Baker McKenzie.

HEALTHCARE UPDATE

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Baker McKenzie recently published its Simplifying Business in a Complex World series in partnership with Acuris. The reports analyse insights from, among others, senior healthcare executives across the Asia Pacific region. The respondents believe that doing business in healthcare is becoming more complex, where the biggest macro economic challenges and complexities are thought to be:

- compliance and adapting to new or changing regulations;
- environmental threats from natural disasters impacting production and placing a strain on limited healthcare resources; and
- internally driven innovation.

Nearly all respondents think that healthcare will see major technological disruption in the next two years and the major focus areas currently are:

- regulatory change;
- business systems innovation; and
- optimising tax structures.

The reports highlight that the healthcare industry is undergoing a period of rapid change, which presents challenges but also opportunities. With this in mind, we have recapped on some of the key legal developments that have affected Australian healthcare businesses over the past 12 months and will continue to do so moving forward.

See our Simplifying Business in a Complex World series to read the full reports.

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COMPETITION

Significant changes to Australia's competition law now in effect: What does it mean for healthcare companies?

Legislative changes arising out of Harper Review

On 6 November 2017, a number of significant changes to Australia's competition law came into effect. The changes are the result of a series of recommendations arising out of the Harper Competition Policy Review and reflect the most substantial reform of Australian competition law in the past two decades.

The amendments aim to simplify the *Competition and Consumer Act 2010* (Cth) (CCA), thereby reducing costs on the economy and burdens on business, as well as promoting pro-competitive behaviour.

The key changes that have the potential to impact upon the healthcare sector are set out below.

Misuse of market power

The test for misuse of market power under section 46 of the CCA has been revised and broadened. A corporation with a substantial degree of market power is now prohibited from engaging in conduct that has the purpose or effect (or likely effect) of substantially lessening competition. Importantly, the revised section 46 removes the requirement that a corporation "take advantage" of its substantial market power and introduces, for the first time, an "effects" test in addition to the current "purpose test".

The broader test for misuse of market power has the potential to impact healthcare companies in a range of different circumstances including, for example, when considering strategic initiatives in anticipation of the end of a patent term.

Concerted practices

A new broadly framed prohibition against "concerted practices" that have the purpose or effect (or likely effect) of substantially lessening competition has been introduced. This is intended to capture co-operative conduct that falls short of a "contract, arrangement or understanding". The Australian Competition and Consumer Commission's (ACCC) Interim Guidelines on Concerted Practices indicate that one-off interactions and one-way exchanges of information may, in some circumstances, amount to a "concerted practice".

Healthcare companies will need to be vigilant when disclosing or receiving commercially sensitive information with third parties (for example in dealings with industry organisations or competitors).

Cartels

A number of changes have been made to simplify the cartel laws. One of the more significant changes is that the scope of the joint venture exemption for cartel conduct has been expanded. The exemption now includes procurement joint ventures and also applies to cartel provisions in arrangement or understandings (previously it only applied to cartel provisions in contracts).

To be able to rely on the joint venture exemption, parties will need to demonstrate that the relevant cartel provision is for the purposes of (and reasonably necessary to) undertake the joint venture, and that the joint venture is not carried on for the purpose of substantially lessening competition.

Third Line Forcing

Third line forcing is no longer prohibited "per se". It is now only prohibited where it has the purpose or effect (or likely effect) of substantially lessening competition.

Resale Price Maintenance

It is now possible to notify the ACCC of resale price maintenance (RPM) conduct (i.e. the setting of minimum prices) as an alternative to seeking authorisation. Notification is a quicker and cheaper process than authorisation. Conduct between related bodies corporate is also now exempt from the RPM prohibition.

What can healthcare companies expect in 2018?

In 2017, the health and medical sectors were an enforcement and compliance priority for the ACCC. We expect that healthcare will remain a focus area for the ACCC in 2018, particularly with the reforms arising out of the Harper Review now in effect.

We also expect 2018 will see more enforcement proceedings in relation to cartel conduct, an ongoing enforcement priority for the ACCC. We also anticipate that the ACCC will be looking to test the revised misuse of market power and new concerted practices provisions and consider that there is likely to be investigation and enforcement activity in these areas in the near future.

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COMPLIANCE

Proposed amendments to bribery legislation and whistleblower protections

There have been a number of proposed changes to legislation and prosecution procedures which signal a determination to increase the ability to investigate and pursue corporate wrongdoings, particularly in the area of bribery and corruption. If implemented, these changes would require healthcare companies to place even greater focus on their internal compliance procedures.

The key developments are the introduction by the Federal Government of two new bills - the *Crimes Legislation Amendment (Combatting Corporate Crime) Bill 2017* (the Corporate Crime Bill) and the *Treasury Laws Amendment (Enhancing Whistleblower Protections) Bill 2017* (the Whistleblowing Bill), and the release by the Senate Economics References Committee of its report on foreign bribery making 22 recommendations to strengthen Australia's foreign bribery framework.

Proposed amendments to the bribery legislation in Australia

Following the Federal Government's proposals for amendments to the foreign bribery legislation in Australia and the introduction of a Deferred Prosecution Agreement scheme in Australia, the Corporate Crime Bill was introduced into the Senate in December 2017.

The Corporate Crime Bill:

- introduces a new strict liability corporate offence of failing to prevent foreign bribery under the *Criminal Code Act 1995* (Cth) unless the company can establish it had "adequate procedures" in place to prevent such misconduct. This would be similar to the regime that has operated in the UK since 2010 and the Attorney General's department has said that its guidance will be informed by the guidance that the United Kingdom Ministry of Justice has published in relation to section 9 of the *Bribery Act 2010* (UK) to ensure minimal impact on Australian corporations that have already framed their anti-bribery policies on international guidelines;
- lowers the threshold to establish the foreign bribery offence by:
  - expanding the definition of "foreign public official" to include candidates for office;
  - expanding the offence of bribery to obtain a personal advantage; and
  - removing the requirement that a foreign public official be influenced in the exercise of their duties as a foreign public official; and

- introduces a proposed Deferred Prosecution Agreement scheme (DPA) which would apply not only to foreign bribery, but also the bribery of Commonwealth public officials and other identified Commonwealth crimes. The DPA scheme seeks to combat the current issues associated with detecting and addressing serious corporate crime and the scheme also aims to encourage companies to report issues detected internally.

The Corporate Crime Bill is currently before the Senate Legal and Constitutional Affairs Legislation Committee which is due to provide its report by 20 April 2018. If the bill is passed, the amendments will come into effect six months after the Act receives royal assent.

