and refreshed on at least an annual basis, and employees should be required to acknowledge that they have read and understood them.

Treatment of information

Courts will only protect information which is truly confidential, so companies should look carefully at how its confidential information is treated

and controlled internally. These measures should only be applied to truly confidential information – not all information, otherwise the value is diluted.

Truly confidential information should be disclosed on a “need to know” basis and marked confidential. It should be kept under lock and key and/or password protected, and encryption software should be used when sending it by email. Induction programmes should place a heavy emphasis on the importance of confidentiality and policies should be rigorously implemented to help to demonstrate that certain information is zealously guarded. Action should be taken promptly in the event of breaches.

Monitoring

Employees should be made aware that email communications are monitored, in case an investigation is ever needed. Businesses should be on alert for high risk employees – those with access to a high level of confidential information and those who are the sole contact for certain clients pose the biggest threat to businesses. Employees who suddenly

display irregular or unusual behaviour, a downturn in performance, increased absence patterns, or an irregular focus on specific clients should all be monitored more closely.

ENFORCING CONTRACTUAL PROTECTIONS

If a company suspects an employee of breaching confidentiality obligations and/or restraints, the immediate priority is damage limitation: preventing the confidential information from getting into the hands of your competitors, and preventing the employee from breaching their restraints.

Employers can apply to the Court for injunctive relief which, if granted, will require the employee to comply with their contractual obligations and ban them from doing certain things. If made, an injunctive order will prevent damage to the business, so it is a better option than the alternative, which is to seek damages to compensate for the (often unquantifiable) damage caused by the breach.





AUSTRALIAN CLASS ACTIONS OF 2014

By Kieran O'Brien and Adam Stevens (Melbourne)

2014 saw significant local activity in the class action space, with plaintiff law firms aggressively generating interest in pursuing mass tort litigation.

The highpoint of 2014 was undoubtedly the settlement of the Black Saturday Kilmore East-Kinglake bushfires class action. Approved by the Victorian Supreme Court on 23 December 2014 (judgment was still pending following a lengthy trial when the litigation settled), the plaintiffs will receive \$494 million for losses sustained in this bushfire, less costs, making it the largest class action settlement in Australian legal history.

The second largest settlement for 2014 came in the Great Southern litigation involving a failed investor scheme, again a compromise whilst a Victorian Supreme Court judgment was pending following a lengthy trial (and the largest class action settlement until the Black Saturday settlement). The settlement is now subject to a proposed scheme of arrangement. Again in the financial industry, whilst the February 2014 Federal Court Ruling that ANZ Bank charged exorbitant late payment fees might have emboldened the plaintiff law firm involved to continue with its class actions against numerous other banks, the April 2015 full Federal Court judgment which found for the ANZ Bank on all issues may cause both plaintiff lawyers and litigation funders to reflect on whether such speculative litigation is commercially worth pursuing (although a High Court appeal seems likely).

Plaintiff law firms appear to be closely monitoring company reporting and shareholder announcements, and one cannot help but sympathise with companies who are targeted in this fashion, with mass tort litigation proving a costly distraction both on an operational and financial basis. The scope of discovery alone in such disputes can be an incentive to explore settlement options.

The fact that the plaintiff's legal costs in each of these actions will assess in the millions will no doubt encourage plaintiff law firms to pursue similar mass tort litigation opportunities. While class actions arising from fires and financial institutions (particularly continuous disclosure obligations) appear to be growth industries, there is no doubt that the "traditional" product liability class action (i.e., a pharmaceutical manufacturer and a drug or device supplied to the market with adverse effects leading to personal injury) will continue to have a significant footprint in the class action space locally and internationally. The Federal Court approved a settlement (for an undisclosed amount) involving a drug which was alleged to cause (at least in part) compulsive behaviours such as gambling and hypersexuality. There has also been a proposed settlement of a similar but separate class action, subject to receiving court approval. We also witnessed the Victorian Supreme Court approve a settlement in which Australian and New Zealand plaintiffs will receive \$89 million as compensation for the burden of living with severe physical deformities said to be associated with their mothers using a particular drug during pregnancy.

In addition to the 2014 settlement highlights, it appears that the class certification requirements are easier to achieve locally than internationally. By way of example only, we observed two Federal Court class actions being allowed to proceed against several pharmaceutical companies (both settled in 2014 subject to Court approval), however comparable proceedings in the US were not able to proceed as class actions and instead were dealt with in tranches involving numerous US plaintiff law firms. Companies should look seriously at challenging at the outset whether a class can be certified when such mass tort litigation is threatened or issued.

