DLA PIPER

ASIA PACIFIC

LIFE SCIENCES SPOTLIGHT

A NEW WAVE OF REGULATORY ENFORCEMENT ACTIONS IN CHINA

AUSTRALIA'S INNOVATION PATENT

BEST PRACTICE DISCLOSURE FOR LIFE SCIENCES COMPANIES

THE NEW WORKPLACE BULLYING LAWS AND PERFORMANCE MANAGEMENT

CAN REVERSE PAYMENTS IN PATENT SETTLEMENTS CONSTITUTE CRIMINAL CARTEL CONDUCT?

UNRAVELLING THE HELIX

www.dlapiper.com | Issue 3, 2013

GUEST EDITOR'S COLUMN

Welcome to the second issue of *Life Sciences Spotlight* for 2013.

We began ***Life Sciences Spotlight*** in 2012 with the aims of providing a publication that:

- specifically targeted companies in the Life Sciences sector;
- addressed the range of issues confronting companies in that sector by drawing on the expertise of more than 200 lawyers that practice in DLA Piper's Life Sciences sector team around the world; and
- included a discussion of various issues from different legal perspectives within a single jurisdiction or from the same legal perspective across multiple jurisdictions.

We are delighted to offer this issue with a series of articles with these aims in mind.

In our regular *Unravelling the Helix* article, Andrew Ball, Elizabeth Ticehurst and Simone Mitchell discuss what internal obligations and potential legal risks may arise for Life Sciences companies when their sales representatives make certain misrepresentations during the course of promotion and marketing of pharmaceutical products.

Also in this issue:

- Simon Uthmeyer discusses the recent decisions by the United States Supreme Court and the Director General of Competition in the European Union regarding reverse payments in patent settlements, and then considers how the issue would be treated in Australia;
- Leah O'Brien discusses the most recent decision in the Australian Vioxx case and the recent decision by the United States Supreme Court in the *Myriad Genetics* case;
- Sammy Fang discusses a new wave of regulatory enforcement actions in China;
- Simon Davidson discusses best practice disclosure for Life Sciences companies in Australia;
- Andrew Ball and Tass Angelopoulos discuss the new Australian workplace bullying laws and performance management;
- Jessie Buchan and I discuss Australia's innovation patent system, which offers a patenting opportunity to Life Sciences companies not available anywhere else in the world; and
- Q&A with Sammy Fang, one of our Life Sciences partners based in China.

On a separate note, Dr. Lisa Haile, one of the leaders of DLA Piper's global Life Sciences sector team based in the United States and I will be presenting a session at the upcoming AusBiotech 2013 National Conference at the Brisbane Convention & Exhibition Centre on 31 October 2013. We hope to see you there.

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

Nicholas Tyacke
Partner, Sydney
T +61 2 9286 8502
nicholas.tyacke@dlapiper.com
Web Profile

IN THIS ISSUE...

FEATURES

REGULAR COLUMNS

CONTRIBUTORS

Andrew Ball, Partner, Employment

Simon Davidson, Partner, Corporate

Sammy Fang, Partner, Litigation and Regulation

Dr Simone Mitchell, Partner, Intellectual Property & Technology

Nicholas Tyacke, Partner, Intellectual Property & Technology

Simon Uthmeyer, Partner, Litigation and Regulation

Tass Angelopoulos, Special Counsel, Employment

Leah O'Brien, Senior Associate, Intellectual Property & Technology

Elizabeth Ticehurst, Senior Associate, Employment

Jessie Buchan, Solicitor, Intellectual Property & Technology

UNRAVELLING THE HELIX

In each issue of *Life Sciences Spotlight*, partners in the DLA Piper Life Sciences team will assist in unravelling the legal aspects of a real-world Life Sciences dilemma using a hypothetical fact situation. In this issue, Andrew Ball, Elizabeth Ticehurst and Simone Mitchell discuss what internal obligations and potential legal risks may arise for Life Sciences companies when their sales representatives make certain misrepresentations during the course of promotion and marketing of pharmaceutical products.

FarmaPharma Pty Ltd (FP) has released a new pharmaceutical product indicated for the treatment of diabetes. As part of the marketing and promotion of this product, FP has employed a team of sales representatives to detail and promote the product to general practitioners. During a series of visits to general practitioners, one of FP's sales representatives makes a number of misrepresentations to general practitioners regarding the product. This includes false representations regarding the efficacy and side effects of the product.

FP wishes to terminate the sales representative as an example to its other employees. FP comes to you for advice regarding its internal obligations and potential legal risks. FP would also like advice on the types of training required to be undertaken by sales representatives and how to make training as effective as possible so that FP can avoid, as best it can, future problems.

ANDREW BALL AND ELIZABETH TICEHURST'S PERSPECTIVE

Andrew Ball is a partner in the Employment group, based in Sydney. He has extensive experience across all areas of employment and workplace relations including industrial relations, employment, discrimination and sexual harassment issues, as well as occupational health and safety. You can reach him at: andrew.ball@dlapiper.com

Elizabeth Ticehurst is a senior associate in the Employment group, based in Sydney. She has significant experience advising on a wide range of employment issues, including performance management and discipline; terminations and redundancies; discrimination and harassment claims; work health and safety; employee investigations; and transmission of business. Elizabeth is fluent in English and Japanese and can speak conversational Mandarin. You can reach her at: elizabeth.ticehurst@dlapiper.com

Whether FP can validly dismiss the sales representative depends on the following factors:

(i) whether the company has any policies that cover representations to clients;

(ii) whether the sales representative has been previously warned about making these kind of representations, or other misconduct; and

(iii) the process that the company goes through to dismiss the sales representative.

