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LIFE SCIENCES SPOTLIGHT

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Patent term extensions in the biotechnology sector in Australia

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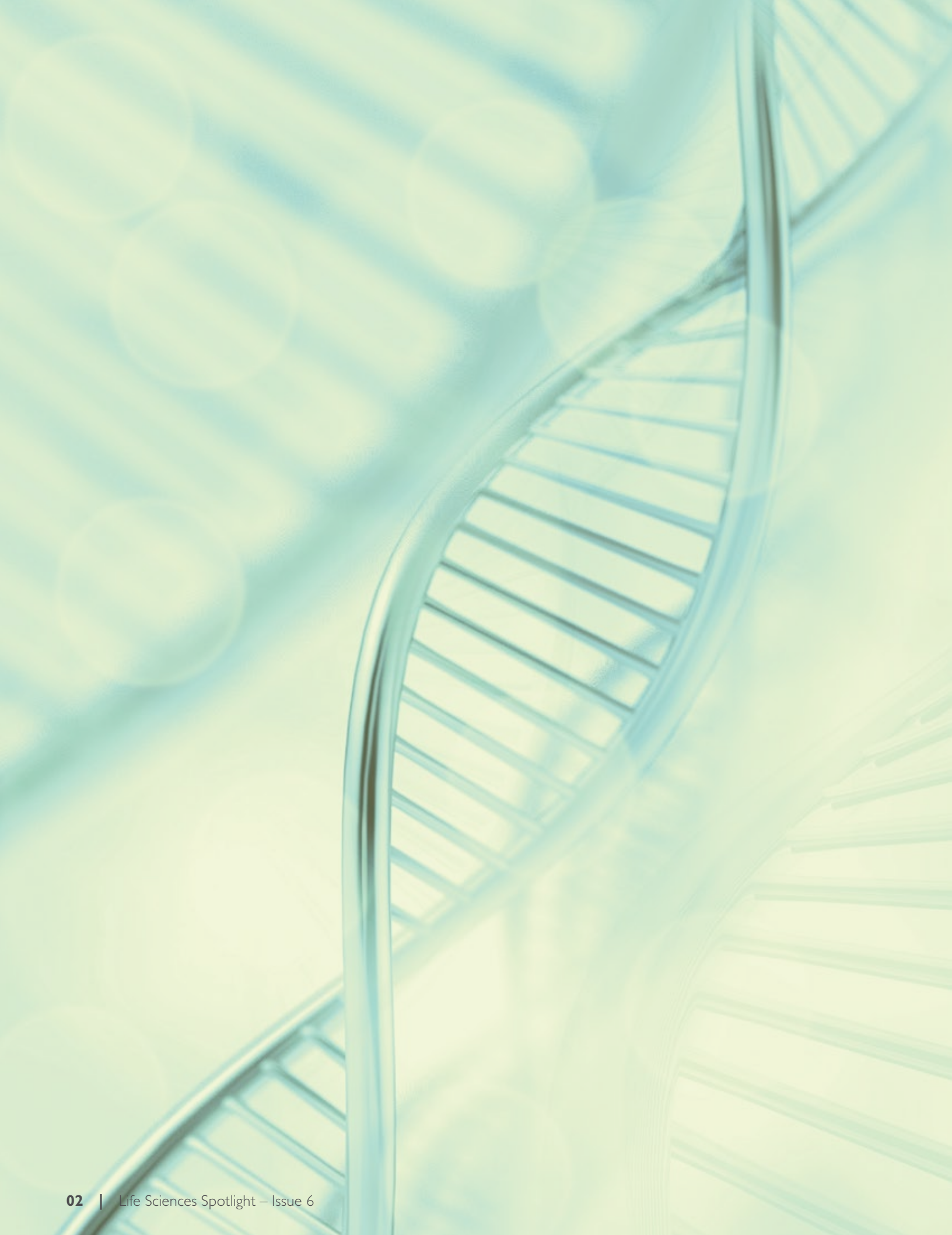

A NOTE FROM THE GUEST EDITOR

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

Pharmaceutical and life sciences companies are increasingly the target of cyber-attacks and cyber-espionage. In the first article, our cyber security experts discuss trends, developments and why life sciences companies should take action in cyber security and data protection.

Our patent specialists provide a number of updates in this edition, including recent developments regarding the patentability of naturally occuring products in Australia and the US, discussion of the recent Australian High Court Crestor® decision and discussion of the recent decisions regarding the patent term extensions in the biotechnology sector in Australia.

Our team in Asia discuss the advantages and implications of telemedicine, specifically in Japan and China and our competition team highlight the current competition trends in the Australian life sciences sector including, competitive responses to the threat of generic competition and preserving shareholder value and offsetting losses.

The longstanding view was that corruption is an inevitable aspect of doing business in Thailand, in large due to the constant allegations of graft against government officials coupled with historically weak enforcement by local regulators. Our 'Getting tough on corruption' article, points out several indicators that this is changing.

Finally, our team in New Zealand examine international mobility and the need for upfront planning and provide insights into the recent Pfizer/ Hospira merger. We also provide an introduction to Marie Evans, a partner in our litigation & regulatory practice in Auckland.

We hope that you continue to enjoy ***Life Sciences Spotlight,*** and that you learn something new in every issue. We are always open to your thoughts and suggestions so please do not hesitate to contact us.

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UNRAVELLING THE HELIX

In this edition of Life Sciences Spotlight, members in the DLA Piper Life Sciences team will assist in unravelling the legal aspects of a real-world Life Sciences dilemma. In this issue, DLA Piper's IP specialist , Ian Jebbitt and patent specialist, Bing Li discuss implementing intellectual property enforcement strategies in China as part of a worldwide strategy to prevent counterfeit pharmaceuticals from entering global markets.

FarmaPharma (FP) markets a prescription hormone replacement therapy pharmaceutical, ProductX, internationally. After FP's Australian Customer Care Complaint Centre received calls from patients who claimed to be experiencing unprecedented and alarming side effects after using ProductX, FP investigated and determined that counterfeit ProductX had entered the Australian market. With DLA Piper's assistance (see Unravelling the Helix in Spotlight, Issue 4), FP filed copyright and trade mark Notices of Objection with Australian Customs, who successfully intercepted and seized a number of shipments of ProductX en route to the Australian market and provided FP with details regarding the exporters. FP's subsequent investigations revealed that counterfeit ProductX has been imported into and exported from various ports located in South and East Asia, including China, and that the supplier of the active pharmaceutical ingredient (API) used in the counterfeit ProductX is a manufacturer located in Shenzhen, China.

FP's Customer Care Complaint Centres in Asia, Europe and the United States have now begun receiving complaints from customers complaining of side effects identical to those experienced by Australian patients who were using counterfeit ProductX.

FP holds a granted Chinese patent covering the API in ProductX, and a registered Chinese trade mark covering its distinctive 'green and gold' ProductX branding. As part of a worldwide strategy to minimise the amount of counterfeit ProductX entering global markets, FP comes to you for advice about what it can do to minimise any counterfeit ProductX being imported into or exported from China, and stop the counterfeit ProductX API supply at its source in China.

IAN JEBBITT'S PERSPECTIVE

Ian Jebbitt is an IP specialist based in Hong Kong. Ian focuses on a broad range of intellectual property matters throughout the Asia Pacific region. He has extensive experience assisting multinational clients with the acquisition and enforcement of IP rights, trademark and other IP litigation, licensing and commercial IP matters. You can reach him at ian.jebbitt@dlapiper.com

HOW TO MINIMISE THE FUTURE IMPORTATION AND EXPORTATION OF COUNTERFEIT PRODUCTS TO AND FROM CHINA

As set out in Spotlight – Issue 4, FP has an obligation to ensure ProductX and all its pharmaceutical products are of the highest quality and to prevent counterfeit medicines entering the market. FP should take the following steps to minimise the future exportation of counterfeit products from China:

1. FP owns a registered Chinese trade mark covering its distinctive ProductX branding. If it hasn't already done so, and as a matter of priority, FP should record this trademark with the General Administration of Customs in China (GACC). Once recorded, the trade mark information will then be uploaded to the national GACC computer system and shared with local Customs offices throughout mainland China. GACC proactively seizes counterfeit products. As such, the recordation of the Chinese trademark with the GACC will result in the seizure and destruction of any imported or exported counterfeits that bear FP's distinctive "green and gold" ProductX branding, or anything similar thereto.
2. If FP is aware of any particular shipments of counterfeits entering or leaving China, it should file a complaint with the GACC seeking the seizure and destruction of such counterfeits.
3. FP should also consider meeting with Chinese Customs to train Customs officers on how to identify counterfeit product.

HOW TO STOP THE COUNTERFEITING AT THE SUSPECTED SOURCE IN CHINA

As a priority, FP should try to identify the source of the counterfeits. In order to do this, FP should:

1. analyse the packaging of the counterfeit product seized to try to ascertain who is manufacturing the counterfeit product (to the extent it is not the company based in Shenzhen);
2. conduct on-the-ground intelligence gathering investigations into the API manufacturer based in Shenzhen and/or any other entity that is referenced on the packaging of the seized products to try to ascertain the size and scale of the counterfeiting operation and where any counterfeits are being seized; and
3. monitor the internet to see if anyone is selling counterfeit ProductX online (in both Chinese and English).

If a supply factory is identified, FP should seek to further identify: customers, suppliers, any sub-contractors and the ways in which counterfeit product is being imported, exported and/or distributed in China. This should make subsequent investigations and enforcement action easier to execute.

Once FP has compiled this information, FP should, depending on the scale of the infringement, undertake either or both of administrative enforcement action to seize counterfeits and/or Court based infringement proceedings.

It would also be prudent for FP to formulate a strategic anti-counterfeiting plan which involves it being proactive rather than reactive in terms of dealing with the import and export of counterfeits to and from China. This would involve continuing to gather intelligence and taking enforcement action in a systematic and strategic manner against specific predetermined targets, as opposed to undertaking enforcement action on a piecemeal basis.

OTHER CONSIDERATIONS FOR FP

If the production of counterfeit ProductX involves infringement of FP's patented active pharmaceutical ingredient, this could be another ground on which FP could take action. However, as Chinese customs and enforcement officials are normally unwilling to take action on patent cases without a court decision which found infringement, this will normally involve FP having to first obtain a successful court decision which increases the costs involved and the time it will take for FP to take action.

BING LI'S PERSPECTIVE

Bing Li is a patent specialist based in Shanghai. Bing focuses on Chinese patent drafting, filing and prosecution as well as on international patent prosecution, especially in the biotechnology/pharmaceutical sector. You can reach him at bing.li@dlapiper.com

WHAT ARE FP'S ENFORCEMENT OPTIONS?

In terms of patent enforcement in China, FP will have two options:

1. initiating a court action to seek both damages and injunctions, or
2. filing an administrative complaint with the local intellectual property bureau who has the authority to order the infringer (counterfeit company) to cease and desist from the infringement.

Due to various limitations on the administrative authorities, such as no damages rewards and possibly no forum shopping, filing a civil lawsuit with the court is a more popular patent enforcement mechanism in China, especially in the pharmaceutical area. However, it shall be noted that some administrative authorities may have certain advantages over the courts with respect to evidence collection primarily due to their familiarity with the industry.