For other matters, the courts have adopted a far more conservative approach. In the case of *Treasury Wine Estates* (*Treasury*), for instance, which has been targeted in two separate class actions arising from a 2013 write-down announcement, *Treasury* was successful in having the Victorian Supreme Court rule that a minor shareholder's company, known as "MC I" (of which a practicing lawyer is the sole director and sole shareholder) could not continue as both the lead plaintiff and the solicitor on the record in the separate class action that his company had issued. *Treasury* was unsuccessful, however, in having the Victorian Supreme Court conclude that the class action was an abuse of process. On appeal, however, the Victorian Court of Appeal overturned the decision. The Court of Appeal, by majority, held that the class action was an abuse of process on the basis that the predominant purpose of the proceeding was enabling MC I's sole director and sole shareholder to earn legal fees and said (at [13] to [14]):

"The nature of the cause of action – as a claim based on an alleged breach of disclosure requirements – is immaterial to MCI's purpose. Its sole purpose has only ever been to create for itself – in this case, by acquiring a small parcel of shares – a cause of action to sufficient merit to induce the defendant company to pay Mr Elliott's [the practicing lawyer, sole director and sole shareholder of MCI] fees.

It seems to us that this is a clear example of an abuse of process. The process of the Court do not exist – and are not to be used – merely to enable income to be generated for solicitors. On the contrary, they exist to enable legal rights and immunities to be asserted and defended. In the common form of class action, that is the sole purpose of proceedings. The members of the class wish to vindicate their rights. The fact that success will result in the solicitors' fees being paid does not affect the proprietary of the proceeding"

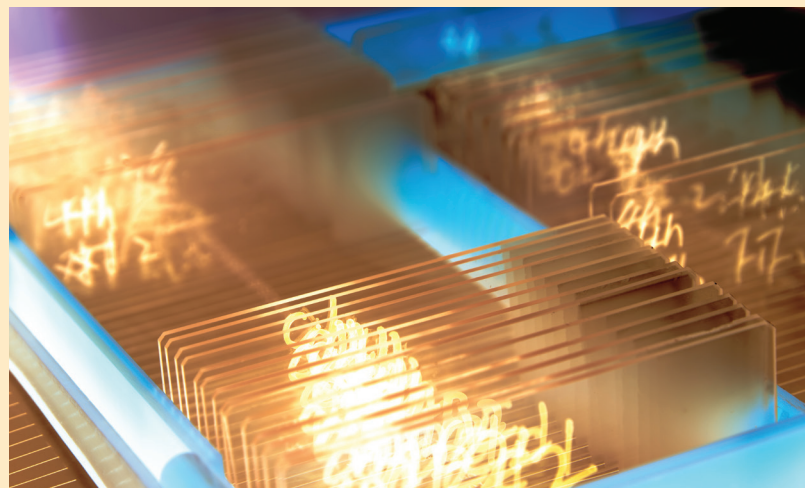
(Citation/Footnote: *Treasury Wine Estates Ltd v MCI* [2014] VSC 351)

The Court went on to say (at [21]):

"... there would have been very few cases in the history of Anglo-Australian litigation where a plaintiff has instituted a proceeding with the predominant purpose of enriching its solicitor, and indeed it would probably not have been a realistic possibility until the advent of the modern form of class action litigation during the last 20 years."

(Citation/Footnote: *Treasury Wine Estates Ltd v MCI* [2014] VSC 351)

2015 is expected to see continuing interest in mass tort litigation, particularly in view of the settlements achieved in 2014, the ongoing influence of litigation funders, and the Productivity Commission still pondering the benefits of recommending the introduction of contingency fees. If contingency fees were to be introduced in any form, that may diminish the influence of litigation funders as plaintiff lawyers seek to increase their share of the costs, thereby mirroring the situation in the US where litigation funders have little influence on account of the fact that the US Plaintiff Bar self-funds and in the process recovers significant costs, often in frivolous consumer class action claims and the like (such claims may have some attraction to Australian plaintiff lawyers given the ever-increasing focus by regulators on product misrepresentation, and the fact that such claims would not be subject to tort reform). The prospect of additional financial incentives to litigate on a mass tort scale being rolled out is something that corporate Australia (insurance, financial, pharmaceutical or otherwise) should be very wary about given the appetite for class action litigation that already prevails, although decisions like the recent ANZ Bank full Federal Court decision will no doubt be welcomed by large corporates who might be targeted.



Q&A WITH SCOTT THIEL



Scott Thiel is a partner in the firm's life sciences sector and intellectual property and technology practice.

What are your key areas of practice?

Regulatory and commercial, particularly to assist clients access new markets. Information law issues including cyber security and data privacy are some of the key challenges for clients operating in Asia as the moment.

You have a background in engineering and dual qualifications in both ip law and science. How has this assisted you with your practice in the life sciences sector?

The science background gives me an greater appreciation of the core business of our life sciences clients and this enables me to provide more tailored and commercially focussed advice. The masters in Intellectual Property enables me to understand the technical legal issues surrounding some of the most valuable assets in any life sciences business.

You have worked as a lawyer in Australia and the uk, and are now a partner in Hong Kong. What attracted you to working in Asia?

It is a region with huge opportunities for our global client base, and I wanted to be at the coal face of that process. It is also a great place to live and work.

What is your favourite thing about living in Hong Kong?

I can be walking though the concrete jungle and madness of the central district and 20 minutes later be running along a track in the real jungle.



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