Senate inquiry – Recommendations to strengthen Australia's foreign bribery framework

On 29 March 2018, the Senate Economics References Committee also released its report on foreign bribery which it was commissioned to prepare back in June 2015. The Committee made 22 recommendations to strengthen Australia's foreign bribery framework and to consider ways to develop a corporate culture of awareness and compliance (including self-reporting foreign bribery).

Some of the recommendations have already been raised in the draft Corporate Crime Bill (such as the introduction of the DPA scheme and the corporate offence of failing to prevent bribery) but in addition, its recommendations include:

- encouraging the publication of an exposure draft of the guidance on adequate procedures to ensure that companies can implement the necessary compliance measures;
- introducing a debarment framework to require companies to disclose if they have been found guilty of foreign bribery offences and to empower agencies to preclude the tenderer from being awarded a contract;
- introducing a Code of Practice to provision for the appointment and methodology of independent external monitors to monitor a company's compliance with a DPA (at its expense); and
- that ASIC expands the register of beneficial ownership to require companies, trusts and other corporate structures to disclose information regarding their beneficial ownership and to maintain the information in a central register.

Proposed amendments to the regime for whistleblower protections in Australia

On 13 September 2017, the Parliamentary Joint Committee on Corporations and Financial Services released its report on recommended changes to whistleblower protections in the corporate, public and not-for-profit sectors (Report).

In December 2017, the Treasury then introduced the Whistleblowing Bill which did not include all of the Report's recommendations. The bill proposes a single whistleblower protection regime by consolidating and broadening the existing protections and remedies for whistleblowers in the corporate and financial sectors within the *Corporations Act 2001* (Cth). The Whistleblowing Bill also proposes amendments for the *Taxation Administration Act 1953* (Cth) to provide a similar framework to protect those who expose tax misconduct, for example, breach of tax laws or misconduct relating to an entity's (or its associate's) tax affairs.

Some of the key proposed amendments include:

- by 1 January 2019, all public companies are required to implement an internal whistleblower policy which contains information about the protections available to whistleblowers and the fair treatment of employees mentioned in whistleblower disclosures and other regulated matters. "Large proprietary companies" (as defined in the *Corporations Act 2001*) and proprietary companies that are trustees of registrable superannuation entities would have a longer period of time to comply with this requirement;
- expanding the scope of protected disclosures and the categories of whistleblowers who may be protected by introducing a single concept of "disclosable matters" and "eligible whistleblower" respectively;
- removing the requirement for whistleblowers to reveal their identity when making a report if they wish to seek protections;
- strengthening the immunities for whistleblowers by ensuring that information that is part of a protected disclosure is not admissible in evidence against the whistleblower in criminal proceedings;

- introducing an offence for those who disclose the identity or information likely to lead to the identification of the whistleblower; and
- allowing whistleblowers to bring a claim for compensation where they have been victimised as a result of their whistleblower report.

On 22 March 2018, the Senate Economics Legislation Committee released its report and has recommended that the Whistleblowing Bill be passed with minor amendments.

With thanks to Natalie Wee for her assistance.

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Employment developments

There were a number of significant employment developments throughout the past 12 months that Australian healthcare companies should be aware of and consider in relation to their workplaces.

Confirmation regarding when Healthcare employers need to consult regarding major workplace changes

The Federal Court has affirmed the position set out in *Port Kembla Coal Terminal Ltd v Construction, Forestry, Mining and Energy Union* (2016) 248 FCR 18 (Port Kembla Coal) that not all workplace changes are "major" enough to trigger notification and consultation obligations under modern awards and enterprise agreements (and, in particular, based on the "model clause" in schedule 2.3 of the *Fair Work Regulations 2009* (Cth) (FW Regs)).

Relevantly, the model clause contains the following wording:

> *This term applies if the employer:*
>
> 1. *has made a definite decision to introduce a* major change *to* production, program, organisation, structure or technology *in relation to its enterprise that is likely to have a* significant effect *on the employees; or*
> 2. *proposes to introduce a change to the regular roster or ordinary hours of work of employees.*
>
> *In this term, a major change* is likely to have a significant effect on employees *if it results in:*
>
> 1. *the termination of the employment of employees; or*
> 2. *major change to the composition, operation or size of the employer's workforce or to the skills required of employees; or*
> 3. *the elimination or diminution of job opportunities (including opportunities for promotion or tenure); or*
> 4. *the alteration of hours of work; or*
> 5. *the need to retrain employees; or*
> 6. *the need to relocate employees to another workplace; or*
> 7. *the restructuring of jobs.*
>
> *(our emphasis)*

In the case of Port Kembla, the Court stated whilst the number of employees being made redundant may well reflect that there has been a major change with which those redundancies were associated, the size and importance of the change would have to be assessed by reference to facts which went beyond, although they may include, the facts of the redundancies. It further stated that simple comparison between the number of employees to be terminated, and the number of the employees in its workforce overall, would not be regarded as necessarily conclusive of the question of whether a change is "major". Much may depend on the circumstances of a given case including, for example,

the seniority and importance of the employees in the healthcare employer's operations, the extent to which the healthcare employer's employees work in an integrated or disconnected manner; the consequences for the continuing employees of the redundancies and consequent terminations, as well as other matters.

General protections claims on the rise

The Fair Work Commission's latest Annual Report for 2016/2017 shows that general protections claims are on the rise, noting that there has been a 12.3% increase in general protections claims involving dismissals over the last year, with 3,270 claims involving dismissals in 2015/2016 and 3,729 such claims in 2016/2017.

Under the general protections provisions in the *Fair Work Act 2009* (Cth), an employer must not take adverse action (including dismissal) against an employee because they exercised or proposed to exercise a workplace right (such as a right to take leave or a right to request flexible work arrangements), or otherwise because the employee made a complaint in relation to their employment, and must not dismiss an employee because of any protected attribute identified in state, territory or commonwealth discrimination law.

Reasons for the trend

This trend towards employees favouring general protections claims over other types of legal claims is occurring for a number of reasons, including:

- general protections applications are cheap to file, costing only $70.60;
- the application form is easy to prepare and legal advice is not necessarily required;
- there is little commitment required from individuals lodging an application in the early stages, as the matter goes straight to a telephone conciliation (rather than a face to face conference with a commission member as used to be the case);
- if an employee cannot bring an unfair dismissal claim (because they earn above the high income threshold of $142,000 and are not covered by a modern award or enterprise agreement) this is often seen as the next best claim to lodge to try to put pressure on an employer to pay the employee some monetary compensation;
- pinpointing a workplace right that was exercised or was proposed to be exercised by the former employee is not that hard, it is connecting the workplace right to the dismissal that is more difficult and often overlooked;
- there is a reverse onus of proof placed on employers meaning employees do not have to prove the connection between the adverse action and the dismissal, rather the employer has to disprove this;
- unlike discrimination claims in the Australian Human Rights Commission conciliation is compulsory and takes place quickly within a month or two; and
- it is a non-costs jurisdiction so employees have protection from being ordered to pay costs (except in limited circumstances).