Thus, unless we conclude otherwise after detailed review of the matter, it appears advisable to focus on filing patent infringement lawsuit against the infringer for the remedies of both damages and permanent injunctions (which is almost always available in China), with the possibility of seeking assistance from local (Shenzhen) intellectual property and/or FDA authority primarily for evidence collection purpose.

Depending on the merits of the case, we will also aim to seek a preliminary injunction which will significantly impact the targeted infringer's operation with immediate effect. Although it has become rather difficult in securing such a preliminary injunction, it is our experience that chance of success could be enhanced through thorough preparation of the case and good communications with the court.

Apart from patent enforcement, it should be kept in mind that the local FDA (Shenzhen FDA) authority supervises the local pharmaceutical industry. Should an investigation confirm that there may be quality issues in certain infringement products (counterfeit products), the complaint could be filed with such local FDA authority with a view to, at least, deter the business activities of such infringers.

EVIDENCE COLLECTION

Given that there is no discovery proceedings in China, a patent holder will need to collect the necessary evidence to build a patent infringement case. It is recognized that difficulties exist in collection of certain evidence. Thus, Chinese Court's have the discretion to intervene in such an exercise by issuing an "evidence preservation" order (which essentially asks the targeted infringer or other relevant party to disclose certain information) or conducting certain "court investigations."

If necessary, we would aim to:

- have a discussion with the local FDA (and/or other governmental authorities) in advance with a view to have such governmental bodies collect certain information from the targeted infringer(s); and
- aggressively seek an "evidence preservation" order from the Court in order to collect certain necessary evidence from the targeted infringer and possibly governmental bodies.

TIMING AND SEQUENCE OF LEGAL ACTION

Our proposed strategy involves a possible combination of both administrative complaints and court actions and therefore requires delicate management of the timing and sequence of actions. We anticipate to run the administrative complaint proceeding (if necessary) in parallel to preparation work of the lawsuit. As such, we expect to initiate the lawsuit within six months upon completion of the review and to receive a court decision in a 12 – 18 month time-frame at the first Instance Court level.

The timing of initiation of the lawsuit will be dependent upon two major factors: (1) the possible pursuance of a preliminary injunction, which shall require an immediate action to enhance the chance of success, and (2) the statute limitation of two years which essentially allow the patentee to collect damages for the infringement activities occurred during the past two years before the initiation of lawsuit.

PROSECUTION HISTORY ESTOPPEL

In case the infringer initiates an invalidation against the patent, please note that any statement made during the invalidation proceedings will also form the prosecution history and may therefore stop the patentee from expanding the scope of the patent under the Doctrine of Equivalents. As such, any pending or future invalidation proceedings should be closely managed to avoid potential adverse impact on future enforcement actions.

TRENDS AND DEVELOPMENTS IN CYBER SECURITY AND DATA PROTECTION – WHY PHARMA AND LIFE SCIENCES COMPANIES SHOULD TAKE ACTION

By Nicholas Boyle, Peter Jones, Nitesh Patel and Jacques Jacobs

WHY SHOULD THE PHARMACEUTICAL AND LIFE SCIENCES SECTOR PLACE AN INCREASED EMPHASIS ON CYBER SECURITY?

Pharmaceutical and life sciences companies are increasingly the target of cyber-attacks and cyber-espionage. Two key factors behind the increasing level of threat facing the pharmaceutical and life sciences sector are:

1. The intellectual property – including drug formulas and manufacturing processes – held by organisations in the sector is incredibly valuable. Not only does a new drug or medical device have the potential to generate billions of dollars of revenue, but it is also expensive and time consuming to undertake the research and development required to generate that intellectual property.
2. Organisations in the pharmaceutical and life sciences sector appear to lag behind those in the financial and utility sectors in implementing measures to protect against and mitigate the effects of cyber-attacks and cyber-espionage. Pharmaceutical and life sciences companies may therefore be perceived to be and targeted as the "low hanging fruit."

It is perhaps the case that organisations in the pharmaceutical and life sciences sector have seen themselves as holding relative limited amounts of personal information compared to banks, insurers, retailers, telecommunications service providers and utilities, and therefore considered that they face a lower risk of suffering "privacy" and "data protection" breaches. However, the potential operational, financial and legal impact of there organisations' intellectual property should cause the boards and management of organisations in the pharmaceutical and life sciences to come to grips with cyber security issues and invest in their systems, processes and procedures to manage these risks.

WHAT IS THE NATURE OF THE THREAT?

The threat environment is not only increasing in terms of the volume of attacks, but it is also evolving and continues to encompass both external threats and internal vulnerabilities and actors.

For organisations that hold large amounts of valuable intellectual property and trade secrets, it is insiders rather than external hackers that pose the biggest threat – although nobody knows the true impact of insider theft, the general consensus is that company insiders are the biggest thieves of proprietary information. In 2012, a (former) trusted employee of DuPont pleaded guilty to stealing trade secrets concerning DuPont's proprietary manufacturing process for titanium dioxide, the white pigment used in paint and plastics, which must by any measure be very valuable to DuPont.

WHAT ABOUT CLINICAL TRIAL DATA AND MONITORING DATA?

While we noted above that organisations in the pharmaceutical and life sciences sector may hold lower volumes of personal information than some organisations in other industry sectors, it is nevertheless the case that they generally are still holding personal information are both trial participants and end users of products. In holding this type of information, organisations in the pharmaceutical and life sciences sector may be subject to legislative and regulatory requirements around the collection, storage, handling and disclosure of such information, which also raises the potential for regulatory and/or civil actions in the event of breaches.

The level of regulatory attention on organisations' cyber security measures and compliance with relevant data protection regimes is, in general terms, increasing globally –

for example, new and enhanced privacy regimes in a number of Asian jurisdictions include the potential for significant fines and/or imprisonment as part of the mix of available sanctions for non-compliance. Coupled with this, increased media attention for large-scale data breaches has had an impact on individuals' own level of concern as to how personal information is treated.

CURRENT TRENDS AND DEVELOPMENTS OF RELEVANCE TO THE SECTOR

With that background in mind, we will explore below a handful of the current trends and developments in cyber security and data protection that are relevant to organisations in the life sciences sector with their valuable intellectual property assets and personal information.

1. Mandatory breach notifications and worldwide complications

Mandatory reporting regimes for incidents in which there is unauthorised access to and/or disclosure of personal information (data breaches) have been implemented in a number of jurisdictions and have increased the attention given to data breach incidents. It is arguable that without mandatory breach notifications, the massive data breaches experienced by Sony, Adobe, Target, Anthem and many others would not have become widely known until long after the breach occurred, if ever.

However, there is a growing perception that mandatory breach notifications may not be the panacea for the exposure of cyber-attacks and data breach incidents that it first appears to be.

There are concerns, primarily originating from the United States where mandatory breach notifications were first introduced, that the volume of breach notifications may desensitise society to the impact of all but the largest breach incidents. Smaller notifications may also get lost as background noise in the face of larger breach notifications.

Of far greater concern is the increasingly complex and differing notification regimes being implemented worldwide. In our experience, breach incidents often involve the data of entities from multiple jurisdictions. Identifying the jurisdictions and breach notification laws of each relevant jurisdiction as soon as possible after a breach incident is critical given the diversity of requirements imposed by notification laws across the world.

From our experience, notification requirements across the globe can differ significantly for even a relatively minor breach, with regulations in some jurisdictions stipulating that a minor breach amounts to criminal conduct, whereas no action may be required in other jurisdictions. The deadlines by which a breach needs to be notified also tend to vary by jurisdiction.

Cyber security has an inherently global dimension and the jurisdictions in which a company may face exposure is an often overlooked risk that companies do not properly consider. In fact, a 2015 Cyber Impact Report revealed that only 24 percent of respondents are fully aware of the consequences that could result from a data breach or security exploit in countries other than those in which their company operates.

We expect that the complexity and diversity of breach notification requirements across the world will only increase in the next five years. Indeed, breach notification requirements in the United States itself will likely become more complex in the near future on account of the anticipated introduction of Federal notification laws in addition to pre-existing state laws. It is and will increasingly be a major cost for companies. We cannot see there being any unification of breach notification laws across many countries in the near or long term future.

2. Cyber insurance as a standalone product and rapid response

Insurers are taking steps to ensure that cyber related risk is excluded from policies never designed to cover these risks. For example, many insurers are refining management liability policies to exclude cyber related incidents they were not designed to cover. Claims relating to electronic records and data are also being excluded from general liability policies.

Coinciding with this is the growth in specific cyber cover extensions for these policies (as opposed to stand-alone cyber policies). These products fit a current market demographic of insureds who are not yet willing to purchase a stand-alone cyber insurance product.

However, cyber cover extensions generally have limitations as to cover as compared to stand-alone products. This can include limiting the range of potential attacks covered, providing low policy sub-limits, or often limiting the heads/classes of loss as compared to a standalone policy – and the types of losses arising from a cyber-attack are very broad.

In addition, many stand-alone cyber policies provide a rapid response cover. The protection afforded by rapid response comes into play as soon as a cyber-attack has been identified. Rapid response cover can play a pivotal role in controlling the fallout from an attack and also limit the financial and reputational damage by controlling what happens in the first 48 hours after a company has identified it is under a cyber-attack.

The decisions made during this period will affect all future decisions and measures relating to the attack. This includes the protection of sensitive communications, how best to address the attack itself from an IT perspective (a brute force approach is often not the best approach) and the extent of notifications that need to be made (including the number of jurisdictions involved). In this respect, not all cyber-attacks result in a data breach incident (a common misconception).

Since the benefits of having expert teams to handle cyber claims in a consistent manner for all clients are significant we expect that the offering of access to a rapid response team will become a standard component of policies.

3. Increased legislative and regulatory focus

There are increasing legislative and regulatory pressure on organisations to ensure that they take "reasonable steps" that their data and systems are secure. Given the generally accepted view that the pharmaceutical and life sciences sector has a low level of preparedness and performance in relation to cyber security, this increasing regulatory focus should be of concern to organisations in the sector.

Australia's corporate regulator, ASIC, noted in Report 429 (Cyber resilience: Health check), issued in March 2015, that effective corporate governance should involve active engagement by directors and the board in managing any applicable cyber risk and that directors may need to take cyber risks into account when undertaking their duties. While boards and directors have been aware of these issues for some time, the fact that ASIC expressly identified these issues in its report highlights that cyber security and information security are very much "front of mind" issues for corporate regulators in Australia and the Asia-Pacific region.

Listed entities are also subject to continuous disclosure obligations in relation to market sensitive information. Given the potential financial and reputational impacts of data breach incidents, the occurrence of a cyber-attack or data breach incident is potentially market sensitive information that must be disclosed under these continuous disclosure obligations.