The sales representative is likely covered by the Commercial Sales Award 2010. This award covers sales people who are *"employed away from, or substantially away from, the employers' place of business"* and are engaged in soliciting orders for or selling goods, or promoting the employer's products. The sales representative could also be covered by an enterprise agreement, if the employer has one.

Coverage by a modern award or an enterprise agreement means that the sales representative can make a claim for unfair dismissal, even if his or her salary exceeds the high income threshold (currently AU$129,300), as long as he or she has been employed for at least six months. If FP wishes to terminate the employee, the company needs to give careful consideration to the following elements of an unfair dismissal claim, to make sure that it can defend any claims by the employee.

Is there a valid reason to dismiss the sales representative?

The sales representative has potentially exposed FP to liability by making false representations about the product. However, this may not be sufficiently serious to constitute a "valid reason" for dismissal, unless the employee has been given training about how to describe the product, and specifically instructed not to deviate from the company's approved descriptions. The existence of a policy or code of conduct that covers representations about products will also be helpful to the company, as long as the employee has been made aware of the policy. If the employee has previously been warned about similar behaviour, this could also make the current conduct more serious, and is more likely to be a valid reason.

Proper process

FP should notify the sales representative of the misconduct (i.e. the false representations) and give him/her a chance to respond. If the sales person has a reasonable explanation for the conduct, FP should take that into account. If FP is considering dismissal of the employee, it should allow him/her to have a "support person" present at any meetings if the sales representative requests it.

Personal circumstances of the employee

The sales representative may have certain personal circumstances that mean it would be harsh to dismiss them, even if there is a valid reason and FP follows proper procedure. These could include if the employee has a long period of unblemished service prior to making the false representations; or if the employee has a disability or difficult family circumstances.

After considering all these factors, FP should weigh up the risk of the sales representative making a successful unfair dismissal claim. If the risk is high, FP may wish to consider issuing the employee with a formal warning and having him/her undergo additional training instead of dismissal.

DR SIMONE MITCHELL'S PERSPECTIVE

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

Pursuant to the Medicines Australia Code of Conduct (Code), it is incumbent on companies to ensure that the content of all promotional and medical claims are balanced, accurate, correct and fully supported by the Product Information, literature or "data on file" or appropriate industry source, where these do not conflict with the Product Information. This responsibility goes beyond claims made in respect of the product being promoted and extends to any information given or claims made about other products, disease states or conditions. Importantly, and pertinent to this set of circumstances, these obligation expressly apply to any verbal statements made by a company representative.

In addition to ensuring the accuracy of all claims made in relation to a product, the Code requires that company representatives maintain a high standard of ethical conduct and professionalism in the discharge of their duties at all times.

Failure to ensure the accuracy of claims made by your sales representatives is a recipe for disaster. False and misleading claims made by individual sales representatives, even in circumstances where those claims are not condoned by a company, may lead to a complaint and the imposition of sanctions under the Code or may result in court proceedings alleging that the company has engaged in misleading and deceptive conduct under the Australian Consumer Law (ACL).

Consequently, companies need to ensure that they have in place a robust compliance program which ensures that all company representatives are aware of their duties and responsibilities under the Code as well as other laws which relate to the promotion of goods in Australia.

Section 6 of the Code specifies the types of qualifications and training that are required to be held or undertaken by company

representatives. However, in practice, the requirements outlined in this section of the Code should not be considered a comprehensive training and compliance program which will be sufficient in all circumstances and for all representatives. The Code makes it clear that companies have responsibility to maintain high standards of on-going training for company representatives and this clearly indicates that further training may be required in certain circumstances.

The type of training which is required under the Code includes:

- company representatives must possess sufficient medical and technical knowledge to present information on the company's products in a current, accurate and balanced manner and should be cognisant of all provisions of the Code. The endorsed Medicines Australia education program provides sufficient background to satisfy this requirement.
- all medical representatives are required to have completed or be currently undertaking an endorsed Medicines Australia education program for medical representatives.
- any person who is directly involved in the development, review and approval of promotional material and educational materials to the general public or has direct interactions with healthcare professionals for the purpose of promoting a prescription only product or providing medical or clinical education must complete the Code of Conduct component of the endorsed Medicines Australia educations program.
- any person who is directly involved in the development, review and approval of promotional material and educational materials to the general public or has direct interactions with healthcare professionals for the purpose of promoting a prescription only product or providing medical or clinical education must also undertake training on a regular basis to ensure that they have sufficient knowledge to comply with the Australian privacy legislation and ACL to the extent relevant to their roles.

In addition to the training requirements set out in the Code, it may be that additional training is also appropriate to mitigate the risk that company representatives will engage in the inappropriate promotion of products and/or services. For instance, it is almost always necessary to provide sales representatives with comprehensive training in relation to the product that they will be promoting, including, amongst other things, training on the Product Information and the product's safety and efficacy profile.

It is important for a company to be in a position to demonstrate that it has adequately trained its employees and agents. Although not a defence to a complaint made pursuant to the Code, in determining appropriate sanctions, the Code committee may refer to various matters including:

- internal procedures for the development and approval of company activities and materials;
- the circumstances in which the activity took place – and whether any explanation can be offered by the subject company;
- any evidence that the breach related to an activity that was not sanctioned by the company's operating procedures or training of personnel; and
- co-operation, acknowledgement of the offence and evidence of internal procedures implemented to avoid similar breaches in future.