Resolving claims or holding out

According to the Fair Work Commission's Annual Report, of the 3,729 general protections claims involving dismissal, 73% were resolved at conciliation, withdrawn or were refused an extension of time. This means that only 27% may have been pursued to the next stage of potentially filing their claim in the Federal Courts.

Seventy-seven per cent of the general protections matters involving a dismissal which did end up in conciliation resolved with either a monetary payment or both a monetary payment and some other non-monetary terms of settlement.

These settlement rates are high and show that employers are deciding, for the most part, to resolve these matters early on.

While bringing a Fair Work Commission claim is relatively easy for former employees, the next stage of the process, taking the matter to the Federal Courts, is tougher and there are a number of disincentives to this process. The time involved to get to hearing, which is likely to be 12 to 18 months at a minimum, the legal costs if the former employee is represented, and the public nature of any decision are significant barriers to many former employees.

Termination of maximum term contracts may trigger unfair dismissal rights

A recent decision by the Full Bench of the Fair Work Commission has opened access to unfair dismissal laws for workers employed on successive, maximum term contracts. Maximum term or "outer limit" contracts are contracts for a specific period of time which may also be terminated before the end of that period by the giving of notice.

The Full Bench in *Khayam* v *Navitas* [2017] FWCFB 5162 (Navitas) has determined that, in the context of a dismissal, the Fair Work Commission (FWC) should not simply look at the expiry of the most recent contract, but take into account the employment relationship as a whole. Where, for example, an employee has been engaged on a succession of contracts and is not offered a fresh contract due to performance issues, the termination of employment may now be seen to give access to the unfair dismissal regime.

However, importantly for employers, where the terms of a maximum term contract (written or otherwise) reflect a genuine agreement as to the conclusion of the employment relationship on expiry of the term, the employee will remain precluded from accessing the unfair dismissal jurisdiction.

Immigration – changes to the 457 visa

On 18 April 2017, the Government announced that the Temporary Work (Skilled) visa (subclass 457) will be replaced with the completely new Temporary Skill Shortage (TSS) visa by March 2018.

Current 457 visa holders

The Government has confirmed that there will be a grandfathering arrangement to ensure that all current 457 visa holders will continue under the conditions of their current visa.

What has already changed?

Occupation lists

The lists which specify the occupations that are eligible for the 457 programme have been changed significantly. As of 19 April 2017, these lists will replace the former "Skilled Occupation and Consolidated Skilled Occupation" lists. The new occupation lists now in place are:

- The Medium and Long-term Strategic Skills List (MLTSSL); and
- The Short-term Skilled Occupation List (STSOL).

These lists have removed over 200 previously eligible occupations for 457 visa purposes and introduce caveats to 59 other occupations. These caveats, which have been attached to selected occupations on the list, will mean that the applicant and sponsor will be required to satisfy additional requirements in order to be eligible for the 457 visa.

Visa validity period

As of 19 April 2017, the visa period available to applicants will be determined by the nominated occupation. This means that 457 visas granted on or after 19 April:

- will be granted for a period of **four years** to primary applicants whose occupation falls on the MLTSSL;
- will be granted for a maximum period of **two years** to primary applicants whose nominated occupation falls on the STSOL.

Note: Subsequent entrants (i.e. family members applying as secondary visa applicants) who wish to be added to a primary subclass 457 visa will not be impacted by this new policy. That is, subsequent entrants can still have their 457 visa "match" the visa period of the primary visa holder's current 457 visa.

New character requirements

As of 1 July 2017, all applicants for visa periods of 12 months or more are now required to also provide police clearances from any countries lived in for 12 months or more in the previous 10 years. The previous exemption to this requirement which applied to 457 applications has been removed.

Looking ahead

The new TSS visa will reflect many of the changes which have already occurred in the 457 visa programme in the last 12 months.

Eligibility criteria for both TSS visa streams will include:

Work experience At least two years' relevant work experience.

Labour market testing (LMT) LMT will be mandatory, unless an international obligation applies.

Character Mandatory penal clearance certificates to be provided.

Workforce A non-discriminatory workforce test to ensure employers are not actively discriminating against Australian workers.

Training requirement A strengthened training requirement for employers to contribute towards training Australian workers through the payment of a Skilling Australians Fund (SAF) Levy with each new TSS application lodged.

Limited onshore TSS visa renewal for occupations on the STSOL.

Changes have also been made to the permanent Employer Nomination & Regional Sponsored Migration Schemes.

Introduction of Vulnerable Workers Act to increase penalties

On 14 September 2017, the *Fair Work Amendment (Protecting Vulnerable Workers) Act 2017* (Cth) came into effect (the Act). The Act introduced higher penalties for healthcare employers who engage in serious contraventions of the Fair Work Act, including but not limited to, knowingly or systematically underpaying employees, coercing them to pay back a certain proportion of their wages to the employer in cash or otherwise knowingly or systematically exploiting workers.

Healthcare employers who engage in serious contraventions of the Fair Work Act can now be issued with penalties of up to $126,000 per contravention, whilst healthcare corporations can be issued with penalties of up to $630,000 per contravention.

The Act also introduced provisions whereby healthcare franchisors or holding companies can be held responsible for breaches of the Fair Work Act by their franchisees or subsidiaries if the healthcare franchisor or holding company knew or could reasonably be expected to have known that the franchisee or subsidiary would breach the Fair Work Act. In order to avoid such a claim, healthcare franchisors and holding companies are expected to take reasonable steps to prevent a contravention by a franchisee or subsidiary.

Whilst the Courts have not yet been asked to consider what will amount to "reasonable steps", the Act does provide some guidance as to factors that will be considered, including:

- the size and resources of the organisation;
- the extent to which the healthcare franchisor or holding company had the ability to influence or control the franchisee or subsidiary's conduct;
- any action taken by the healthcare franchisor or holding company towards ensuring that the franchisee or subsidiary had a reasonable knowledge and understanding of the requirements under the Act;
- the healthcare franchisor or holding company's arrangements for assessing the franchisee or subsidiary's compliance with the Act;
- the healthcare franchisor or holding company's arrangements for receiving and addressing possible complaints about alleged underpayments or other alleged contraventions by the franchisee or subsidiary; and
- the extent to which the healthcare franchisor or holding company's arrangements with the franchisee or subsidiary encourage or require the contravening employer to comply with the Act or other workplace law.