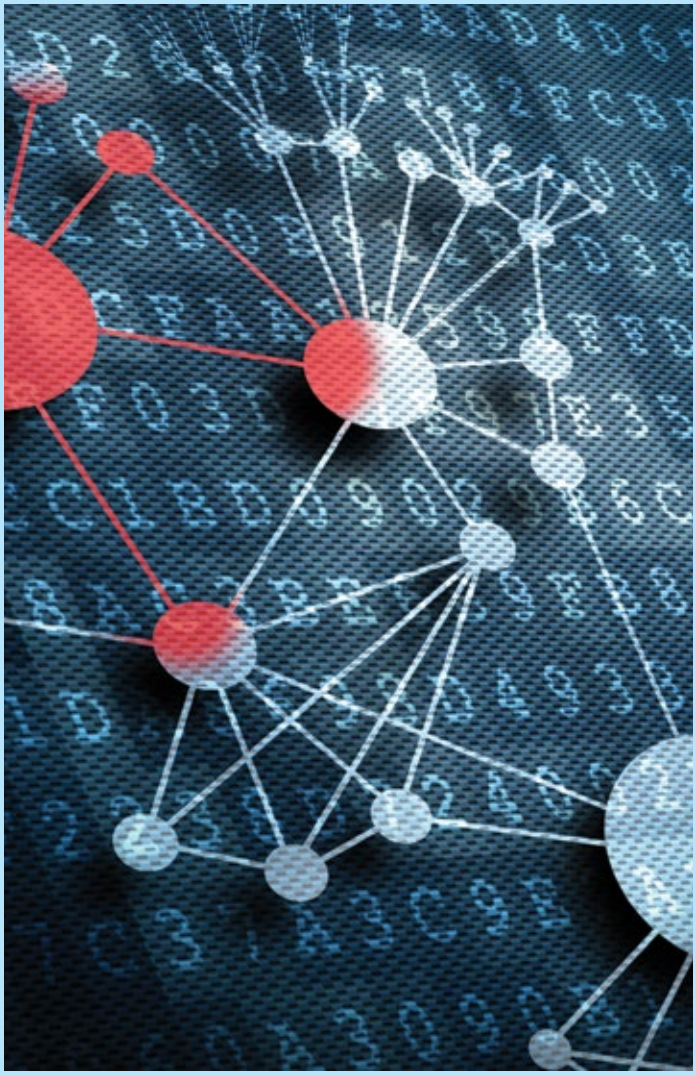
4. A change in the nature of attacks

The current threat environment stems from the lack of attention that cyber security has received prior to the last few years. This has led to a volume of wide and varied vulnerabilities across many systems as businesses struggle with making their systems more resilient. The resultant nature of cyber-attacks have been wide and varied, including ransomware, distributed denial of service, watering hole, remote access, phishing and malware attacks.

We expect that as consolidation and standardisation of security tools and systems increases over the next six to eight years, cyber attackers will focus their attention on identifying and attacking vulnerabilities within these "standard" tools and systems so that they maximise the potential number of targets.

An example of this is the exploitation of the Heartbleed vulnerability (which affected systems that used OpenSSL, a secure networking protocol) that was identified in April 2014. The vulnerability was exploited en masse within hours of its release, before a fix had been developed or could be applied. The risks posed by these exploits in "standard" tools and systems are exacerbated by the slow responses of organisations to address them – in the case of Heartbleed, approximately 84 percent of Australian businesses had yet to fully address the vulnerability 12 months after its release.

There will always be targeted attacks on high profile businesses. However, it might be the case that cyber attackers move from attacking a range of different, high profile targets to attacking many organisations, large and small, based on a newly released vulnerability.



THE *MYRIAD* OF PROBLEMS AND OPPORTUNITIES CONTINUES – AN UPDATE ON THE PATENTABILITY OF NATURALLY OCCURRING PRODUCTS IN AUSTRALIA

By Nicholas Tyacke, Eliza Mallon and Louis Italiano

In *Life Sciences Spotlight – Issue 5*, we discussed the then current state of the law regarding the patentability of isolated genetic material and other naturally occurring products in the US and Australia, and the impact of those decisions.

As discussed in detail in that article, at that time:

- The US Supreme Court had held that isolated genetic material was not patent eligible under US law, and US courts and the US Patent and Trademark Office (USPTO) had been consistently extending that decision to hold claims directed to other naturally occurring products, such as proteins and cells, as well as claims to methods utilising those products, to also be patent ineligible under US law.
- Australian law stood in stark contrast, with an expanded 5 judge appeal court unanimously affirming a lower court decision and confirming long held understanding and Australian patent office practice that isolated genetic material was patentable subject matter in Australia.

Since that article, there have been significant developments in each jurisdiction. In Australia, the High Court of Australia (Australia's highest court – High Court) recently overturned the decision of the expanded appeals court referred to above and held that the claims-in-suit to isolated genetic material did not claim patentable subject matter under Australian law, and the Australian patent office has since issued for comment details of its proposed revised examination practice following that decision. In the US, the US Court of Appeals for the Federal Circuit (CAFC) recently held that a patent directed to a method for detecting a paternally inherited nucleic acid sequence of fetal origin (cell-free fetal DNA (cffDNA)) in maternal serum or plasma from a pregnant woman is invalid and ineligible for patent protection. In this article, we discuss the High Court's decision in Australia and its implications in more detail and on pages 15 – 16, Dr. Lisa Haile discusses the CAFC's decision and its implications.

THE HIGH COURT OF AUSTRALIA – *D'ARCY v MYRIAD*

In *D'Arcy v Myriad Genetics Inc* [2015] HCA 35 *(D'Arcy v Myriad)* the High Court unanimously held[1] that the claims-in-suit to isolated nucleic acids coding for mutations or polymorphisms of the BRCA1 gene[2], **do not** meet the requirements of a "manner of manufacture" within the meaning of the *Patents Act 1990* (Cth) (Act) and are therefore not a patentable invention in Australia.

The High Court's decision overturned Justice Nicholas' decision at first instance, and a unanimous decision of an expanded bench of five judges of the Full Federal Court of Australia. The earlier decisions had held that the claimed isolated nucleic acid sequences in question were indeed

[1] The High Court's decision was unanimous as to result, but not as to reasoning, with the court issuing three separate judgments: majority judgment (French CJ, Kiefel, Bell, and Keane JJ) and two concurring judgment (Gageler and Nettle JJ; Gordon J). This article will focus on the majority judgment.

[2] Claim 1 is representative of the 3 claims in suit, and was in the following form:
"An isolated nucleic acid coding for a mutant or polymorphic BRCA1 polypeptide, said nucleic acid containing in comparison to the BRCA1 polypeptide encoding sequence… one or more mutations or polymorphisms selected from [specified] mutations..."

"manners of manufacture" on the basis that they were an "artificially created state of affairs of economic significance", following the criteria identified in the longstanding High Court authority on patentable subject matter in Australia, *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252 (*NRDC*), and that an invention that satisfies these criteria will constitute a "manner of manufacture."

In *D'Arcy v Myriad,* the majority of the High Court rejected the primary judge and the Full Court's application of the principles propounded in *NRDC*, stating that they rested upon an unduly narrow characterisation of the effect of that decision, and that the terminology "artificially created state of affairs of economic significance" is not a formula, the satisfaction
of which will mandate a finding of inherent patentability.

The majority held that the lower courts had asked the wrong question:

"The question for… determination… was not whether a claimed invention, prima facie patentable, should be denied patentability by judicial fiat. The question was whether the claimed invention lay within the established concept of a manner of manufacture and, if not, whether it should nevertheless be included in the class of patentable inventions as defined in s 18(1)(a) of the Act."

The majority then held that, properly characterised in accordance with **substance rather than form**, the subject matter of Myriad's claims was to the **"genetic information"** of the nucleotide sequences which coded for mutated or polymorphic BRCA1 polypeptides, rather than to classes of chemical compounds. Based on this construction, their Honours held the claims in issue were not within the established boundaries of the concept of a "manner of manufacture" as developed through case law.

The majority further held that where such a new class of claim involves a significant new application or extension of the concept of "manner of manufacture", the following factors, including those derived from the *NRDC* decision (being the first two factors listed below), may be relevant to determining whether that concept should be extended by judicial decision to include that class of claim, including:-

1. Whether the invention as claimed is for a product made, or a process producing an outcome as a result of human action.
2. Whether the invention as claimed has economic utility.[3]
3. Whether patentability would be consistent with the purposes of the Act; in particular:
   - Whether the claimed invention could give rise to a large new field of monopoly protection with potentially negative effects on innovation;
   - Whether the claimed invention could have chilling effects on activities beyond those within the formal scope of the claims; and
   - Whether according patentability would require the court to assess important and conflicting public and private interests and purposes.
4. Whether according patentability to the claimed invention would enhance or detract from coherence of the law relating to inherent patentability.
5. Factors relevant to Australia's place in the international community:
   - Australia's international legal obligations; and
   - The patent laws of other countries.
6. Whether according patentability would involve law-making of a kind which should be done by the legislature.

The majority held with respect to the first factor that the genetic information was not modified by mere isolation and was not "made" by human action:

"The information is not "made" by human action. It is discerned. That feature of the claims raises a question about how they fit within the concept of a "manner of manufacture." "As appears from s 6 of the Statute of Monopolies, an invention is something which involves "making"... Whatever it is, it must be something brought about by human action. The requirement, in each claim, that the sequence in the isolate bear specified mutations or polymorphisms raises the same problem in a particular way. Satisfaction of that integer depends upon a characteristic of the human being from whom the nucleic acid is isolated, a characteristic which is not shared by all human beings. It has nothing to do with the person who isolates the nucleic acid bearing the mutant sequence."

and

"[T]he fact of the existence of the requisite mutations or polymorphisms is a matter of chance. It is not something "made." It is not "artificially created."

[3] The majority stated that when the invention falls within the existing concept of manner of manufacture as developed through case law, applying factors 1 and 2 will ordinarily be sufficient.

As to the second factor, the majority can be understood to have considered that this factor was also not satisfied by the claims as the isolated genetic sequence (which is not sold and therefore does not have a direct economic benefit) is but a step in the process in which the economic significance resides, the genetic screening test:

"The economic significance necessary to the patentability of an 'artificially created state of affairs' in the sense used in NRDC is not demonstrated by stating that the artificially created state of affairs is a step along the way to a process or method itself claimed as an artificially created state of affairs of economic significance."

The majority held that the above wider considerations also militated against characterising the claimed invention as a "manner of manufacture." The majority stated:

"Claims 1 to 3 include the products of applying any process, known or unknown, to the cells of a human being which extracts or replicates from them nucleotides which code for mutant or polymorphic BRCA1 in the sequences specified in the Patent, whether or not the isolate contains other components and sequences. The size of the class of the products as defined is large… The boundaries of the class are not defined by a limiting range of chemical formulae. There is a real risk that the chilling effect of the claims, on the use of any isolation process in relation to the BRCA1 gene, would lead to the creation of an exorbitant and unwarranted de facto monopoly on all methods of isolating nucleic acids containing the sequences coding for the BRCA1 protein. The infringement of the formal monopoly would not be ascertainable until the mutations and polymorphisms were detected. Such a result would be at odds with the purposes of the patent system."

and also:

"[if the] claims are properly the subject of a patent, the patent could be infringed without the infringer being aware of that fact. That consequence coupled with the very large, indeed unquantified size of the relevant class of isolated nucleic acids, all of which bear the requisite information, raises the risk of a chilling effect upon legitimate innovative activity outside the formal boundaries of the monopoly and risks creating a penumbral de facto monopoly impeding the activities of legitimate improvers and inventors."