In summary, FP should ensure that it meets not only the minimum training requirements specified in the Code but that its representatives have undergone adequate training in order to undertake their roles and responsibilities. Where the employee is a sales representative, FP should undertake adequate training so that the person will be able to speak knowledgeably and accurately about the new diabetes treatment they are promoting, competitor products and the disease state. In addition, FP should consider whether it should optimise any training program it has in place to ensure (as best it can) that future breaches are avoided, including:

- implementing testing of company representative as well as training;
- ensuring that each employee gets the training they need – this acknowledges the different roles and functions of employees;
- ensuring consistency in training given;
- ensuring that an appropriate person(s), with the requisite qualifications and technical expertise, delivers the training;
- ensuring the company maintains a register of training that is regularly checked; and monitors and observes sales representatives, particularly when the company has been put on notice of potential breaches.

A NEW WAVE OF REGULATORY ENFORCEMENT ACTIONS IN CHINA

ARE WE WITNESSING A PROLONGED ENFORCEMENT CYCLE?

By Sammy Fang

A new leadership heralds change

China is currently witnessing an extended government campaign to tackle corruption on an unprecedented scale. The change in the Communist Party's leadership that began at the end of last year coincided with the arrest and indictment of the former Chongqing Party Secretary, Bo Xilai (the most senior official charged with corruption in recent memory). The wave of enforcement actions against corrupt officials that followed Bo's arrest has continued, recently leading to the head of the once powerful Ministry of Railways being sentenced to death for corruption. He is the most powerful former government official sentenced for corruption since President Xi Jinping became China's leader in March this year.

Recent regulatory and investigative action in China

However, the government's focus does not appear to be limited to public officials alone. In recent months, there have been a spate of regulatory and investigative enforcement actions by Chinese government authorities against companies in the private sector (including both multi-national companies and local Chinese companies), which are likely to have a major impact on the Life Sciences sector in China in the near and medium terms. These include:

1. New regulations issued by the State Council which came into effect in May 2013 now impose tougher market entry requirements on infant formula manufacturers, including among others, requiring them to own their own milk sources, forbidding them to outsource production or use several brand names for the same infant formula. This has already led to a number of dairies being acquired by Chinese infant formula brands.
2. China's anti-trust regulator, the National Development and Reform Commission (NDRC), announced in early July 2013 that it is investigating 33 Chinese domestic pharmaceutical companies and 27 international pharmaceutical companies operating in China (or their Chinese agents) with respect to the production costs of some of their products. The implication here is that similar to the NDRC's earlier investigation into the price of infant milk formula products, the NRDC considers the price of these pharmaceutical products are too high and are causing a financial burden on the public health insurance scheme.
3. Reports of recent anti-bribery investigations against a number of international players in the pharmaceuticals industry led by the Chinese police, the Public Security Bureau (PSB), as well as the Administration of Industry and Commerce (AIC).

What it will mean for Life Science sector players and multi-nationals operating in China?

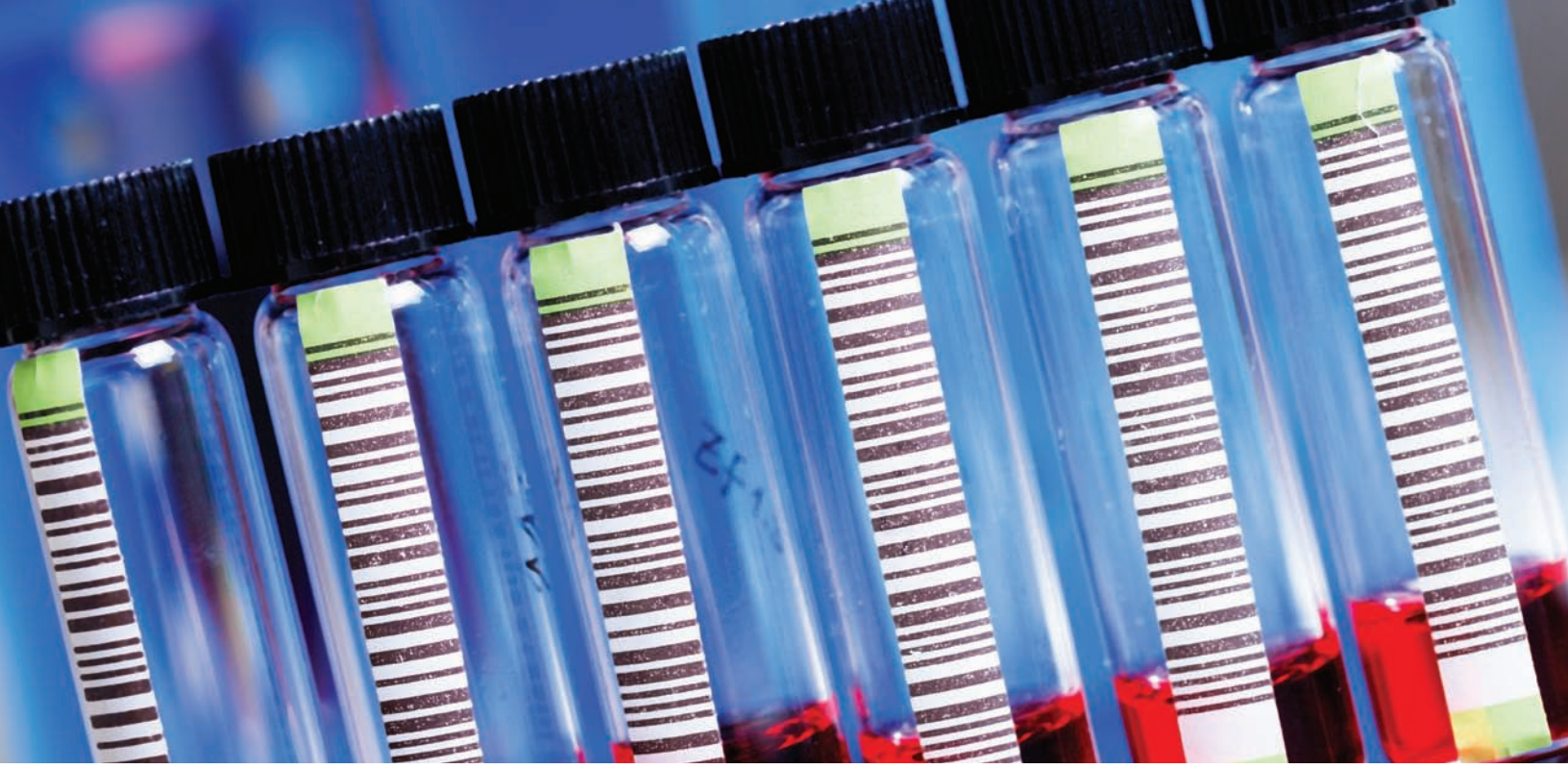
In the past, government anti-bribery enforcement actions would target principally those government officials involved, rather than the companies that actually paid the bribes to these officials. The breadth of the latest investigations and regulatory intervention is, however, unprecedented, particularly as they involve so many government authorities and agencies (NDRC, PSB, and the AIC) who appear to be taking enforcement action concurrently. There has been no shortage of rumours coming out of the Chinese market in recent months as to how many foreign companies have been targeted by the government and the reasons that led to these investigations.