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Patents update

Warner-Lambert Company LLC v Apotex Pty Limited [2017] FCAFC 58

The Full Federal Court has held that an application for Pharmaceutical Benefits Scheme (PBS) listing of a generic product is not an act of infringement.

Warner-Lambert, part of the Pfizer group of companies, is the patentee of a patent for the use of pregabalin in the treatment of neuropathic pain, epilepsy, fibromyalgia and neuralgia. Warner-Lambert's pregabalin product is listed on the PBS for the treatment of neuropathic pain. In an earlier patent infringement proceeding,[1] the Federal Court upheld the validity of Warner-Lambert's patent and granted final injunctions restraining infringement by Apotex Pty Limited (Apotex). A range of aspects of the substantive patent proceedings are subject to appeal.

The primary judge granted an injunction restraining Apotex's threatened acts of infringement but did not prevent Apotex from taking any steps required to obtain listing of the generic pregabalin products on the PBS on the basis that an application to obtain PBS listing of the products was not an "exploitation" of the patent.

On appeal, the Full Court addressed the question as to whether the guarantee of supply, required as part of the PBS application process, would amount to an infringing offer to supply. The Full Court confirmed that an application for PBS listing of a generic product was not an act of infringement and that the guarantee of supply to the Minister, that sufficient stock of the product to meet demand will be available in time for the PBS listing day, was not an offer to the Minister to supply those third parties during the guaranteed period, but an assurance that the responsible person *would be able to supply* those third parties during the guaranteed period if requested to do so. The fact that Apotex was required to guarantee supply was not considered "an offer to sell or otherwise dispose of a product" that would amount to exploitation of a patent.

Warner-Lambert made an application for special leave to appeal which was refused by the High Court on 15 August 2017.[2]

This decision has important implications for originator and generic pharmaceutical companies, and biologic and biosimilar sponsors, in the context of entry into the market as it clarifies the limits of patent holders' rights to restrict the preparatory steps taken by generic or biosimilar suppliers in anticipation of launch.

This decision has subsequently been followed in *Janssen Sciences Ireland UC v Alphapharm Pty Ltd* [2017] FCA 1399. Janssen sought to injunct Alphapharm on an interim basis (pending final hearing) from infringing a patent in respect of darunavir. The Court granted the injunction, however, due to the decision in *Warner-Lambert Company LLC v Apotex Pty Limited*, the Court refused to injunct Alphapharm from seeking to obtain PBS listing.

The Court did order Alphapharm to notify the Department of Health that it could not sell, supply or dispose of its darunavir products pending determination of the proceeding and that it could not assure supply for the purpose of seeking a PBS listing. The Court did not address what impact that would have on Alphapharm's PBS application. That will be a matter for the Minister.

Pfizer Ireland Pharmaceuticals v Samsung Bioepis Au Pty Ltd [2017] FCAFC 193

Is a high level of biosimilarity sufficient to infer similarity of manufacturing processes? Pfizer Ireland Pharmaceuticals (Pfizer), the sponsor of Enbrel (etanercept) in Australia sought preliminary discovery from Samsung Bioepis AU (Samsung) in relation to whether its activities in respect of Brenzys, a biosimilar of Enbrel, are likely to constitute patent infringement.

Pfizer asserted that it had a reasonable belief that Samsung may be infringing its patents for Enbrel and sought orders for preliminary discovery of confidential documents that Samsung lodged with the Therapeutic Goods Administration to enable Pfizer to determine whether or not to commence proceedings against Samsung for patent infringement.

1 *Apotex Pty Ltd v Warner-Lambert Company LLC* (No 2) [2016] FCA 1238.
2 *Warner-Lambert Company LLC & Ors v Apotex Pty Ltd* [2017] HCASL 190.

To obtain orders for preliminary discovery, Pfizer needed to persuade the Court that:

1. Pfizer reasonably believes it may have a right to relief, but does not have sufficient information to decide whether to commence proceedings, and
2. Samsung is likely to have documents which would assist in deciding whether to commence proceedings.

The trial judge concluded that Pfizer's belief that it had a right to obtain relief in the Court from Samsung was not reasonably held because Pfizer's claims for patent infringement were speculative.

On appeal to the Full Federal Court, however, Pfizer was granted leave to appeal and successfully appealed the decision. The Full Court held that the foundation of a preliminary discovery application is that an applicant reasonably believes that he, she, or it may have a right to relief. The belief must be reasonable and it is about something that **may be** the case, not **is** the case. The Full Court considered that the trial judge erred in considering the expert evidence as to whether there were similarities between the Brenzys process and the Pfizer process (relevant to the question of potential patent infringement). It was not open to the primary judge to dispose of Pfizer's application on the basis that he preferred the evidence of one expert over another; even if the primary judge was of that view, that could not of itself have provided the answer to the question of whether Pfizer reasonably believed that it may have the right to obtain relief for patent infringement.

The matter has been remitted to the primary Judge for orders for preliminary discovery of the documents held by Samsung. Subsequent to anticipated documentary disclosure by Samsung, it is expected that Pfizer will consider whether to commence substantive patent infringement proceedings. Significantly, this is the first Australian court decision relating to a dispute in respect of the market entry of a biosimilar.

Commissioner of Patents v AbbVie Biotechnology [2017] FCAFC 129

The Full Federal Court has held that a pharmaceutical patent term can only be extended if a pharmaceutical substance itself falls within the scope of the patent claims, and patents containing Swiss-style claims do not meet the requirement for extensions of term for pharmaceutical patents.

AbbVie is the owner of three patents which claim the use of adalimumab in the manufacture of medicaments to be administered for therapeutic purposes including ulcerative colitis, Crohn's disease and rheumatoid spondylitis (the Patents). The patent claims – the use of a pharmaceutical substance in the production of a medicament for a specific therapeutic condition – are known as Swiss-style claims.

AbbVie applied for an extension of the term of each patent under section 70(2)(b) of the Patents Act. The extensions were refused by the Deputy Commissioner of Patents, but this was overturned on appeal to the Administrative Appeals Tribunal, which was then subsequently appealed to the Full Federal Court of Australia.

The Full Court's decision focused primarily on the construction of section 70(2)(b) of the Patents Act which provides that the term of a standard patent can be extended where the following conditions are satisfied:

- One or more pharmaceutical substances per se are in substance disclosed in the complete specification of the patent and in substance fall within the scope of the claim or claims of that specification; 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.

AbbVie asserted the Patents satisfied the second condition in relating to a pharmaceutical substance, adalimumab, produced by recombinant DNA technology. However, the Full Court held that:

- the Patents Act recognizes a broad, dichotomous division of inventions as products, or as methods or processes;
- a "pharmaceutical substance" for the purposes of the Patents Act is defined in terms which indicate that such a substance is a "product";
- the provision of the Act relating to extensions of term require a pharmaceutical substance to be the subject of a claim; and
- Swiss-style claims are directed to:
  - a method or process in which a substance is used to produce a medicament; and
  - an additional method or process element constituted by a specific purpose for which the medicament is to be used.