Factor 6 also played an important role in the majority's analysis:

"The proposition that a broad statutory concept [manner of manufacture] applies to a new class of case on the boundaries of existing judicial development of that concept requires consideration of the limits of judicial law-making... Where an affirmative application of the concept is likely to result in the creation of important rights as against the world, to involve far-reaching questions of public policy and to affect the balance of important conflicting interests, the question must be asked whether that application is best left for legislative determination. The patentability of nucleotide sequences derived from human DNA is in that category. The inherent patentability of the invention as claimed would powerfully imply patentability of any claim for an isolated nucleic acid coding for a specified polypeptide."

and its ultimate conclusion:

"The substance of the invention as claimed and the considerations flowing from its substance militate against that characterisation. To include it within the scope of a "manner of manufacture" involves an extension of that concept, which is not appropriate for judicial determination."

However, in assessing the impact of the High Court's decision, it is important to note that the patentability of the other claims of the patent-in-suit, directed to probes, vectors, methods of production, and methods of diagnosis, had not been challenged in the litigation. Thus, the High Court did not make any finding with respect to those claims.

AUSTRALIAN PATENT OFFICE'S PROPOSED REVISED EXAMINATION PRACTICE

On 16 October 2015, the Australian Patent Office published for consultation its proposed revised examination practice in view of the *D'Arcy v Myriad* decision. Unlike the several guidances issued by the USPTO following the US Supreme Court's *Myriad* decision, which adopted an expansive interpretation of that and subsequent decisions (see the detailed discussion of both these decisions and the USPTO guidances in our earlier article), the Australian patent office has proposed a narrow interpretation of the *D'Arcy v Myriad* decision, stating that that decision concluded that a claim to an isolated nucleic acid that merely represents information coding for a polypeptide is not patent eligible, and that on that basis, it considers the following are not patent eligible in Australia:

- Naturally occurring human and non-human nucleic acid sequences encoding polypeptides or functional fragments thereof – either isolated or synthesised;
- cDNA;
- Naturally occurring human and non-human coding RNA – either isolated or synthesised.

The Australian Patent Office proposal further indicates that it will continue to treat claims directed to the following as patent eligible as *"they do not merely represent information coding for a polypeptide";*

- Naturally occurring isolated regulatory DNA (e.g. promoters, enhancers, inhibitors, intergenic DNA);
- Isolated non-coding (e.g. "Junk") DNA and RNA (e.g. miRNA);
- Naturally occurring isolated bacteria and viruses;
- Isolated polypeptides and synthesised/modified polypeptides;

- Isolated polyclonal antibodies and monoclonal antibodies;
- Chemical molecules purified from natural sources (e.g. new chemical entities, antibiotics, small molecules);
- Isolated cells including isolated stem cells;
- Probes and primers;
- Isolated interfering/inhibitory nucleic acids (e.g. antisense, ribozymes) and fusion/chimeric nucleic acids; and
- Transgenes comprising naturally occurring gene sequences and vectors, microorganisms, animals, and plants comprising a transgene.

Comment was sought by 6 November 2015. The Australian Patent Office is currently considering these comments before finalising examination practice and has placed on hold the examination of patent applications containing claims directed to technology that could be impacted by the *D'Arcy v Myriad* decision until patent office practice is settled.

CONCLUSION

The majority's decision in *D'Arcy v Myriad* suggests that the High Court's decision is a narrow one, the majority explicitly stating:

"This court is not concerned in this appeal with 'gene patenting' generally but whether the invention as claimed in claims 1 to 3 falls within the established concept of manner of manufacture."

The proposed examination practice issued for comment by the Australian patent office in light of that decision indicates that the patent office intends to apply that decision reasonably narrowly. It thus appears that Australia will not head down the path adopted by US courts and the USPTO (discussed in our earlier article and in the below counterpart article in this edition, where broad areas of technology have been deemed patent ineligible. The Australian legal environment thus remains one conducive to research and development, and investment, in the Australian biotechnology industry.

AN UPDATE ON THE PATENTABILITY OF NATURALLY OCCURRING PRODUCTS IN THE US

By Dr. Lisa Haile

The US Court of Appeals for the Federal Circuit (CAFC) ruled on 12 June 2015 that Sequenom Inc's patent directed to a method for detecting a paternally inherited nucleic acid sequence of fetal origin (cell-free fetal DNA (cffDNA)) in maternal serum or plasma from a pregnant woman is invalid and ineligible for patent protection because it applies to a natural phenomenon.

The dispute began several years ago when Sequenom claimed that Ariosa Diagnostics' Harmony Test, a non-invasive test for prenatal diagnosis of certain fetal characteristics, infringed US patent number 6,258,540, which was issued in 2001.

Following Sequenom's action against it, Ariosa sought a declaratory judgment from the US District Court for the Northern District of California that it did not infringe the patent. Sequenom counterclaimed, alleging infringement and seeking to preliminarily enjoin Ariosa from selling the Harmony Test. In 2012 the district court rejected Sequenom's request for a preliminary injunction, indicating that Ariosa's Harmony Test did not infringe Sequenom's patent and, further, that the patent was invalid. The court found that the asserted claims of the patent were not directed to patent-eligible subject matter and were invalid under 35 USC §101.

The CAFC's Sequenom ruling supports the district court ruling with all three judges deciding in Ariosa's favour. In a concurring opinion by Judge Linn, he acknowledged that the inventors' discovery regarding cffDNA may have been a significant contribution to the medical field, but that alone does not make it patentable. He distinguished Sequenom's claimed invention from the claims in the *Mayo* case, however it was clear that he felt his hands were tied by the Supreme Court's ruling in that case. Based on *Mayo*, Judge Linn and the court agreed that detecting cffDNA in maternal plasma or serum is a positive and valuable contribution to science, although it still falls short of statutory patentable subject matter.

Reflecting on the *Sequenom*, *Mayo* and prior *Myriad* decisions (the latter two which we discussed in our previous article a question arises as to what constitutes a new and patent-eligible invention today in the diagnostics and personalised medicine fields in the United States and are the patent owners in *Sequenom*, *Mayo* and *Myriad* victims of early disclosure for inventions that have been acknowledged as being important to science and medicine? Patent law is designed to encourage inventors to disclose their new technology to the world as soon as possible by offering the incentive of a limited time to prevent others from making, using or selling their technology.

The lesson from these cases is that while the discovery or observation of a natural phenomenon may be very important, and in certain instances reflects a critical medical breakthrough, discovery or observation alone does not rise to the level of patent-eligible subject matter. In order to take the discovery or observation to the next level to be considered patent eligible the inventors must apply it in a way that adds substantially more, including identification and application of novel mutations or polymorphisms, for example.

It is becoming abundantly clear that the courts and the US Patent and Trademark Office are consistently relaying a message that if method claims do no more than recite routine or conventional methods and steps, and the claims do not provide significantly more, then they will be found to be invalid or patent ineligible, regardless of the significance of the invention to science and medicine.

On 13 August 2015, Sequenom requested an *en banc* review of the CAFC's decision to invalidate its patent in its dispute with Ariosa arguing that decision creates an "existential threat" to patent protection. Sequenom's petition for *en banc* review is based on the premise "that the panel's decision allegedly misinterprets *Mayo* both by failing to read that decision in light of the key Supreme Court precedent that *Mayo* endorses and by reaching a result the Supreme Court has twice disavowed in recent opinions." It is unclear whether the Federal Circuit will hear the case with several Supreme Court cases hanging over it in the diagnostics field.

Unfortunately, the diagnostics and personalised medicine industry is many years into the patent process relying on specifications filed with early priority dates but with the rules of the game changing mid-stream. If the Sequenom patent had disclosure in it at the time of filing based on certain novel mutations that correlated with the diagnosis of foetal characteristics, claims including these mutations in the method of amplifying and detecting cffDNA may be considered patent-eligible and valid.

In pursuing claims today, rather than trying to pre-empt the broad scope of a natural phenomenon or observation, it is more realistic for companies to initially focus on claiming their commercial embodiments first and work outward from there. Clearly this is counterintuitive to the approach taken to obtain patents in the past, where one would start as broad as possible and work inward.

IMED: TELEMEDICINE AND THE LAW

By Lance Miller and Ann Cheung

Telemedicine, sometimes referred to as telehealth, is, in brief, the remote diagnosis, care and treatment of a patient by using technologies. There are many definitions of telemedicine. The interpretation of telemedicine adopted by the World Health Organization in its policies on health telematics is: "the delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities." A more liberal interpretation of telemedicine includes doctor-to-doctor and generalist-to-specialist interactions. The discussion in this article primarily covers doctor-to-patient telemedicine.

Biometric technologies and healthcare analytics are being developed to allow diagnosis and treatment (for example, prescription of medicine) via telephone or internet-based medical consultations between patients and their medical doctors. Increasing amounts of investment from venture capitalists in the life sciences industry are being directed into digital healthcare.

Advantages of telemedicine include cost-effectiveness, access to specialty and sub-specialty medical care, access to medical care for patients in rural or underserved areas, and the use of advanced telecommunications technologies to provide continuous or periodic clinical assessment and monitoring of remote patients. One example of government-sanctioned use of telemedicine is from the United States Department of Health and Human Services, which allows a hospital to share neuro emergency telemedicine resources with another hospital, in the interest of improving medical care for stroke patients by reducing unnecessary patient transfers and, correspondingly, decreasing the costs associated with these transfers, such as ambulance services. The timely treatment of stroke patients also decreases the incidence of stroke-related disabilities, which, in turn, decreases the costs associated with treating and supporting such patients. Details can be found in the United States Office of Inspector General Advisory Opinion No. 11-12.

"Telemedicine is an open and constantly evolving science, as it incorporates new advancements in communication technology and responds to the changing health needs of aging, widely disbursed and time-deprived societies."

As such, telemedicine providers face many commercial and compliance challenges. On the commercial side, before health services providers can encourage patients to explore telemedicine, they must first deal with the issues of insurance coverage and reimbursements. One legislative solution is to have parity laws that require national and private health insurers to cover and provide reimbursement for services provided via telemedicine in a comparable manner to how the health insurers would for the equivalent services provided in an in-person consultation or examination.

On the compliance side, telemedicine is sufficiently different from usual care as to require its own medical practice

protocols, which govern matters such as training, technology, standards of care, professional liability, maintenance of medical records, insurance coverage, informed consent, disclosures, continuity of care, and bona fide doctor-patient relationship. In countries where telemedicine is more developed, there are laws and regulations that set minimum standards of practice for medical care provided via electronic means, such as the online prescription of medications.

CYBERSECURITY IMPLICATIONS OF TELEMEDICINE

Telemedicine requires individually identifiable information, in the form of audio files, clinical data, digital images and videos, to be captured and stored online and offline in multiple databases and devices. Therefore, in addition to medical laws and regulations, sharing medical information via technology comes with significant telecommunication, cybersecurity and personal data privacy implications. From an information technology law perspective, implementation of telemedicine will require:

- patient privacy protocols that:
  - are compliant with data protection laws in multiple jurisdictions; and
  - include guidelines on data disclosures and the sharing of data and management responsibilities with other health care providers and telemedicine service providers.
- data storage, processing and transmission security protocols for protecting health information from unauthorized access by unauthorized persons;
- personnel training for the proper storage, processing and transmission of medical data of individuals;
- compliance programs for using internet-based platforms to deliver medical care;
- incorporation of telemedicine-specific risks into any existing compliance programs; and
- guidelines on what data are to be maintained as part of the medical record of patients.