However, as modern socialist China enters into its fourth decade of economic development, there are complex and intertwined social, political and economic factors that are now driving this regulatory enforcement action by the government. With the public's interest on food safety and healthcare at an all-time high and the public becoming more willing to criticise corrupt behaviour, China's new leadership appears to be more willing to increase regulatory oversight on various high priority industries such as food, healthcare, real estate and construction, and telecommunications.

Eager to prove itself to the Chinese public and to establish a strong mandate to govern, greater regulation and stronger enforcement action is likely to continue into the second half of the new leadership's first five-year term in office (ending in 2017). This is likely to mean that practices that traditionally have been viewed as grey areas will be targeted and ultimately punished.

From a regulatory and compliance perspective, companies with a robust regulatory and compliance program and effective crisis management protocols will be in a strong position to respond to such government enforcement action, hopefully with as little potential negative impact on their business as possible. This should not be limited to a program that only responds to compliance issues as they arise. International companies operating in China will need to localise and update their approach to regulatory affairs and compliance, so that preventative measures are put in place across their entire business cycle covering:

- how market access efforts are managed (such as engagement of consultants to assist with product registration);
- review of sales and marketing practices (how these are monitored and audited for potential compliance breaches);
- interactions with government officials and State-owned enterprises;
- whether present compliance training materials and efforts are sufficient; and
- protocols for responding to government enforcement action and investigations (how a company should respond to a PSB or AIC investigation and what its standard operating procedures are in case of a raid on its business premises).



UPDATE ON RECENT DECISIONS

By Leah O'Brien

In this update, we focus on two recent significant decisions: the decision in the Australian case of *Peterson v Merck Sharp & Dohme (Aust) Pty Ltd* (No 6) [2013] FCA 447 and the decision of the US Supreme Court in *Association for Molecular Pathology v Myriad Genetics, Inc*, 569 US_(2013).

Peterson v Merck Sharp & Dohme

In the most recent iteration of the Vioxx proceedings, Justice Jessup was asked to approve a settlement scheme for the remaining group members in the pharmaceutical class action. Rejecting the proposed settlement scheme, his Honour held that the proposal which had been agreed between the parties was not "fair and reasonable" as is required by the Court. This determination was made predominately on two grounds:

- First, the settlement scheme did not properly take into account any differences in the strength of each of the individual group member's claims (including the fact that some group members would have had independent risk factors for the injury, while others would not); and
- Second, the payment of the proposed lump sum amounts to all group members without adequate discretion would constitute a windfall gain for those group members who did have other risk factors for injury and injustice for those group members who did not.

Justice Jessup's decision reiterates the need for any class action settlement scheme to be in the interests of all of the group members. Absent this requirement, it is clear that the Court will not act as a rubber stamp of a settlement scheme, even where the parties reach agreement.

Association for Molecular Pathology v Myriad Genetics

A few months after the Federal Court of Australia held in *Cancer Voices Australia v Myriad Genetics Inc* [2013] FCA 65 that isolated naturally occurring nucleic acid constituted "an artificially created state of affairs" and **is** patentable subject matter, the US Supreme Court has handed down its decision in the similar US case. The US Supreme Court has ruled that isolated naturally occurring DNA is **not** patentable subject matter, but that cDNA is.

An appeal has been filed in Australia and is expected to be heard in August 2013. While there is no direct precedent created by the US decision, it is still likely to be referred to by the Australian parties. We will keep you updated on any further decision in Australia.

AUSTRALIA'S INNOVATION PATENT

THE STRONGEST PATENT IN THE WORLD THAT YOU HAVE PROBABLY NEVER HEARD OF

By Nicholas Tyacke and Jessie Buchan

While many countries offer a single type of patent to protect inventions, Australia offers two – a standard patent and an innovation patent. As this article will show, the innovation patent is probably the strongest patent in the world and also the least known.