The Full Court held that adalimumab must be the subject matter of the claims, not methods or processes concerning or involving adalimumab. This was not the case and therefore the conditions for extension of the patent terms had not been satisfied.

Bayer Pharma Aktiengesellschaft v Generic Health Pty Ltd [2017] FCA 250

Bayer secured a considerable damages award in relation to infringement of its Australian patent for Yasmin, a female oral contraceptive product and the Federal Court decision reiterates that damages in pharmaceutical cases will be assessed on a case by case basis by reference to market conditions and prescribing practices unique to the patented product.

Bayer Pharma Aktiengesellschaft (Bayer) is the owner of a patent for an invention of a pharmaceutical combination of ethinylestradiol and drospirenone for use as a female oral contraceptive product (expiring on 8 February 2023) and markets the product under the brand name "Yasmin". On 23 January 2012, Generic Health Pty Ltd (Generic Health) commenced selling "Isabelle".

Bayer commenced patent infringement proceedings and elected to receive damages, arguing that every sale of Isabelle was a lost sale of Yasmin. During the infringement proceedings, Bayer applied to amend a number of claims of its patent and these amendments were approved by the Federal Court.

Bayer also launched Petibelle, a generic version of Yasmin on 26 June 2014, a week after Generic Health was required to cease selling Isabelle on the basis its conduct constituted patent infringement.

The Federal Court was asked to determine the quantum of damages (and related discounts) to which Bayer was entitled. Bayer's damages claim was based on its assessment of its lost profits in which each sale of Isabelle and Petibelle was taken to be a lost sale of Yasmin.

Good faith

On the question of whether Bayer was entitled to recover damages for infringement prior to the amendment of the patent, Generic Health argued that the original patent specification was not framed "in good faith and with reasonable skill and knowledge" as required by section 115(1)(1) of the Act, and Bayer should not be entitled damages before the amendment.

The trial judge was satisfied that Bayer had discharged its onus of proving that the unamended claims and specification as a whole were framed in good faith and reasonable skill and knowledge so as to entitle Bayer to recover damages in respect of infringing conduct occurring prior to the amendment. Importantly, Justice Jagot agreed with Bayer's submission that "the mere fact of the amendment does not justify a hindsight conclusion that the unamended claim was drafted other than in good faith or without reasonable skill and knowledge. Such an approach would be a requirement that claims at all times be drafted perfectly. This has never been the law." [3]

One-for-one

Distinguishing the Australian oral contraceptive market from other markets where there is substantial consumer choice and substitutability, the Court found that in the oral contraceptive market:

- a product could only be obtained on a doctor's prescription for a specific brand and that the patient would take advice from a doctor as to the brand which best meets the patient's requirements;
- brand substitution by a pharmacist may be permitted or prohibited by the prescribing doctor;
- generally patients did not change from one oral contraceptive product to another without good reason; and
- in the case of Isabelle, the only brand for which it could be substituted was Yasmin.

The evidence established that doctors generally prescribed by reference to the originator brand, Yasmin, and pharmacists dispense Isabelle where there is a prescription for Yasmin - but there was no evidence of any prescriptions for Isabelle. The Court was satisfied with Bayer's evidence and accepted the submission that **every sale** of Isabelle was a lost sale of Bayer's Yasmin. The trial Judge also accepted evidence from Bayer that its sole motivation for launching Petibelle was to mitigate any reputational damage because of the risk or reality that Isabelle had damaged the market's acceptance of the higher price that Bayer charged for Yasmin over the past 10 years. The Federal Court concluded that Bayer's launch of Petibelle was reasonable and foreseeable and there was a sufficient causal connection between Generic Health's infringement of Bayer's patent and Bayer's launch of

3 *Bayer Pharma Aktiengesellschaft v Generic Health Pty Ltd* [2017] FCA 250 at [188].

Petibelle such that Bayer was entitled to also claim that every sale of Petibelle for two years following its launch was a lost sale of Yasmin.

Commonwealth's claim to damages

Innovative pharmaceutical companies have been imploring the Federal Government to reconsider its policy of pursuing damages against patentees in cases where they have been granted interlocutory injunctions but their patents on PBS-listed medicines have been ultimately revoked. The damages sought to be recovered by the Government relate to PBS savings that would otherwise accrue to the Government (as a result of statutory price reduction and price disclosures) if a patent injunction had not been granted and a generic product had entered the market.

By way of example, Sanofi and Wyeth obtained interlocutory injunctions to prevent generic companies marketing and supplying generic clopidogrel and venlafaxine whilst substantive patent infringement proceedings were underway. In order to secure the injunctions, the patentees were required to give the "usual undertaking" as to damages prescribed by the Federal Court being an undertaking:

> *(a) to submit to such order (if any) as the Court may consider to be just for the payment of compensation, (to be assessed by the Court or as it may direct), to any person, (whether or not that person is a party), affected by the operation of the order or undertaking or any continuation (with or without variation) of the order or undertaking; and*
>
> *(b) to pay the compensation referred to in (a) to the person affected by the operation of the order or undertaking.*

Subsequently, Sanofi and Wyeth lost their substantive patent infringement proceedings. The Federal Government is now bringing an action against them for damages pursuant to the undertaking. Whilst there has always been an underlying risk that the Government could apply to recover compensation as a result of the PBS implications of an interlocutory patent injunction, the Government has not until now chosen to do so. Innovator pharmaceutical companies have raised serious concerns with the Government's change in policy in circumstances where there is no corresponding compensation for a patent holder if a generic product is listed on the PBS and subsequently found by the courts to have infringed a valid patent.

We are closely monitoring these cases as they progress through the Courts. *Commonwealth of Australia v Sanofi-Aventis & Ors* was heard in August and September 2017 before Justice Nicholas in the Federal Court of Australia and judgment has been reserved. The Commonwealth's case against Wyeth is scheduled to be heard in the Federal Court of Australia in June and July 2018 before Justice Jagot.

Australian Government response to Productivity Commission Report into IP

In August 2017, the Government released its long awaited response to the recommendations in the Productivity Commission's (PC's) Report on IP Arrangements. Of relevance in the healthcare industries:

Changes to inventive step test for patents

The Government accepted the PC's recommendation that the "inventive step" threshold for Australian patents should be raised beyond a "scintilla" of invention or the current test for obviousness (i.e. the invention is obvious if the person would be directly led to the claimed invention as a matter of course). The Government intends to make amendments to bring Australian laws more in line with European patent laws.