TELEMEDICINE IN JAPAN

The telemedicine industry in Japan is much less established than that in the United States. Unlike the United States, Japan does not yet have any legislation that specifically regulates telemedicine. On licensure for medical practice, only medical doctors who are licensed in Japan can legally practise medicine in Japan, which essentially prevents overseas telemedicine providers to operate in the Japanese market without Japan-licensed medical doctors on staff.

Article 20 of the Japan Medical Practitioners' Act stipulates that no medical practitioner is to provide medical care or issue any medical certificate or prescription without personally performing an examination. However, a notice issued by the Japan Ministry of Health, Labor and Welfare clarifies that telemedicine is permitted for the remote medical treatment of certain stay-at-home patients, such as those receiving oxygen therapy and those suffering from incurable disease, diabetes, asthma, high blood pressure, atopic dermatitis, decubitus ulcer, cerebrovascular disorder, or cancer. For these patients, telemedicine can only be provided:

- if face-to-face consultation between the patient and his or her medical doctor is impossible; or
- if it is used for the treatment of a chronic disorder suffered by a patient who is in a stable condition.

Much like regulations in other countries, neither diagnosis nor treatment can be provided through telemedicine in Japan without an initial physical examination conducted by a medical doctor licensed in Japan.

TELEMEDICINE IN CHINA

On 29 August 2014, the Chinese National Health and Family Planning Commission (CNHFPC) issued the Opinions of the National Health and Family Planning Commission Regarding Promoting Healthcare Institutions' Telemedicine Services (Circilar51) and the CNHFPCinterpretations of Circular 51, which are China's first comprehensive guidelines on telemedicine. This demonstrates the Chinese government's efforts in promoting the development of telemedicine services under enhanced supervision by regulatory authorities.

Circular 51 defines the scope of telemedicine services as the use of information technologies:

1. where one healthcare institution invites another healthcare institution to use communication, computer and network technologies to provide technical support in the diagnosis and treatment of its patients; or
2. where a healthcare institution provides medical services directly to its offsite patients.

Circular 51 provides a comprehensive framework regarding requirements imposed on healthcare institutions that provide telemedicine services and regarding the implementation of telemedicine practices. Contrary to expectations, Circular 51 does not exclude foreign healthcare institutions from being eligible telemedicine services providers in China. In fact, it is specifically provided that Circular 51 applies to telemedicine services between Chinese and foreign healthcare institutions.

Individual healthcare practitioners cannot provide telemedicine services to patients on their own. Circular 51 stipulates that if healthcare practitioners wish to provide telemedicine services directly to patients outside their own healthcare institutions, they must obtain consent form the healthcare institutions where they are registered to practise, and they must use the medical data platforms established by their healthcare institutions to provide diagnostic and treatment services to their telemedicine patients.

If a healthcare institution is to provide telemedicine services, it must have appropriate equipment and qualified medical professionals to facilitate its operations of telemedicine services. It must ensure that telemedicine service information systems are compliant with medical and data security laws and regulations. This includes designating dedicated departments or persons to run regular tests on the equipment, and where appropriate, to arrange for suitable modifications and updates.

Healthcare institutions are required to suspend telemedicine services and to file reports with local regulatory authorities:

1. if there are any changes to their professional technical staff, key equipment or facilities, or any other conditions that result in it becoming unable to properly provide telemedicine services;
2. if there are any issues with the safety or quality of telemedicine services; or
3. if any telemedicine-related adverse event happens.

On 15 January 2015, the CNHFPC officially announced the publication of the Telemedicine Information System Construction Technical Guide, which presents a broad proposal for building a uniform national telemedicine services network in China. In anticipation of this infrastructure development, foreign life sciences companies and medical care professionals who wish to take part in the Chinese digital healthcare market should consider the compatibility and suitability of their products and services to improve investment opportunities and chances of successful ventures.

CONCLUSIONS

Telemedicine is one development that can help improve the quality of medical services and provide better access to medical care for people living in remote areas around the world.

However, telemedicine presents complex legal issues. This is particularly true since technology eliminates the need to have face-to-face examination or medical consultation in a single geographic place, which was the historic assumption behind the licensing of medical providers and the regulation of medical services previous to advancements in the art of communications through technology. Technology now permits us to cross through geographic and legal barriers with ease. To name just two legal challenges to resolve, regulators must consider:

1. whether cross-border telemedicine will be governed by the laws and regulations of;

   a. the place of residence of the patient who is receiving care and treatment; or

   b. the jurisdiction in which the medical care provider is licensed; and

2. how the laws of the jurisdiction of the patient and the jurisdiction of the medical care provider can be harmonized to permit telemedicine and regulate the rights and duties of both the patient and the medical care provider.

It is not surprising that implementation of laws lags behind technological advancements. In a critically important area such as healthcare, there is a need to pick up the pace.

MAJOR TRENDS GIVE RISE TO COMPETITION CONCERNS IN THE AUSTRALIAN LIFE SCIENCES SECTOR

By Simon Uthmeyer and Matthew Taylor

Many of the global challenges encountered by the life sciences sector in recent years have emerged in Australia. Consistent with the global outlook in 2015, the Australian life sciences sector is grappling with a period of adaptation, reform and uncertainty.

In particular, this period is marked by:

- evolving business models;
- a more competitive market (e.g., increased competition from generic manufacturers);
- the expiration of high-value patents;
- close scrutiny from competition regulators of the responses of originator manufacturers to the threat or entrance of generic competition; and
- sector and wider healthcare reform (e.g., amendments to the Pharmaceutical Benefits Scheme price disclosure arrangements).

Such challenges have necessitated a long-term strategic approach to portfolio management, revenue growth and market expansion. Deloitte's *2015 Global life sciences outlook* contends (at page 7) that '[f]our major trends will capture the sector's attention in 2015: searching for innovation and growth, changing regulatory and risk environment, preserving and building shareholder value and preparing for the "next wave"' of opportunities in the sector.

These major trends will likely give rise to two main competition concerns in Australia, which we disscuss in our article.

1. COMPETITIVE RESPONSES TO THE THREAT OF GENERIC COMPETITION

With the expiration of numerous blockbuster patents in recent years (including Lipitor, Zyprexa, Plavix and Seroquel), the "patent cliff" has arguably passed its steepest point. However, originator manufacturers will continue to sustain significant revenue losses as the procession of patent expiries continues in 2015 and beyond. In several jurisdictions, competition regulators have challenged the legality of commercial strategies and practices employed by patent holders to remain competitive after patent expiry.

Earlier this year, we published a life sciences update about the Federal Court decision in *ACCC v Pfizer*, which upheld Pfizer's strategic response to the threat of generic competition in respect of the atorvastatin market in Australia. Our previous update, sets out the key implications of the decision for life sciences sector clients. However, the Australian Competition

and Consumer Commission (ACCC) is appealing the decision. In particular, the ACCC is seeking clarification from the Full Court on the key issues of market power and anti-competitive purpose.

The ultimate resolution of this case will help demarcate the legal boundaries of legitimate competitive conduct when originator manufacturers respond to the threat of generic competition and therefore set an important precedent for the life sciences sector in Australia. In the meantime, the ACCC will continue to closely scrutinise the conduct of both originator and generic manufacturers.

2. PRESERVING SHAREHOLDER VALUE AND OFFSETTING LOSSES

Rising demand for generic products and significant revenue losses after patent expiry are forcing pharmaceutical companies to implement long-term strategies to diversify their revenue streams, preserve shareholder value and achieve growth. These pressures are driving consolidation in the life sciences sector and shifting the focus toward growth categories, pipeline products and innovative technologies and medicines.

Within the pharmaceutical segment, originator manufacturers are offsetting losses to generic competition by acquiring or expanding their own generic businesses by way of alliance/joint venture or M&A. In addition, M&A activity between pharmaceutical companies and either biotech or medtech companies is expected to blur the lines between the three core segments of the life sciences sector. Recent examples in the Australian context include:

- GlaxoSmithKline's acquisition of Novartis AG's human vaccines business, which received informal merger clearance in Australia in January 2015. The acquisition significantly enhanced the breadth of GlaxoSmithKline's vaccines portfolio and pipeline and strengthened its manufacturing network;
- The merger of GlaxoSmithKline's and Novartis AG's consumer healthcare businesses (forming a new joint venture company, GSK Consumer Healthcare), which received informal merger clearance in Australia in December 2014, subject to a section 87B undertaking accepted by the ACCC. The joint venture combined significant capabilities and expertise in both over-the-counter and fast-moving-consumer-goods; and
- Pfizer's proposed acquisition of Hospira Inc, which received informal merger clearance in Australia in August 2015. Hospira Inc is the world's leading provider of sterile injectable pharmaceuticals and infusion technologies and is a global leader in biosimilars (i.e., generic biopharmaceutical products). Both sterile injectable pharmaceuticals and biosimilars are large and growing categories, and the proposed acquisition represents a strategic, complementary combination of branded and generic sterile injectable pharmaceuticals. The ACCC considered that the proposed acquisition was unlikely to substantially lessen competition in any relevant market.

M&A activity in Australia will give rise to competition concerns where a merger would have the effect, or be likely to have the effect, of substantially lessening competition in a market. Merger parties are not legally required to notify the ACCC and may complete a transaction without seeking any regulatory approval. However, the ACCC may subsequently investigate a merger and, if necessary, take legal action. In Australia, merger parties can have a proposed transaction considered and assessed by:

- either informal or formal merger clearance from the ACCC; or
- applying to the Australian Competition Tribunal for merger authorisation.

The test for whether a merger or acquisition of assets will breach the merger provision contained in section 50 of the Competition & Consumer Act is whether the transaction will likely substantially lessen competition in a relevant market. In essence will the acquirer post-merger face such insufficient constraint that it can "charge more or give less." The application of this test requires an examination of the substitutes for the products and services of the relevant businesses and the constraints upon their competitive conduct.