Australia's unique innovation patent system was introduced with the objectives of providing a "second-tier" system to protect lower level or incremental inventions and to encourage innovation amongst small to medium sized enterprises (SMEs) by providing a faster and more cost effective mechanism for obtaining patent protection for their lower level inventions. However, although introduced to achieve these objectives, the availability of innovation patents is not limited to incremental inventions or to SMEs. Rather, subject to the limited exclusions from patent eligibility referred to below, innovation patents are available for all forms of invention that satisfy the patentability requirements and to all size of enterprise (as well as individuals).

Although the number of patentees that have been applying for innovation patents to protect their inventions has been increasing in recent years, this jewel in Australia's intellectual property regime remains undiscovered by many patentees around the world.

What is an innovation patent?

The Australian innovation patent system was introduced in 2001 to replace the petty patent system (first introduced in 1979), and to respond to perceived deficiencies in the standard patent system and existing design law. In particular, a "gap" was found to exist in the protection of minor and incremental functional innovations and inventions that were not sufficiently inventive to be entitled to protection under the standard or petty patent system and which were not protectable under the designs system, which protects the appearance of articles, and not their functionality. There was also considered to be a lack of access to quick, less expensive and more easily obtainable patent protection for inventions with a short commercial life.

The innovation patent system provides a means for inventors to protect their rights via a relatively quick and inexpensive process. This type of protection also

enables inventors to obtain protection for each stage of development of the invention, long before the broader research project is complete, thereby reducing some of the associated long term financial and commercial risks. Significantly, the fact that the innovation patent system provides the same exclusive rights and remedies as are available under the standard patent system, with the added bonus of having a lower threshold for patentability, is a key feature which is both unique to Australia and advantageous to patentees.

Whilst a number of other jurisdictions have systems in place for protecting low level inventions, such as "utility models", they do not offer the key advantage of the innovation patent, discussed below. Moreover, the US, UK, Singapore, India and New Zealand currently offer no utility model patent protection to patentees.

How are innovation patents different to standard patents?

Innovation patents can provide a fast and cost effective means of protecting intellectual property. Innovation patents are particularly useful tools in supporting first to market advantage and are strategically valuable assets in protecting and enforcing patent rights.

We highlight some of the key differences between standard patents and innovation patents in the table provided. However, in short, some of the key features and benefits of the innovation patent system can be summarised as follows:

- **Fast grant** – usually within one to three months.
- **Broad scope and coverage** – with limited exclusions.
- **Cost-effective** – preparation and application costs are lower than for a standard patent.
- **Less stringent requirements** – in relation to both filing and patentability.
- **No pre-grant opposition** – unlike standard patents.
- **Examination and certification is optional** – yet required for enforcement.
- **Equal rights and remedies** – once certified, the same remedies for infringement are available as exists for standard patents, i.e. injunctions, damages, account of profits.
- **Strategically advantageous** – innovation patent applications can be converted into standard patent applications and vice versa and they can also be filed as divisionals of standard patent applications, allowing them to be used for enforcement and litigation without compromising the standard patent application.

Lower threshold for "inventiveness"

Perhaps more important than any of the benefits mentioned above, while innovation patents are required to meet the same "novelty" test as standard patents, they only need to possess an "innovative step", which is a lower threshold than the 'inventive step' required for a standard patent.

To be regarded as having an innovative step, the invention must differ from the prior art base in a way that makes a "substantial contribution" to the working of the invention. There is no requirement that the invention be non-obvious, as is a requirement of standard patents.

The meaning of what constitutes a "substantial contribution" has been considered by the Full Federal Court of Australia in a number of decisions. That Court has held that it does not matter whether features that distinguish the invention from the prior art were well-known, or obvious to a person skilled in the art. Rather, all that is required is for at least one distinguishing feature of the claimed invention to make a substantial contribution, being a contribution that is both "real" or "of substance." Furthermore, it is the "substantial contribution" made to the "working of the invention" itself, and not the contribution that is made to the art, that is to be assessed. That is, provided that the contribution is a substantial one to the working of the invention, it does not matter that the invention is not an advance in the art.

These decisions have confirmed that it will be fairly easy for patentees to satisfy the innovative step requirement and in turn, it will be fairly difficult for opponents to successfully challenge the validity of an innovation patent on the basis of lack of innovative step. This places the owners of Australian innovation patents in a solid position when seeking to protect and enforce their patent rights in Australia and, combined with the numerous other strategic benefits offered, provides a strong incentive for patentees to seek innovation patent protection.

Comparison of Australia's standard and innovation patent systems

	Standard patents	Innovation patents
Term	Up to 20 years, if annual fees paid (or up to 25 years for pharmaceutical patents)	Up to eight years, if annual fees paid (no extension possible)
Subject matter	Human beings and the biological processes for their generation are not patentable inventions	Same as for standard patents, with the additional exclusion of plants and animals, and the biological processes for the generation of plants and animals
Number of patent claims	Any number of claims	Up to five claims
Patentability requirements	Be new, useful and involve an inventive step	Be new, useful and involve an innovative step
Invention must not be obvious	Yes	No
Examination	Mandatory substantive examination prior to grant. The relevant requirements of the *Patents Act 1990* (Cth) must be met before a standard patent is granted Examination can only be requested by the applicant	Optional, but cannot be enforced until examined. Examination can be requested by the applicant or any third party
Certification	N/A	Optional
Opposition	Pre and post grant	Only post grant
Timing to grant	Typically two to four years from filing	Typically one to three months from filing

Review of innovation patent system

The innovation patent is currently undergoing a series of reviews. In 2012, IP Australia released an "Innovation Patent System Consultation Paper" to invite public comment on a proposal to amend the *Patents Act 1990* (Cth) to raise the patentability threshold for innovation patents to the same level of inventiveness as required for standard patents. The Australian Council on Intellectual Property is also in the process of conducting a review of the innovation patent system, and an options report is expected to be published in late 2013.