Abolition of innovation patents

The Government has also agreed with the PC's recommendation to abolish the innovation patent system in circumstances where it has been found that the majority of small to medium-sized enterprises did not obtain value from it when compared to the costs to those parties and the broader community of having the system in place. Innovation patents (in force for eight years) were intended to provide fast shorter term protection for lower level inventions with a lower standard of patentability compared to standard patents. The Government will put in place arrangements to maintain existing rights.

Extensions of term for pharmaceutical patents

The Government noted the PC's recommendation to reform pharmaceutical patent term extensions such that they are only available for patents covering an active pharmaceutical ingredient, and calculated based on the time taken by the Therapeutic Goods Administration (TGA) for regulatory approval over and above 255 working days (the statutory time frame within which the TGA must evaluate applications for registration). However, in recognition of the importance of patent protection to the pharmaceutical industry, the Government will not proceed with this recommendation.

Pay for delay arrangements

The Government supports in principle the PC's recommendation to introduce a system for transparent reporting and monitoring of settlements between originator and generic pharmaceutical companies to detect potential pay for delay arrangements. The Government intends to further consider the options for implementing this recommendation, including suitable compliance mechanisms where there is a failure by a party, or parties, to lodge relevant agreements with the ACCC.

Data protection

The PC found that there were no grounds to extend the period for data protection for any pharmaceutical products (including biologics) and, at least for now, the Government will not be extending the period for data exclusivity despite calls to bring Australia's data exclusivity period into line with countries such as the US and UK.

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REGULATORY

Reforms to therapeutic goods regulation

In the past 12 months the Federal Government has moved to implement several key recommendations of the Expert Panel Review of Medicines and Medical Device Regulation.

The first tranche of amendments were implemented in June 2017:

- providing a new pathway for the priority review of prescription medicines that represent a major therapeutic advance over currently-available treatments, with a view to providing earlier access to new medicines which may provide a treatment option where there are no existing treatments for life-threatening or seriously debilitating conditions. The Department of Health is empowered to make therapeutic goods priority applicant determinations, allowing the TGA to allocate more resources to fast-track the evaluation of these applications;
- enabling health practitioners to supply certain unapproved therapeutic goods to patients – principally those with an established history of use in similar overseas countries – by way of notification to the TGA, rather than requiring pre-approval;
- allowing sponsors of registered medicines to make straightforward, low-risk variations to their medicines (where product safety, quality or efficacy is not impacted) by notification to the TGA, rather than requiring TGA pre-approval; and
- expanding the population-related criterion for orphan drugs to include medicines for the treatment, prevention or diagnosis of a condition affecting fewer than 5 in 10,000 individuals in Australia, thereby allowing more diseases to be classified as rare.

The second tranche of amendments were implemented on 5 March 2018 including:

- providing a new pathway for provisional marketing approval of prescription medicines based on preliminary data, with a view to allowing patients with significant unmet clinical needs to obtain earlier access to new medicines;
- changing the process for listing intermediate risk medicines whose indications fall outside the lower-risk Permitted Indications List - such medicines will be included in the ARTG after sponsor self-assessment and certification regarding the safety and quality of the product, and evaluation by the Secretary of efficacy data supporting the proposed indications. Sponsors of affected listed medicines will have until 31 December 2020 to bring their products into compliance with the new regulatory requirements; and

- enhancing the TGA's enforcement powers including conferring power on the Secretary to obtain injunctions (including interim injunctions) from the Australian Federal Court or the Federal Circuit Court to compel a person to engage in particular conduct or to prevent them from engaging in particular conduct.

The second tranche of amendments also include an overhaul of the existing direct-to-consumer advertising regulatory framework by:

- abolishing the Complaints Resolution Panel in response to industry submissions;
- establishing the Department of Health as the authority responsible for handling advertising complaints;
- removing the requirement for pre-approval of advertisements in relation to certain therapeutic goods; and
- significantly increasing the penalties and sanctions available in respect of advertising offences.

However, after much debate and negotiation during the passage of the reforms, the implementation of the above change to the pre-approval of advertisements is now scheduled to take effect on 1 July 2020.

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PRICING

PBS reforms and pricing certainty

Medicines Australia and MTAA: New agreements with Federal Government

In April 2017, Medicines Australia signed a five-year Strategic Agreement with the Commonwealth of Australia to ensure the long term sustainability of the PBS in the implementation of the Government's 2017-2018 Budget PBS Medicines Package 2017.

The Strategic Agreement, which operates from 1 July 2017 to 30 June 2022, aims to provide pricing certainty and policy stability for the pharmaceutical industry. The Commonwealth has undertaken not to pursue further changes to PBS pricing policies during the five years of operation of the Agreement (other than those agreed in accordance with the Agreement, further details set out below) without consultation with the pharmaceutical sector.

The Medical Technology Association of Australia (MTAA) has also signed a Letter Agreement with the Federal Government. This agreement will be in force between 15 October 2017 to 31 January 2022 and aims to provide pricing certainty and policy stability by agreeing a range of Prostheses List benefit reductions, but also ensuring the Government does not pursue further changes to benefits during the term of the Agreement without agreement with the MTAA on behalf of the industry. In return for the implementation of $303 million in benefit reductions, the Government has agreed to reduce the time to market for medical devices by removing the requirement for duplicated safety and efficacy assessment by the Prostheses List Advisory Committee in respect of medical devices that have already been evaluated by the TGA for safety and efficacy; and, increasing the frequency of listing to ensure privately funded patients have faster access to reimbursement. Importantly, for small to medium-sized companies and researchers, a $30 million med-tech and biotech grants program will be established to encourage the research and development of new innovative device technologies, clinical trials (and associated registries) and workforce development.

PBS Reforms

The *National Health Amendment (Pharmaceutical Benefits – Budget and Other Measures) Bill 2017* received assent on 20 February 2018. The key changes proposed by the Bill are to:

- extend to 2022 (a two year extension), the 5% statutory price reduction (SPR) for F1 drugs that applies on the first "1 April" on or after being listed on the PBS for five years;
- introduce a once-off 10% SPR that applies on 1 June 2018 for F1 drugs listed on the PBS for ten years or more, but less than 15 years on that date, and a 10% SPR for F1 drugs with their 10 year anniversary of listing after 1 June 2018 that applies on the first "1 April" in any year from 2019 to 2021 on or after the tenth anniversary;
- introduce a once-off SPR of 10% that applies on 1 June 2018 for F1 drugs listed on the PBS for 15 years or more on that date, and a 5% SPR for F1 drugs with their 15 year anniversary of listing after 1 June 2018 that applies on the first "1 April" in any year from 2019 to 2021 on or after the 15th anniversary;
- increase the SPR that applies on the listing of the first new brand of a pharmaceutical item from 16% to 25% (the increased percentage to apply from 1 October 2018 and to 30 June 2022);
- introduce Ministerial discretion regarding the application of SPRs in certain circumstances; and
- provide new circumstances whereby a new brand of a listed pharmaceutical item is considered to be a "new presentation" for pricing purposes and allow listing of the new brand without movement from F1 to the F2 formulary (therefore not triggering SPRs under) where the day the new brand lists on the PBS is on or before the 5th anniversary of the drug in the trigger item being on the F1 formulary and the responsible person for the new brand of the trigger item is the same as the responsible person for the existing listed brand of the item.