GETTING TOUGH ON CORRUPTION

WHY BUSINESSES SHOULD TAKE A CLOSER LOOK AT THEIR ACTIVITIES IN THAILAND

By Jimmy Chatsuthiphan and Lucy Porter

The longstanding view was that corruption is an inevitable aspect of doing business in Thailand, in large part due to the constant allegations of graft against government officials coupled with historically weak enforcement by local regulators. However, companies operating in Thailand should be aware of several indicators that this is changing:

1. The current Military Government has made anti-corruption a centrepiece of their domestic policy from the very start. We have since witnessed an unusual wave of corruption probes and enforcement actions against the public sector, including arrests of high ranking police officers, suspensions of numerous public officials and a recent indictment of the former Tourism Authority of Thailand governor in a well-known bribery scandal. In addition, Former Prime Minister Yingluck Shinawatra and several former ministers have been charged with graft. The Office of the Auditor General has also become extremely active in the anti-corruption space under the new Government regime. Our view is that the overall uptick in enforcement activity signals a renewed commitment to tackling the problem of corruption.
2. The country's primary anti-corruption law, the Organic Act on Counter Corruption, was significantly strengthened through recent amendments which impose harsher penalties for corruption offenses. Fines and prison terms have increased, but, most notably, severe corruption is now punishable by death under the Act. Moreover, these penalties now extend beyond civil servants to Thai and foreign state officials, including officials who work for international government agencies/ organisations who are found guilty of corruption. The head regulator has commented that the changes are justified because of the severity of a corruption offense and the danger it poses to the country.
3. Another key amendment to the Organic Act on Counter Corruption is a new provision that penalizes a company for a bribe made by an employee, agent, or associated company – much like the *UK Bribery Act*. Importantly, the provision expressly provides for a defense if "appropriate internal control measures" are in place to prevent the offense. It is unclear what would specifically meet that standard, but this language presents a compelling reason for Thai companies to implement a robust compliance program that includes educating and training employees to act accordingly.
4. Other legal reforms have gone into effect that reflect the Government's emphasis on rooting out unscrupulous activities that have long flown under the radar in Thailand.

For example, the new *Licensing Facilitation Act* is designed to counter bribery and enhance transparency in relation to the issuance of licenses and permits. The Act requires all agencies that issue licenses and permits to develop a manual that describes the procedural requirements and sets internal timelines for approvals. Importantly, the Act also contains a whistleblower remedy for applicants to file complaints.

5. The target date for the creation of an integrated ASEAN Economic Community (AEC) is the end of 2015. The AEC countries are aiming for regional cooperation to curtail systemic corrupt business practices which have become so deeply engrained in the region. It is expected that the AEC will allow countries to share best practices and develop joint approaches to fight corruption. Many predict that the looming formation of the AEC will continue to put pressure on corrupt business practices in Thailand to be investigated more aggressively and prosecuted with a greater sense of urgency.

Given the convergence of all the above, the perception in the market is that Thailand's stance on corruption is finally hardening after years of rhetoric and inaction. Although the Thai anti-corruption laws and measures have thus far been aimed at Thai and foreign public officials and international government agency/organization officers, it appears inevitable that enforcement actions against private companies are on the horizon. Businesses will want to be more attentive than ever about their operations so as not to find themselves embroiled in a corruption investigation or prosecution in Thailand. Not only could this result in a ban from conducting business in Thailand, but for multinationals this could also trigger a separate investigation by regulators in their home country and/or by US/ UK regulators if subject to the *US Foreign Bribery Corrupt Practices Act* or *UK Bribery Act*.

In light of the changing business environment, establishing a comprehensive compliance program is becoming particularly important for companies operating in Thailand. For the first time, it is expressly indicated that appropriate compliance measures can serve as a defense for companies under the new amendments to the anti-corruption law. Internal anti-bribery policies, procedures and guidelines must be established and actively enforced. Any company engaging in transactions with Government entities or interactions with Government officials and agencies is well advised to conduct regular compliance audits, and address any complaints or "red flags" immediately.

Some of the areas worth paying attention to include:

- Maintain up-to-date policies and procedures and codes of conduct and ethics in both English and Thai.
- Regular training of staff, presented in both Thai and English, to ensure they understand their roles and responsibilities and applicable procedures.
- Set out clear instructions/guidance to applicable staff regarding interactions with Government officials and reporting of interactions and work to their direct report.
- Check and assess document management and data retention policies and whether these are well communicated to employees.
- Periodic monitoring and auditing of sales and marketing practices, as applicable.
- Check and assess the current procedures for the handling of whistleblower complaints.
- Have a plan in place for an unannounced visit from local authorities and for a potential regulatory investigation, including protocol to properly implement and train your employees to respond in an orderly and effective manner.

INTERNATIONAL MOBILITY AND THE NEED FOR UPFRONT PLANNING – A NEW ZEALAND PERSPECTIVE

By Laura Scampion and Ashleigh May

The modern workforce is one of increasing international mobility. In New Zealand, our workforce is already heavily reliant on skills from overseas. New Zealand businesses and companies are increasingly looking abroad to recruit top executives and skilled employees. The "Christchurch rebuild", following the February 2011 earthquake, provides a clear example of the effect the new global workforce has on New Zealand. During the first six months of 2013, it was reported in *Stuff News, Christchurch Gains 22 Migrants a day, 27 July 2013*, that 22 skilled international migrants joined the rebuild each day.

The international mobility of the modern workforce is only set to increase. Research from *PwC's Talent Mobility 2020: The next generation of international assignments, 2010*, shows that the number of people working outside their home country will increase by 50 percent between 2010 and 2020. To this extent, the future of our workforce (for employers) and the global opportunities (for employees) looks exciting. However, moving employees around the globe comes with its own set of legal challenges from an employment law perspective. Therefore, it is important that during periods of international mobility, employers document their arrangements carefully and remain cautious about any disparate treatment between local employees and secondees.

SHORT-TERM INTERNATIONAL TRAVEL/BUSINESS VISITS

If an employer only envisages periods of short-term travel abroad for an employee (essentially "visits") it can be fairly straightforward to document. We recommend a clause in the relevant employment agreement that makes it clear to the employee that they will be required to spend a good deal of their time travelling to other countries. We also recommend seeking specialist tax and immigration advice in the relevant jurisdictions to ensure compliance with local laws.

INTERNATIONAL SECONDMENTS

Documentation

If an employer plans to relocate an employee for an extended period of time (say three months or more) it is often labelled a secondment. A secondment can be described simply as a temporary "loan" of an employee. Secondments can take place through a number of different scenarios, both nationally and internationally. However, sending employees on secondment to work in a different jurisdiction often poses complex considerations for employers. Ideally, such arrangements should be facilitated through an assignment/secondment agreement. A secondment agreement is a contract or letter designed by the existing, or "home", employer that sets out the terms under which the employee will be seconded to work for the "host" employer.

It is vital that the secondment arrangement is properly documented and agreed from the outset to avoid uncertainty and unexpected costs or liabilities. The following points are just some of the questions employers should ask themselves when:

a. Drafting secondment documentation for employees heading off on overseas secondments; or

b. Considering secondment documentation that has been drafted in another jurisdiction for an employee seconded to New Zealand.

- **How long is the secondment and how/when does it end?** It is important to set out the duration of the secondment, as well as what will happen when it ends. Issues such as who will be responsible for relocation costs, what will happen if there is a redundancy situation, or the employee becomes incapacitated, need to be carefully documented. Any agreement should state how the secondment will terminate and whether the employee has a guaranteed return to their previous role with the home employer after the secondment.
- **Are there any minimum code requirements in the host country?** Employment laws vary between different jurisdictions. In some jurisdictions, compulsory minimum entitlements available to employees who are working in the jurisdiction (even if temporarily), such as sick pay, holiday entitlement and rights on termination, will apply irrespective of the employees home country. Employers should seek local employment law advice to ensure the secondment agreement meets any minimum code requirements in the host country.
- **Who will be the employer during the secondment?** Generally, the employee who is on international assignment will remain an employee of the home employer and the secondment will not sever the contractual link between the employee and the home employer. This should be clearly spelt out in the secondment agreement, together with what rights and obligations the host employer will have during the period of secondment.
- **Who will the secondee report to and who will supervise?** This is particularly important in relation to managing performance and misconduct issues. All parties should understand who is responsible for what, and who they are responsible to, during the period of secondment. The employee should be clear as to who the decision maker is with regard to their employment whilst they are on international assignment.
- **What about confidentiality/intellectual property obligations?** The secondment documentation should expressly set out or refer to any on-going confidentiality and/or intellectual property obligations the seconded employee may have to their home employer. Many employers overlook the fact that the employees will need to agree to separate binding legal obligations with regard to confidentiality and/or intellectual property to the host employer. This can be done within the secondment agreement/letter or by separate deed.
- **Who pays, where is it paid and what is the effect on pension arrangements?** The secondment documentation should state who is responsible for paying the employee during their secondment. Is the host employer paying on behalf of the home employer for the duration of the assignment or will the employee continue to be paid by their home employer? The documentation should also state whether the employee will continue to receive or accumulate any benefits they would have been entitled under their individual employment agreement with the home employer while on secondment. Minimum code obligations may have a bearing on these arrangements.
- **Do we need specialist advice?** Specialist immigration and tax advice should be sought, as well as advice on any relevant local laws that may apply.

Discrimination

One particularly interesting challenge associated with international secondments is the potential for race discrimination, which includes discrimination on the grounds of ethnic or national origin. The risk of discrimination in secondment arrangements is twofold. Either those employees on international assignment are treated less favourably by the host employer than local employees or vice versa – the seconded employees are offered enhanced benefits by the host employer that local employees are not offered by virtue of the fact that they are on an international assignment. For example, a seconded employee might be

offered full healthcare benefits, whereas local employees are not offered this on the basis that they are entitled, as citizens, to access a free national health service. As most employers will be aware, discrimination on the grounds of race, ethnic or national origins is prohibited by the *Employment Relations Act 2000 and the Human Rights Act 1993*.

While discrimination claims are on the increase in New Zealand, there is no case law that specifically deals with discrimination in the context of secondment arrangements. However, if an employee were to bring a discrimination complaint, they would need to identify a comparator real or hypothetical) who is of the same or substantially similar qualifications, experience or skills and employed in the same or substantially similar circumstances. Using the example above, this is relevant as if a local New Zealand employee did make a discrimination claim on the basis of not receiving the enhanced health benefit. They would be using the international secondee as the comparator, as it is the secondee who is receiving the enhanced health benefit.

The United Kingdom case *Wakeman & Others v Quick Corporation [1999] All ER (D) 158* dealt with race discrimination in the context of internationally assigned employees.

In *Wakeman*, the Court of Appeal (CA) accepted that it may be lawful in some circumstances to pay local employees and secondees different rates of pay. This case concerned English employees who were employed by a Japanese company in London. They were paid less than those employees who were seconded from Japan to work in London, and as a result raised a race discrimination complaint that they were being treated less favourably because they were not Japanese. The CA held that the differences in pay were due to factors such as market rates in Japan and enhancements for secondees to account for the cost and inconvenience of temporarily living and working abroad. The CA said that the circumstances of the local employees and the secondees were materially different and that the secondees were therefore not appropriate 'comparators' for the purposes of establishing a discrimination claim.

This case highlights the fact that secondees are often subject to quite different working arrangements/contractual terms and therefore are arguably not appropriate 'comparators' for the purposes of establishing a discrimination claim. However, it will ultimately depend on the terms and conditions outlined in the relevant secondment documentation – reinforcing the need for employers to get their documentation right. For example, making it clear that remuneration is to be paid by the host country on behalf of the home employer, that any additional benefits received are to acknowledge the relocation to a foreign country, and that the secondee remains an employee of the home employer, are all distinctions that should be made by employers when drafting secondment documentation.

Secondments have proved, and will likely continue to prove, successful for many businesses, both within New Zealand and globally. However, it is important that they are managed carefully. Employers need to invest appropriate time in the planning and documentation of all secondments to ensure their success.