What these reviews highlight is that there are clear commercial advantages to be gained for inventors in pursuing protection under the innovation patent system as it currently stands.

BEST PRACTICE DISCLOSURE FOR LIFE SCIENCES COMPANIES

By Simon Davidson

Recently, the Australian Securities Exchange (ASX) and Ausbiotech, the peak body for the Life Sciences industry in Australia, released the second edition of the "Code of Best Practice for Reporting by Life Sciences Companies" (Code). This is a timely update from the first edition which was published in 2005, as it coincides with the ASX's recent revamp of the continuous disclosure obligations in Listing Rule 3.1, and its associated Guidance Note 8.

The Code is not mandatory but it is useful guidance for a sector which has not yet been able to establish a mandatory code such as the Australasian code for reporting of exploration results, mineral resources and ore reserves (the JORC code) used for mining companies. There are specific complexities for Life Sciences companies seeking to communicate with the broader investing public – the complex science is combined with long development pathways, regulatory hurdles and intellectual property issues. As such, the Code is a welcome aide to participants in the sector, whether disclosing or reading those disclosures.

The Code clearly explains the interaction between Listing Rule 3.1, Guidance Note 8 and the Code, although the revised Code now relies more on Guidance Note 8 to explain the basic concepts of disclosure and the circumstances in which the disclosure requirements (or the exemptions from them) may apply.

However the Code clearly notes specific issues of relevance to Life Sciences companies. An example is explaining the need to consider what is commercially sensitive information and how much can be withheld while still providing sufficient information to enable the investing public to make an assessment of the impact of a disclosed event on the value of the company. A further issue which is highlighted is the need to include carve outs from confidentiality clauses in joint venture contracts and the like to ensure that disclosure obligations (which cannot be avoided in those circumstances) can be satisfactorily met. New emphasis is given to the importance of maintaining confidentiality and the need to monitor public sources of information, including social media, for signs that an item of information is no longer confidential.

The detail of the Code itself as set out in section 4 is materially the same as the previous edition. However it has been reordered and the few significant changes are:

- The inclusion of a new section on "The reimbursement path", focussing companies on the importance of that process to a company, and therefore its potential materiality.
- A note that companies with earnings who become aware of any material difference in expected or actual earnings with market expectations should consider their obligation to disclose immediately.
- Removal of the (previously short) section on consultant's reports.

The glossary has also been expanded and some of the existing definitions refined or elaborated on.

Notwithstanding the fact that this edition of the Code reflects evolution rather than revolution, its release is important to remind and confirm to Life Sciences companies that their disclosure obligations require real and detailed consideration rather than formulaic responses. While companies clearly need to be aware of the strict legal obligations arising out of Listing Rule 3.1 and the ASX's interpretation of those obligations as set out in Guidance Note 8, the unique characteristics of the Life Sciences industry mean that consistent reporting across companies can only assist in the understanding of the industry as a whole and be beneficial to all participants. If the publication of this revised edition of the Code is a further step towards developing the Life Sciences equivalent of the JORC code, it should be supported.

THE NEW WORKPLACE BULLYING LAWS AND PERFORMANCE MANAGEMENT

By Andrew Ball and Tass Angelopoulos

On 1 January 2014, new workplace bullying laws will form part of the *Fair Work Act 2009 (Cth)*. These laws will entitle workers to apply to the Fair Work Commission (the Commission), Australia's industrial tribunal, alleging that they have been bullied in the workplace. It has been predicted by the General Manager of the Commission that there may be up to 3,500 applications per year to the Commission under these provisions.

The current state of play

At present, there is no Australian legislation that specifically prohibits workplace bullying. Therefore, depending on the type of workplace bullying which is alleged, workers have had to rely on other general laws such as occupational health and safety laws, workers' compensation laws, anti-discrimination laws and the general protection provisions of the *Fair Work Act 2009 (Cth)*, as well as common law claims.

The new laws follow the House of Representatives standing committee on education and employment report of October 2012, "Workplace Bullying, We just want it to stop" (Report). The Report recognises that work provides Australians with a sense of dignity and workplace bullying is a hidden problem, which affects an employee's worth of self and value. The Report estimated that workplace bullying costs the Australian economy between AU$6 billion and AU$36 billion every year and that a workplace bullying case costs employers an average of AU$17,000 to AU$24,000 per claim.

For the first time, there will be an all-encompassing law that makes bullying conduct unlawful with a right to redress workplace bullying through the Commission.

Amendments to the *Fair Work Act 2009 (Cth)*

The new laws will introduce a new part to the *Fair Work Act 2009 (Cth)* headed "Workers Bullied at Work" and will not be limited to employees. Rather, it will cover "workers" as defined in the *Work Health and Safety Act 2011 (Cth)*. This includes contractors, subcontractors, outworkers, apprentices, trainees, and students gaining work experience as well as volunteers.

Under the new laws, a worker is bullied at work if an individual or a group of individuals repeatedly behave unreasonably towards a worker, or a group of workers of which the worker is a member and that behaviour creates a risk to health and safety.

It is important to note the following:

- there must be repeated behaviour;
- the behaviour must be unreasonable; and
- that behaviour must create a risk to health and safety.

However, it is not a requirement that the risk to health and safety is to the workers being bullied.