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PRIVACY

Mandatory data breach notification laws come into effect

On 22 February 2018, mandatory data breach notification (MDBN) laws came into effect. Australian organisations which are subject to the Australian Privacy Principles (including all private health service providers and entities that hold health information) will be required to notify both the Office of the Australian Information Commissioner (OAIC) and impacted individuals of any "eligible data breaches".

Eligible data breaches

Entities must provide notice where there are reasonable grounds to believe that an eligible data breach has occurred – that is, where the loss, unauthorised access or disclosure of personal information (including health information and medical records) is likely to result in serious harm to an individual.

"Serious harm" is not defined in the legislation, however the OAIC has noted that it is likely to include physical, psychological, emotional, financial and reputational harm. Personal health data could cause serious harm to the individual if compromised, given its intrinsically sensitive nature. The Act's Explanatory Memorandum makes specific mention of the possibility of serious harm resulting from data breaches involving health information.

Entities cannot turn a blind eye to a possible data breach. If there are reasonable grounds to suspect that a breach has occurred, the entity must carry out an assessment (within 30 days) to determine whether there was in fact an eligible data breach.

Notification requirements

The entity must notify the OAIC and the affected individuals as soon as practicable after becoming aware of an eligible data breach. As part of the notification process, the entity must prepare a statement which contains:

- identity and contact details;
- a description of the relevant data breach;
- the kinds of information concerned;
- recommended steps to be taken by the data subject; and
- if applicable, identity and contact details of other entities that may be involved.

This statement must be provided to the OAIC and the contents of the statement either sent directly to the affected individuals, or if this is not practicable, made available on the entity's website.

If the entity acts quickly to remediate a data breach before any serious harm has been caused, then there is no requirement to notify the OAIC or the affected individuals. The OAIC may grant an exemption from the notification requirements if it believes it is reasonable in the circumstances to do so.

An exemption also applies if notification of a data breach must be provided under section 75 of the *My Health Records Act 2012* (which contains its own statutory notification requirements where the security of the My Health Record system has been compromised).

Failure to adhere to the notification requirements under the MDBN scheme may result in investigations and the imposition of civil penalties of up to $2.1 million.

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Preparation for the MDBN scheme

The health services sector reported the third highest number of data breaches (behind the federal government and financial services sector) in 2015-2016 under the OAIC's voluntary data breach notification scheme. It is therefore prudent to ensure that appropriate procedures are in place to properly address any future breaches in accordance with the new notification obligations.

It is recommended that organisations prepare or update their data breach response plans. In developing a response plan, consider:

- an analysis of the breach - what elements will trigger alarm;
- who should be involved within the organisation;
- how to triage and remediate;
- who should be informed;
- how should investigations be conducted; and
- what systems and procedures should be updated or improved.

The OAIC has released its Data Breach preparation and response – A guide to managing data breaches in accordance with the *Privacy Act (Cth)* 1988 which sets out guidance on the new regime.

Further information about the scheme can be found on the OAIC website.

With thanks to Nikita Matchado for her assistance.

ACCC priorities and ACL changes

Priorities of the Australian Competition and Consumer Commission

In the Annual Report of the Australian Competition and Consumer Commission (ACCC) released in October 2017, the ACCC noted that its Compliance and Enforcement Policy has prioritised "consumer and competition in the health and medical sectors".

The ACCC's priorities in this area have included the investigation of claims made by pharmaceutical companies, anti-competitive conduct by medical professionals and the communication of changes to private health insurance to consumers.

Since the publication of the Annual Report, the ACCC has continued to commence new legal proceedings against healthcare companies. This indicates that this enforcement priority of the ACCC is likely to continue in 2018. Other regulators including the Australian Taxation Office have also publicised their focus on investigations into, and ensuring compliance by, healthcare companies.

Australian Consumer Law Review

The Australian Consumer Law (ACL) commenced on 1 January 2011. A review of the ACL has been underway since June 2015, when Consumer Affairs Australia and New Zealand (CAANZ) was asked to consider the effectiveness of the ACL, including its product safety provisions, and the administrative and regulatory framework that administers them. In March 2017, CAANZ released its Final Report.

Chapter 2.2 of the Final Report considered issues relating to product safety. While the Final Report concluded that the introduction of the unified ACL regime provided a "clearer and more cohesive approach" in relation to product liability, it noted that the ACL was geared towards reactive "post-market", rather than proactive "pre-market", controls. The Final Report made a number of recommendations in relation to product liability, including various legislative amendments, such as:

- the introduction of a "general safety provision" (with associated penalty regime) to ensure a product is safe before it enters the Australian market;
- maximum penalties of $10 million for contravening the ACL product safety and consumer protection provisions, including the new general safety provision. This would be a significant increase, up from the current maximum penalty of $1.1 million;
- the clarification of "voluntary recall requirements", including the introduction of a statutory definition of "voluntary recall" and an associated penalty regime for failure to notify; and
- the broadening of existing ACCC powers to obtain information in relation to product safety to apply to any person (including a consumer) who may have relevant information, not just the supplier.

Consumer Affairs Ministers must consider the recommendations in the Final Report and then draft provisions amending the ACL are expected. This is likely to occur some time in 2018.

The healthcare industry will be affected by changes to the ACL and businesses are encouraged to review and make submissions on the draft provisions.

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Healthcare companies, their supply chains and modern slavery – Australia's new regulatory approach

There is growing evidence of the existence of serious human rights exploitation (modern slavery) in the supply chains of Australian healthcare entities.

The foreign production of medical gloves, surgical instruments (scissors, forceps, scalpels, suture needles), patient clothing, professional uniforms and footwear, and other goods used on a daily basis, such as sheets and towels, have all been linked to extreme working hours, exorbitant recruitment fees, confiscation of passports, physical and mental abuse, and forced child labour.

Healthcare entities listed on the Australian Stock Exchange produce and source these goods in and from the Asia Pacific region. More than half of all victims of modern slavery are in this region.