IT'S OBVIOUS – THE HIGH COURT RULES ON ASTRAZENECA'S CRESTOR® PATENT

By Nicholas Tyacke, Eliza Mallon, Brodie Williams and Louis Italiano

In AstraZeneca AB v Apotex Pty Ltd; v Watson Pharma Pty Ltd; v Ascent Pharma Pty Ltd [2015] HCA 30, the High Court of Australia (High Court) unanimously upheld the decision of an expanded bench of five judges of the Full Federal Court, and a previous decision of a single judge of the Federal Court, that the invention claimed in AstraZeneca's Australian Patent No. AU200023051 (the '051 Patent) relating to an orally administered, low dosage form of the drug rosuvastatin (marketed by AstraZeneca as Crestor®), lacked an inventive step (was obvious), and that the relevant claims were therefore invalid.

KEY OUTCOMES OF THE HIGH COURT DECISION

1. In determining whether a person skilled in the art would regard prior art information to be relevant for the purposes of determining whether an invention involves an inventive step, regard may be had to one or more sources of prior art information, irrespective of whether such information forms part of the common general knowledge (CGK).
2. Each source of prior art information must be considered separately in light of the CGK. Any single source of prior art information that teaches the claimed invention will invalidate that claim for lack of inventive step, irrespective of whether other sources of prior art information exist that suggest different solutions to the problem.
3. Conducting clinical trials is considered routine where there is a requirement to provide safety data and the mere absence from a source of prior art information of information that could reasonably be obtained from conducting such trials will not preclude a finding of lack of inventive step over that source of prior art information.
4. Under the *Patents Act 1990* (Cth) (the *Act*), inventive step is to be assessed by reference to the CGK and prior art information, and that information is not to be enlarged by reference to the description of the invention (including the problem said to be solved by the invention) in the body of the patent specification (although that information may be taken into account if it is part of the CGK or prior art information). In other words, the description of the invention (including the problem said to be solved by the invention) in the body of the patent specification, which is not part of the CGK or part of the prior art information, is not to be taken as the "starting point" for assessing inventive step. This was the holding of the expanded Full Federal Court, which the High Court did not disturb.

BACKGROUND

The '051 Patent was found to be invalid by the primary judge for want of novelty, inventiveness and lack of entitlement. AstraZeneca appealed these findings to the Full Federal Court, which overturned the decision in relation to novelty and upheld the other grounds of invalidity. AstraZeneca was subsequently granted special leave to appeal the Full Court's findings in relation to inventiveness and entitlement.

ASSESSMENT OF INVENTIVE STEP

Section 18 of the *Act* requires an invention to involve an "inventive step" when compared with the 'prior art base' in order to be patentable in Australia.

The test for determining whether an invention involves an inventive step is set out in section 7(2) of the Act. Section 7(2) provides that an invention is taken to involve an inventive step unless it would have been obvious to a hypothetical person skilled in the relevant art in light of the CGK before the priority date of any given claim, considered separately or together with either of the sources of information specified in section 7(3), each of which need to be considered separately. As it applied to the '051 Patent, section 7(3) specified prior art information publicly available in a single document (or through the doing of a single act) or two or more related documents (or acts) that the skilled person would treat as a single source of information, which the skilled person could be *"reasonably expected to have ascertained, understood and regarded as relevant."*[1]

RELEVANT PRIOR ART

AstraZeneca argued that in determining whether a hypothetical skilled person would be "*reasonably expected to have ascertained, understood and regarded* (a particular document) *as relevant*", the skilled person may use only information that forms part of the CGK, and not information from documents that are not part of the CGK.

The High Court rejected this argument, noting that while section 7 of the Act precluded a skilled person from combining information in individual prior publications when assessing whether an invention is obvious, the skilled person may sort through "*all manner of information with a view to finding something that is 'regarded as relevant'. There is nothing in the provision which would place an embargo upon the skilled person using combinations of sources of information along the road to that destination.*"[2]

PRIOR ART WHICH SUGGESTS "FALSE ROUTES"

AstraZeneca argued that where several prior art documents suggest alternate "routes" to solving the problem that the invention seeks to address, an invention should not be found to lack an inventive step on the basis that the "only course" available to the skilled person was one based on CGK and one relevant prior art document, as this ignores "false routes" suggested by other relevant prior art documents. It was argued that such an approach impermissibly provides the skilled addressee with the benefit of hindsight.

The High Court rejected this argument on the basis that the wording of section 7(2) does not support such a construction and that, once identified, a relevant source of prior art information must be considered in light of the CGK **on its own** in assessing whether a claimed invention lacks inventive step, even if numerous other sources of prior art information exist that are likely to lead a skilled addressee to different solutions.

"STARTING POINT" ISSUE

In affirming the Full Court's finding of lack of inventive step, the High Court found it unnecessary to address the Full Court's decision regarding the "starting point" for assessing inventive step. As a result, the Full Court's decision remains undisturbed that when assessing inventive step under the Act, the invention as claimed must be compared with the CGK and any prior art information, and that the description of the invention (including the identification of the problem) in the patent specification is **not** the "starting point" (or to be taken into account) for such an assessment (unless it forms part of the CGK or the prior art information).

In leaving this issue unaddressed, the High Court did not resolve the potential tension between the Full Court's decision regarding the "starting point" under the Act and the earlier Full Court decision in *Apotex Pty Ltd v Sanofi-Aventis* [2009] FCAFC 134, which had reached a different decision regarding the "starting point" for assessing inventive step under the *Patents Act 1952* (Cth).[3]

THE TEST FOR INVENTIVE STEP

The High Court applied the 'Cripps' question to find that the skilled addressee would have been directly led as a matter of course to try rosuvastatin with the expectation that it might prove an effective treatment for hypercholesterolemia, and that testing the claimed dosage in conventional clinical trials would have been a routine step despite such trials being expensive.

CONCLUSION

The High Court has held that when assessing inventive step, it is permissible to consider a number of relevant prior art documents separately (and each in light of the CGK), and that if the claimed invention lacks inventive step in light of any one of them (even if the other prior art documents suggest alternate routes), the claimed invention will still be invalid for obviousness. The decision also emphasises the routine role of clinical trials and does not disturb the Full Court's earlier decision in relation to the "starting point" for assessing whether an invention involves an inventive step under the Act.

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[1] This section has since been amended to allow documents to be combined for obviousness purposes where the hypothetical skilled person could be reasonably expected to do so, and more recently to remove the requirement to establish that the prior art information is information which the skilled person could be reasonably expected to have ascertained, understood and regarded as relevant.

[2] Quoting Jessup J (with whom the other judges agreed) from the reasons of the Full Court (2014) 226 FCR 324 at 447-448.

[3] Sanofi sought special leave from the High Court to address this issue. That special leave application was heard and denied on 13 November 2015.

PFIZER / HOSPIRA MERGER – GREEN LIGHT FROM NEW ZEALAND

COMMERCE COMMISSION TO GO WITH EU APPROVAL

By Mark Williamson and Lucy Gaffikin

As the deal is reviewed by the Federal Trade Commission in the US, the New Zealand Commerce Commission has cleared the acquisition by Pfizer Inc. to acquire all of the shares in Hospira Inc. Unlike the recent approval by the European Commission, the New Zealand clearance comes with no divestment conditions. The decision highlights the Commerce Commission's robust competitive analysis, even in the face of high levels of potential concentration. It also puts in the spotlight the role of Pharmac, New Zealand's monopoly drug buying agency. How should its countervailing market power be treated in merger analysis?

OVERVIEW OF NEW ZEALAND'S MERGER REVIEW REGIME

The New Zealand Commerce Act prevents a person from acquiring shares or assets of a business if the acquisition would, or would be likely to, substantially lessen competition in a New Zealand market. The Commerce Act puts in place a voluntary clearance regime under which a person contemplating an acquisition can apply to the Commerce Commission for a clearance. Once cleared, the acquirer has twelve months to undertake the acquisition free from competition concerns.

The Commerce Commission must grant a clearance if it is satisfied that the acquisition would not, or would not be likely to, substantially lessen competition in any market. A formal application is filed and the Commerce Commission then undertakes a detailed investigation prior to reaching its decision.

Pfizer filed its application for clearance on 28 April 2015 with the Commerce Commission reaching its decision by 17 June 2015 (modestly outside the Commerce Commission's 40 working day target for "straight forward" clearance applications).

The written reasons for the decision were recently published.

WHAT WERE THE KEY NEW ZEALAND ISSUES FOR THE HOSPIRA MERGER?

The Commerce Commission looked at competition issues in the supply of both biopharmaceuticals (in particular biosimilars) and pharmaceuticals.

In its application for clearance, Pfizer noted that there were no actual overlaps in existing biopharmaceuticals registered in New Zealand. Consistent with the European Commission approach, Pfizer's clearance application also analysed

the extent of overlaps between pipeline biologic/biosimilar products that were at a sufficiently advanced stage that they should be considered competitors. Pfizer argued that no such overlaps existed.

With regard to pharmaceuticals, Pfizer noted that it has a broad product base encompassing both hospital drugs and consumer medication in a wide range of forms. In contrast, Hospira is focussed on generic speciality injectable pharmaceuticals. Pfizer therefore argued that competitive overlaps in New Zealand were very limited. More specifically, Pfizer identified ten molecules where the proposed acquisition would result in actual or potential overlap.

With regard to market definition, Pfizer urged the Commerce Commission to focus on the key molecule active in the medicine (for example Heparin) although in the case of some medicines submitted that a more narrow approach is appropriate, such as galenic form. The Commerce Commission had previously adopted an approach based on Anatomical Therapeutic Classification Level 3 (albeit for different pharmaceuticals).

Pfizer then considered each actual and potential overlap and argued one or more of the following:

- An absence of close competition between the applicable products, often due to a lack of clinical substitutability.
- The presence of actual or potential competitors. Emphasis was given to the presence of global competitors and the relative ease in terms of obtaining New Zealand registrations.
- The countervailing market power of Pharmac as a "powerful constraint on the merged entity."

WHAT DID THE COMMERCE COMMISSION DECIDE?

The Commerce Commission was satisfied that the acquisition would not, or would not be likely to, substantially lessen competition in any market. For pharmaceuticals, the Commission considered that the most appropriate way in which to define the markets was to begin at the molecular level, but to further differentiate markets on the basis of route of administration and galenic form to reflect the granularity of Pharmac's demand.

In these markets, the Commission found that Pfizer and Hospira were not particularly close competitors for the supply of the overlapping small molecule drugs, and that sufficient competition would remain in the markets with the merger. The countervailing market power of Pharmac was also relevant. The Commission noted that generally "three to two" mergers were likely to be of concern. However, this concern was lessened in the situation where the market included a large and sophisticated purchaser, which could choose the competitive strategy most effective for a given situation. The Commission also viewed Pharmac as in a strong position to solicit an alternative supply in the relevant markets (although because of the existing competition, it was not necessary for the Commission to further consider market entry). In relation to biosimilars, the Commission found that while Pfizer and Hospira have new biosimilar drugs in development, there are a number of other pharmaceutical companies developing the same drugs which are likely to compete vigorously with the merged entity.