Exception – Reasonable workplace management

If the conduct complained of is "reasonable management action carried out in a reasonable manner," that conduct does not contravene the workplace bullying provisions. However, there is no definition of what is "reasonable management action carried out in a reasonable manner." We expect that reasonable performance and conduct management will fall within this exception. However, we also expect workers will allege that performance and conduct management amounts to bullying conduct and allege that the management was neither reasonable nor was it carried out in a reasonable manner.

Although this exception is welcome, the provision does not operate as a jurisdictional objection but as a defence. Consequently, it will be incumbent upon an employer to provide evidence to the Commission that the performance management is "reasonable management action" and that that it has been "carried out in a reasonable manner." This could lead to a significant cost for employers as they will be required to participate in a hearing in order to establish that the performance management is "reasonable management action carried out in a reasonable manner." It is also worth keeping in mind that the Commission is essentially a no costs jurisdiction.

Powers of the Commission

The Commission must start to deal with an application within 14 days after the application is made. No explanation is given whether that involves considering the application or listing the matter for hearing or conference, although we expect matters will proceed to conference first.

If bullying has occurred, the Commission cannot order payment of a pecuniary amount but it can make interim or interlocutory type orders to restrain the conduct of the employer. If such orders are made, the employer may, depending on the scope of the order, be prevented from continuing with the performance management, on an interim basis, until the matter is either resolved by the parties in conference or determined by the Commission with a final order.

Non-compliance with the Commission orders

If the Commission makes an order which effectively restrains the continuation of the performance management process, and the employer does not comply with that order, the worker could apply to the Federal Court or Federal Circuit Court to enforce the order. If the Federal Court or Federal Circuit Court determines that the employer has contravened the Commission's order it can impose a civil penalty on the employer. The maximum penalty that may be imposed on a corporation is AU$51,000 and AU$10,200 on an individual.

Individuals involved in the contravention such as managers and directors could also be penalised (section 550, *Fair Work Act 2009 (Cth)*).

The Coalition policy

Even if there is a change of government at the next federal election this year, the proposed workplace bullying laws will be maintained in the *Fair Work Act 2009 (Cth)* with amendment. The Coalition policy, however, will require a worker to seek the assistance of an independent State or Territory based work health safety regulator before the worker can make the application to the Commission.

Conclusion

With the introduction of the workplace bullying laws, it will be essential that all employers have an effective workplace bullying policy in operation. That policy should be in line with the language of the new provisions and should include:

- a definition of workplace bullying including a statement that workplace bullying is unlawful;
- a complaints process; and
- consequences for the worker that has engaged in workplace bullying.

It will be important that employers also ensure that their performance management processes are fair and reasonable. This will mean that employers must have appropriate documentation that backs up their performance concerns.

We are happy to assist you with developing the policy and provide the necessary training to both staff and human resources personnel responsible for dealing with bullying complaints.

CAN REVERSE PAYMENTS IN PATENT SETTLEMENTS

CONSTITUTE CRIMINAL CARTEL CONDUCT?

By Simon Uthmeyer

It is a well-established and universally accepted principle of competition law that a payment by one competitor to another competitor not to enter a market is anticompetitive, and in Australia since 2010 a criminal offence. In the US over the past decade pharmaceutical companies, the Federal Trade Commission (FTC) and class action applicants have battled the question of whether this established principle of competition law applies in the context of a settlement of a patent dispute. The answer is now clearly and unequivocally yes.

Recent decisions of the US Supreme Court and the Director General of Competition (DG Comp) in the EU have confirmed that reverse payments in patent settlements are subject to competition law and are potentially anticompetitive. If the Australian Federal Court were to follow these two clear decisions then a reverse payment could constitute criminal cartel conduct under the Competition & Consumer Act (CCA), in addition to potentially constituting an anticompetitive agreement. Therefore, such settlements could be at risk of criminal sanctions, pecuniary penalties and damages claims by private parties including class actions.

Whilst there is no Australian authority on this issue, the jurisprudence in the US is now very clear and strong. The EU, whilst not having jurisprudence, has a very clear and strong prosecution by the DG Comp consistent with the US Supreme Court. Accordingly, it is inconceivable that the ACCC, State Governments, private health insurers and class action law firms can ignore the clear legal position now being adopted in both the US and the EU that reverse payment settlements are subject to competition law and are potentially anticompetitive. It can only be a matter of time before enforcement proceedings are brought by the ACCC or private proceedings by an affected party that a reverse payment is in breach of the CCA.

FTC v Actavis, Inc (Androgel) **US Supreme Court 17 June 2-13**	***Lundbeck (Citalopram)*** **European Commission 19 June 2013**
Offending reverse payment settlement terms: ■ Generic Androgel would not be marketed for nine years with the period ending 65 months before the patent expired; ■ Generic company agreed to promote Androgel to urologists; and ■ Generic company receives annual payment of between US$19 million and US$30 million for nine years for "other services."	Offending reverse payment settlement terms: ■ Generic companies agreed not to market generic citalopram for agreed period; ■ Generic companies received guaranteed profit for distributing Citalopram; and ■ Lundbeck (innovator) acquired generic citalopram stock for destruction.

FTC v Actavis, Inc (Androgel) **US Supreme Court 17 June 2-13**	*Lundbeck (Citalopram)* **European Commission 19 June 2013**
US Supreme Court finding: ■ The restraint "has the "potential for genuine adverse effects on competition". ■ Payment in return for staying out of the market – simply keeps prices at patentee-set levels, potentially producing the full patent-related US$500 million monopoly return while dividing that return between the challenged patentee and the patent challenger. The patentee and the challenger gain: the consumer loses. ■ Such payments are subject to antitrust scrutiny under a rule of reason approach and are not immune under 'scope of the patent' protection. Matter remitted to District Court to apply rule of reason test to the settlement terms.	European Commission finding: ■ It is unacceptable that a company pays off its competitors to stay out of its market and delay the entry of cheaper medicines. Agreements of this type directly harm patients and national health systems, which are already under tight budgetary constraints. The Commission will not tolerate such anticompetitive practices. ■ Lundbeck fined €93.8 million and each of the four generics fined €52.2 million.