Australia, like other countries, now views business as an effective conduit in combating modern slavery. A Parliamentary Committee began considering whether Australia should adopt a modern slavery supply chains reporting requirement in February 2017. In August 2017, the Australian Government released its proposed reporting requirement model. The committee tabled its final report in December 2017, responding to the Australian Government's proposed model. The Australian Government is currently considering the committee's recommendations, with draft legislation expected in the first half of 2018.

Modern slavery in supply chains reporting requirement

Under the Government's proposal, healthcare entities (companies or partnerships) that are headquartered in Australia or that have part of their operations in Australia with total annual revenue of $100 million will be subject to a reporting requirement. In its final report, the committee considered a threshold of $50 million would be most appropriate as it provides for international consistency.

Covered healthcare entities will be required to publish annually a modern slavery disclosure statement in which they must report on:

- their structure, operations and supply chains;
- the modern slavery risks present in their operations and supply chains;
- their policies and process to address modern slavery in their operations and supply chains, and their effectiveness; and
- their due diligence processes relating to modern slavery in their operations and supply chains and their effectiveness.

The committee has suggested including an additional reporting area – further action taken to eradicate modern slavery. Further, the committee recommended enabling smaller entities to provide modern slavery statements to other entities as evidence of them having found no modern slavery in their own supply chains.

Healthcare entities will be required to have board level approval for their disclosure statement and ensure it is published on their business' website. The Australian Government will also create a publicly accessible central repository of these statements. Whilst the committee supports this approach, it has also recommended that the central repository contain a list of entities required to report, entities that have reported, and entities below the threshold who have reported voluntarily.

The Australian Government did not propose to include punitive penalties for non-compliance. The committee has recommended the introduction of penalties for entities that fail to report, applying to the second year of reporting onwards. In doing so, it has called upon the Australian Government to consider the appropriate level of penalties and how penalties should be administered, including a possible role for the Australian Securities and Investments Commission.

Implications for Australian healthcare entities

The existence of modern slavery in medical goods supply chains has implications for Australian healthcare entities. The Australian Government's proposed reporting requirement means healthcare entities will need to gain visibility into their supply chains and take action to manage identified risks. This will involve a range of operational measures and updating of supplier contracts.

Operational measures include:

- establishing a supply chain policy that articulates a commitment to responsible business conduct in its own operations and sets out expectations of suppliers;
- undertaking due diligence, such as pre-screening of suppliers and supplier audits;
- designing and implementing a strategy to respond to identified risks, which may involve a range of responses such as corrective actions plans, training and technical assistance;
- verifying that the actions taken have been effective, which involves the development of performance indicators and data monitoring;
- training key personnel in the entity's own business as well as suppliers on how to identify and mitigate the risks of modern slavery;
- establishing a clear chain of responsibility and assigning senior level approval for policy oversight and in relation to the modern slavery statement; and
- developing a web page dedicated to the publication of the modern slavery statement.

Supplier contracts should be updated to include:

- audit rights, including the right to undertake announced and unannounced audits, audits by third parties, and the requirement for full cooperation;
- immediate notification of actual or potential non-conformance with policy;
- consent to follow corrective actions plans in instances of non-compliance with policy;
- rights to impose penalties and/or suspend or terminate the contract for failures to meet policy standards, cooperate with an audit process or follow a corrective action plan; and
- right to inform relevant authorities, as necessary.

Public procurement

In 2016-17, healthcare represented the ninth largest category of procurement contracts entered into by the Australian Government. Ethical procurement, including the procurement of medical goods, has become an issue of significant legal, political and social importance. There is now an expectation that the Australian Government will be a "model procurer".

In June 2017, the Joint Select Committee on Government Procurement completed its review into the revised Commonwealth Procurement Rules (Rules) which commenced on 1 March 2017. This committee expressed concern that human rights were not specifically provided for in the Rules and recommended the establishment of a procurement connected policy on human rights which will require suppliers to be audited or accredited if participating in Commonwealth procurement. The Australian Government responded to the committee's report in November 2017, noting that outcomes from the current consultation process on a modern slavery supply chains reporting requirement could inform further the consideration of a procurement connected policy on human rights. Thus, the amended Rules which came into force on 1 January 2018 remain unchanged in this respect. It is notable that the committee examining the introduction of a reporting requirement, in its final report, recommended that the Australian Government introduce a requirement to only procure from entities that complete a modern slavery statement. The Australian Government is currently considering its response to this recommendation.

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TAX

Introduction of DPT, increased transparency and a focus on pharmaceutical companies

There have been several tax developments over the past 12 months that may have an affect on the healthcare industry, in particular multinational entities operating within the industry. Most notably, the introduction of Australia's Diverted Profits Tax and a renewed focus by the Australian Taxation Office (ATO) in conducting audits in the healthcare industry.

Diverted Profits Tax

Australia's Diverted Profits Tax (DPT) regime applies to tax periods starting on or after 1 July 2017. Broadly, the DPT may apply to multinationals with annual global income of at least A$1 billion where it is reasonable to conclude that profits have been artificially diverted from Australia. If the DPT applies, tax will be payable on the amount of the diverted profits at a rate of 40 per cent. The DPT provides the ATO with significant powers to scrutinise global supply chains and in particular, examine whether the economic substance is aligned with the form of the contractual arrangements.

Read more on the DPT in our Healthcare DPT alert.

ATO focus on pharmaceutical companies

The Australian Taxation Office (ATO) announced in September 2017 that it plans to closely examine the tax profiles of companies operating in the pharmaceutical industry in Australia. Based on the ATO's announcement, the renewed interest in pharmaceutical companies is driven by the strategic importance of the industry to the Australian economy, the significant volume of annual sales (approximately A$42 billion), and the diverse nature and structure of companies operating in industry.

As a result, the ATO has dedicated a team of senior tax officials across a range of tax functions to review the tax profiles and transfer pricing practices of the pharmaceutical industry. A primary focus of the ATO is likely to be non-arm's length conditions operating between entities in connection with their cross-border commercial and financial relations.

Read more on this renewed audit focus in our Australian Taxation Office: Pharmaceutical Industry now in the Spotlight alert.

Tax transparency

There is an increased level of scrutiny being applied to the tax profiles of multinationals operating in Australia by the ATO and Australian media. Recent legislative changes have increased the level of tax-related information provided to the public and may result in increased attention on the tax position of multinationals.

Legislative reforms that have increased publically available tax-related information, include:

- the ATO report on entity tax information – the annual corporate tax transparency publication of total income, taxable income and tax payable of corporate tax entities earning over A$100 million (Australian public and foreign owned) or A$200 million (Australian-owned resident private); and
- requirement for "significant global entities" to provide general purpose financial statements to the ATO and for those statements to be published by the Australian Securities and Investments Commission for tax periods from 1 July 2016.

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