We note the Australian Competition and Consumer Commission is currently considering Pfizer's proposed acquisition of Hospira Inc, in the Australian market. See Simon Uthmeyer and Matthew Taylor's *Major trends give rise to competition concerns in the Australian life sciences sector article* for further information.

KEY LESSONS

For those considering mergers in this space, the following are some key lessons from the Hospira acquisition for preparing clearance applications and engaging with the Commerce Commission:

- Market definition will be very fact specific and a detailed analysis of the applicable pharmaceuticals will be required. A molecule based approach further differentiated by galenic form is likely to be the appropriate starting point, but a case-by-case analysis is still required.
- The extent of "close competition" between the acquirers' and the targets' products is critical and detailed analysis is required.
- Even high levels of existing concentration will not deter the Commerce Commission where there is evidence of likely potential competition from meaningful competitors.
- The countervailing market power of Pharmac will be an important factor in merger analysis, particularly the extent to which Pharmac can choose competitive strategies and facilitate market entry.

PATENT TERM EXTENSIONS IN THE BIOTECHNOLOGY SECTOR IN AUSTRALIA

By Nicholas Tyacke, Eliza Mallon and Louis Italiano

Recent decisions in the Australian Patent Office have clarified the circumstances under which patent term extensions will be granted for patents that are directed to pharmaceuticals produced by a process involving recombinant DNA technology. These decisions will reassure innovators in the biotechnology sector that Australia's pharmaceutical patent term extension regime affords sufficiently strong protection to ensure that patent rights are not prejudiced by delays in obtaining regulatory approval.

CRITERIA FOR PATENT TERM EXTENSIONS IN AUSTRALIA

Patent term extensions can be obtained in Australia in relation to standard patents that disclose and define a pharmaceutical substance *per se* or a pharmaceutical substance produced by recombinant DNA technology.

The term of a standard Australian patent can only be extended if the patent satisfies the following criteria (Section 70):

a) one or more pharmaceutical substances *per se*, and/or one or more pharmaceutical substances when produced by a process that **involves** the use of recombinant DNA technology, must in substance be **disclosed** in the complete specification of the patent and in substance fall within the scope of the **claim** or claims of that specification; and

b) goods containing, or consisting of, the pharmaceutical substance must have regulatory approval; and

c) at least five years must have passed between the date of the patent (this is usually the date that the application for the patent was filed), and the date of first approval of *any* product containing the pharmaceutical substance; and

d) the term of the patent must not have previously been extended.

An application for a patent term extension must be made within six months of grant of a patent, or six months from first regulatory approval, whichever is later (Section 71).

The period of extension

The maximum patent term extension that can be obtained in Australia is **five years**, making the maximum term for a standard Australian patent 25 years (Section 77). The period of the extension is determined by calculating the period beginning on the date of the patent and ending on the date of first regulatory approval, minus five years (to a maximum period of five years) (ID). For example, if the period between the date of a patent and the date of regulatory approval is seven years, the term of extension will be two years.

Importantly, although the term of the entire patent will be extended if it satisfies the above criteria, the rights of a patentee during the extended term are limited as compared with the exclusive rights the patentee enjoys during the ordinary term of the patent. During the extended term, the following activities do not constitute patent infringement (Section 78):

- exploitation of any form of the invention that is not a pharmaceutical substance; and
- exploitation of the pharmaceutical substance for non-therapeutic uses.

There is no limit on the number of patents that may be extended in relation to a pharmaceutical product, provided the aforementioned criteria are satisfied.

PHARMACEUTICAL SUBSTANCES *PER SE*

A **"pharmaceutical substance"** is defined in the Australian *Patents Act* as a substance (including a **mixture** or compound **of substances**) for therapeutic use whose application (or one of whose applications) involves:

a) a chemical interaction, or physico-chemical interaction, with a human physiological system; or

b) action on an infectious agent, or on a toxin or other poison, in a human body.

but does not include a substance that is solely for use in *in vitro* diagnosis or *in vitro* testing (Schedule 1).

The use of the term "*per se*" requires that the patent claim be to the substance alone, unqualified by, for example, process or method components. Therefore, a claim that claims pharmaceutical substances produced by a particular method or process (other than processes that involve the use of recombinant DNA technology) will generally not satisfy this requirement.

PHARMACEUTICAL SUBSTANCES PRODUCED BY PROCESSES INVOLVING THE USE OF RECOMBINANT DNA TECHNOLOGY

Recent Australian Patent Office decisions have clarified the requirements for determining whether a pharmaceutical substance is "*produced by processes involving the use of recombinant DNA technology*."

ImmunoGen decision

In *ImmunoGen, Inc.* [2014] APO 88, ImmunoGen, Inc sought to extend the term of a patent directed to the preparation of antibody-maytansinoid conjugates. The basis for ImmunoGen's patent term extension request was the inclusion in the ARTG of its breast cancer drug KADCYLA®, the active ingredient of which is trastuzumab emtansine.

A delegate of the Commissioner of Patents initially rejected ImmunoGen's application for a patent term extension on the basis that the process defined in the claims for preparing the antibody-maytanisnoid conjugate was a crosslinking process which did not involve recombinant DNA technology.

In answer to the delegate's rejection, ImmunoGen argued that the humanised monoclonal antibody trastuzumab in its KADCYLA® product was indeed produced by recombinant DNA technology, and that the use of that particular antibody in the process was both described and claimed in the relevant patent.

The Deputy Commissioner noted:

"in simply requiring a process that involves the use of recombinant DNA technology the legislation appears to encompass a range of scenarios including the present one where the processes described includes forming a conjugate from an antibody produced by known recombinant techniques."

The Deputy Commissioner held that a pharmaceutical substance "*produced by a process that involves the use of recombinant DNA technology*" was disclosed in the complete specification, and within the scope of the claims, of ImmunoGen's patent.

Novartis decision

Like the *ImmunoGen* decision, the *Novartis Vaccines and Diagnostics S.r.l.* [2015] APO 2 decision also involved a patent directed to processes of producing a composition. The basis for the patent term extension was the inclusion in the ARTG of the meningococcal B vaccine Bexsero® which contains, amongst other ingredients, four antigenic ingredients, three of which are produced using recombinant technology.

The application for a patent term extension was initially rejected on the basis that the claims were not specifically restricted to a recombinantly produced pharmaceutical substance. Following a hearing in the matter, the delegate found that processes for preparing antigenic ingredients using recombinant DNA technology were incorporated by reference into the specification, and that a substance produced by a process involving recombinant DNA technology was "*amongst the things claimed*." The delegate held that this was sufficient for the purposes of satisfying the requirement that a pharmaceutical substance produced using recombinant DNA technology must in substance be disclosed in the complete specification of the patent and in substance fall within the scope of its claims.

AbbVie Biotechnology decision

In *AbbVie Biotechnology Ltd* [2015] APO 45, AbbVie Biotechnology Ltd (AbbVie) applied for extensions of term in respect of patents which included "Swiss-type" claims characterised by the manufacture of a medicament comprising a recombinant human antibody for use in the treatment of ankylosing spondylitis, Crohns disease or ulcerative colitis. The patents were, according to the decision, part of a "*larger chain of divisional patents… that have already been granted an extension of term*" based on the initial listing on the ARTG of AbbVie's blockbuster auto-inflammatory product Humira® (adalimumab).

The new extensions were sought on the basis of regulatory approval for Humira® for new indications for treating ankylosing spondylitis, Crohns disease and ulcerative colitis. AbbVie argued that the patents' "*claims expressly require the human antibody be produced by a process that involves the use of recombinant DNA technology.*"

Citing his same day decision in *ThromboGenics NV* [2015] APO 44, the Deputy Commissioner of Patents rejected AbbVie's arguments and held that while the "Swiss-type" claims of the patent were notionally directed to a method or process of manufacturing a medicament, they were characterised by a therapeutic use. The Deputy Commissioner noted that there was no support for the proposition that the extension provisions were intended to provide extensions for methods of treatment that are merely "*in some way associated with recombinant techniques*".

The Deputy Commissioner noted that, on the contrary, "*the intention seems clearly to exclude therapeutic methods and to provide extensions only for new and inventive pharmaceutical substances per se and, as an exception, substances produced by new and inventive processes involving recombinant technology.*" As such, the Deputy Commissioner concluded that no "substance" produced by a process involving the use of recombinant DNA technology fell within the scope of the Swiss-type claims of AbbVie's patent.

CONCLUSION

The above decisions provide clarity for the biotechnology sector where the significant amount of time spent obtaining regulatory approval can greatly affect the "time to market" (or commercialisation and marketing) of a product containing a new active substance.

In particular, the *ImmunoGen* and *Novartis* decisions confirm that extensions of term will be granted in respect of patents that encompass products of recombinant DNA techniques (including process claims resulting in such products) even if the recombinant DNA technique is not recited in the claims, and even if a product produced by DNA recombinant techniques is merely *"amongst the things claimed"*.

In contrast, the *AbbVie* decision will act as a cautionary tale, confirming that the Australian Patent Office will not deem a Swiss-type patent claim directed to a method or process of manufacturing a medicament to encompass a substance produced by a process involving the use of recombinant DNA technology for the purposes of Australia's patent term extension regime.

Q&A

Marie Evans is a Partner in the firm's Life Sciences sector and Litigation and Regulatory practice.

1. What are your key areas of practice?

Medico-defence work; Healthcare regulatory matters (including advising on Affiliated Provider Schemes, Clinical trials, Accident Compensation Act, Commerce Commission issues); Privacy issues (particularly those concerning Health Information); Life, Health and Disability Insurance Regulatory and Claims advice; and general Insurance/ Commercial litigation.

Significant clients include New Zealand's largest medical indemnity provider, the Medical Protection Society (which provides indemnity cover to over 17,000 New Zealand healthcare professionals), and for whom we currently act in several hundred cases. Other significant clients include the Accident Compensation Corporation (ACC), and some of New Zealand's largest Life, Health and disability insurers (Sovereign Assurance Company Limited, ACE Insurance Group and NIB NZ Limited).

2. What are your career highlights?

Being offered partnership within seven years of admission (and becoming the youngest female partner at the time) and then being asked to become managing partner within seven years of partnership.

More recently, moving to New Zealand and passing the necessary exams/requirements in order to obtain my dual qualification and admission on to the roll of barristers and solicitors of the High Court of New Zealand.

WITH MARIE EVANS

3. What are the two biggest issues/challenges facing the Asia Pacific life sciences/healthcare sector?

a) Intensifying containment of costs

Containment of costs continues to intensify as a result of Governments and healthcare organisations instituting price controls and pricing models and increasing their use of generics with a view to contain drug, device and healthcare service costs.

b) Changing regulatory and risk environment

Uncertainty arising from the changing regulatory and risk environment (in particular cross border regulation) as governments in the Southeast Asia/Asia Pacific region move towards establishing a more organised regulatory framework.

4. What's the best advice you've ever been given?

To always give 100% – advice instilled in me whilst a training instructor in the British Army, but just as applicable to my legal career and personal life.

5. What is your favourite thing to do outside of work?

Spending quality time with my family is very important and travel… seeing/experiencing new places/cultures. So many corners of the world yet to explore!

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