In a nutshell what is the problematic conduct?

Both the US Supreme Court and the European Commission (EC) have ruled that a settlement of patent litigation proceedings which involves the innovator paying consideration for the delay of the entry of competing generic drugs raises competition law issues (pay for delay).

However, "where a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of non-infringement." Accordingly, where justifiable consideration is paid a limitation on the ability of a generic company to enter is unlikely to raise competition concerns.

Examples of problematic reverse payment settlements

Problematic reverse payment settlement agreements have two essential terms:

1. Settlement agreement that the generic company will:
   - refrain from challenging the validity of the innovator company's patent(s) (non-challenge clause); and/or
   - refrain from entering the market until the patent has expired (non-compete clause); and/or
   - solely be a distributor of the innovator product concerned; and/or
   - source its supplies of API from the innovator company; and
2. Unjustifiable consideration is paid by the innovator company to the generic company, which can take many forms:
   - payment of a lump sum for unspecified services;
   - payment for purchasing the generic company's stock of the generic drug; or
   - annual payments for distribution services.

How wide spread is the problem?

The EC over the period 2009 to 2011 reviewed a large sample of patent litigation settlements in the EU. The EC's analysis indicated that of the patent settlements it reviewed in 2011, 11 percent are problematic from an antitrust perspective. Therefore, these issues are not one off and are reasonably prevalent in the industry to attract scrutiny.

Exposure is to past and future reverse payment settlements

Both past and future reverse payment settlements are potentially subject to the CCA. Therefore, all past reverse payment settlements should be carefully reviewed to assess competition law risk, as it can only be a matter of time before the Australian Competition and Consumer Commission, State governments, private health insurers or class action applicants follows the clear and strong jurisprudence set by the US Supreme Court and the EC in June 2013.

Q&A

What are your key areas of practice?

My practice focuses on regulatory compliance, investigations and product liability. In China, so much is regulated by the government. Coupled with the local authorities' increasing appetite for regulatory enforcement, companies operating in or looking to invest in China can no longer focus primarily on growth and the bottom line. Regulatory and compliance will be the new insurance policy for businesses in China. This will lead to localisation of policies and standard operating procedures, greater focus on due diligence, stricter controls and procedures on interactions with state-owned enterprises and government officials, and ongoing monitoring and review of business practices.

What do you consider are the two biggest issues or challenges currently faced by Life Sciences companies in China?

- **Anti-bribery and anti-corruption enforcement**

This remains top of the agenda for the Communist Party and China's new leadership led by President Xi Jinping. The public campaign to tackle corruption that started with the arrest of former Chongqing Party Secretary, Bo Xilai, and the change of leadership at the end of last year remains a focus of the Communist Party. On the back of this, we are also seeing a fresh wave of anti-bribery enforcement action against companies in the private sector, with reports of recent government investigations against major international players in the pharmaceuticals and infant milk formula industries.

- **Product liability and food safety**

Almost five years after the Sanlu Dairy melamine scandal, food safety concerns remain a major problem in the Chinese infant milk formula industry. With the public's interest in food safety and healthcare at an all-time high, the government has shown its willingness to increase regulatory oversight on food safety and product liability generally. This has seen the break-up of the once powerful General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) and the elevation of the State Food and Drug Administration (SFDA) into a state administration with full ministerial status (now called the China Food and Drug Administration) in March 2013, with a specific mandate to improve food and drug safety. In recent months, there has been intense media coverage and government intervention in the infant milk formula industry. The new regulations issued by the State Council in May 2013 will require infant formula manufacturers to own their own milk sources, forbid them to outsource production, or use several brand names for the same formula.

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

I have been working on a product liability case that has led the Chinese government to issue new regulations governing entry into this particular industry. What makes it so interesting is the fact that it combines legal issues (which are themselves complex), as well as public relations input and negotiations with local government authorities.

What is your favourite thing to do outside of work?

There is no shortage of great food in China, and Beijing has much to offer. Sampling new restaurants is one of my favourite past times, together with golf and a day out exploring the Great Wall (there are many sections around Beijing that are left pretty much untouched and not crowded by tourists).

WITH

SAMMY FANG

BRINGING SCIENCE TO LIFE

At DLA Piper, we provide innovative solutions and support our clients to make their business decisions come alive, providing the legal expertise needed to maximise strategic opportunities while balancing risk.

From research and development through to regulation, commercialisation, patent protection and enforcement, we act as a trusted adviser for a number of bioscience, pharmaceutical and medical technology companies.

Our global Life Sciences team are based in more than 30 countries, and many of our lawyers are highly qualified former Life Sciences professionals. With our industry knowledge we are ideally placed to understand and support your business.

For more information, please contact:

Nicholas Tyacke, Sydney
T +61 2 9286 8502
nicholas.tyacke@dlapiper.com

Simone Mitchell, Sydney
T +61 2 9286 8484
simone.mitchell@dlapiper.com

Sammy Fang, Beijing
T +86 10 656 1178 8823
sammy.fang@dlapiper.com

Kit Kwok, Shanghai
T +86 21 3852 2100
kit.kwok@dlapiper.com

www.dlapiper.com

DLA PIPER