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Life Sciences Update

In this update

From the Editors

Welcome to the October 2013 edition of *Life Sciences Update*.

In this edition Amruta Bapat discusses Eli Lilly's success in the Federal Court in which its patent for olanzapine, the active ingredient in blockbuster antipsychotic drug ZYPREXA, was affirmed as valid (*Eli Lilly and Company Limited v Apotex Pty Ltd* [2013] FCA 214 (15 March 2013)). Amruta also details the Court's analysis of the principles applicable to selection patents in Australia.

Jessica Norgard comments on the *Intellectual Property Laws Amendment Bill 2013*, under which Australian manufacturers may apply for a compulsory licence to exploit a pharmaceutical patent to supply eligible importing countries with generic versions of patented medicines in response to public health concerns. The Bill also seeks to implement a number of changes to clarify the scope of authorities able to rely on the 'crown use' provisions. Although the Bill was passed by the House of Representatives and moved into the Senate in June 2013, its progress through the Senate was stalled by the recent Federal election.

Cecillia Suatan reports on the US Supreme Court decision on gene patents (*Association for Molecular Pathology, et al v Myriad Generic, Inc, et al* (2013) Case No 12-398), to the effect that isolated DNA that is otherwise naturally occurring is a "product of nature" and not patent eligible but that cDNA is patent eligible because it is not naturally occurring. Cecillia considers the parallel proceedings in Australia, which are presently on appeal to the Full Court of the Federal Court of Australia.

Phoebe Vertigan provides an overview of the key recommendations made in the *Draft Report of the Pharmaceutical Patents Review*, published in April this year, which aimed to determine whether the current system for pharmaceutical patents balances the objectives of securing timely access to competitively priced pharmaceuticals, fosters innovation and supports employment in research and industry in Australia. The Final Report was provided to the Government in May 2013 but has not been released at the time of printing.

Elizabeth Holzer reports on the decision of the Federal Court in *Otsuka Pharmaceutical Co., Ltd v Generic Health Pty Ltd (No 2)* [2013] FCA 554 (7 June 2013), in which Generic Health's application for discovery to support its claim of inutility was denied on the basis that the allegation was speculative and the requested documents would not facilitate the just, quick and efficient resolution of the proceedings.

Katherine Payne reports on the forthcoming restructure of the guidelines for complementary medicines, which will comprise the final part to the revised Australian Regulatory Guidelines for Complementary Medicines. Once the TGA has considered submissions received in relation to all four

parts of the ARGCM, the part will be consolidated into a final revised document.

Mary Papadopoulos and Christina Forsyth examine the present regulatory status of mobile medical device "apps" in Australia, discuss recent industry comments and developments in this area by the US FDA, and query whether this may influence the approach to be taken in Australia.

Ben Hopper and Stuart D'Aloisio discuss the recent Federal Court decisions in *Ranbaxy Laboratories Limited v AstraZeneca AB* [2013] FCA 368 (23 April 2013) concerning AstraZeneca's patents for blockbuster proton pump inhibitor Nexium, in which Middleton J delivered a quick judgment affirming the validity of the patents. Ben and Stuart provide some analysis of the novelty and inventive step arguments considered by the Court.

We hope you enjoy the latest edition of *Life Sciences Update*.

Other news in brief

- IP Australia has released a consultation paper seeking comments on the Government's proposed amendments to the *Patents Act 1990* (Cth) to introduce:
  - an objects clause to assist in the interpretation of the Act, and
  - an exclusion from patentability for inventions, the commercialisation of which would be considered wholly offensive by the Australian public.

  Submissions were due by 27 September 2013.
- In April 2013, the UK Intellectual Property Office introduced a "Patent Box" scheme, which provides a reduced company tax rate on profits earned from patents after this date. Several other European countries have implemented similar schemes, which are aimed at encouraging innovation. The US Congress is now also considering new legislation that seeks to implement such a scheme in the US. Commentators have called for the introduction of a similar scheme in Australia to help drive research and development, particularly in the manufacturing and pharmaceutical industries, and discourage companies from seeking patent protection and commercialising inventions elsewhere in order to take advantage of such schemes in those countries.
- The TGA recently published submissions it received in response to its consultation on the exposure draft of the "Regulation Impact Statement: Changes to premarket assessment requirements for medical devices". The consultation sought responses to the TGA's paper outlining three proposed regulatory reforms for premarket assessment of higher risk medical devices. Copies of the public submissions are available from the TGA website here.
- In September 2013, the ACCC announced that it will not oppose a proposed global acquisition of Gambro AB by Baxter International Inc. on the basis that Baxter divests its Renal Replacement Therapy business. The ACCC will now issue a public competition assessment. See here.

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Victory for Eli Lilly in Federal Court as ZYPREXA patent found to be valid

Eli Lilly and Company Limited v Apotex Pty Ltd
[2013] FCA 214 (15 March 2013)

WHAT YOU NEED TO KNOW

- The Australian patent for olanzapine, the active ingredient in blockbuster antipsychotic drug ZYPREXA, has been affirmed as valid by the Federal Court.
- The decision included an analysis of the principles of selection patents as they apply under Australian law.

Facts and key issues

Eli Lilly and Company Limited was the registered owner of Australian Patent No 643267 for the antipsychotic compound olanzapine (**Patent**). Eli Lilly Australia Pty Ltd, the exclusive licensee of the Patent, markets and sells olanzapine products in Australia under the brand name ZYPREXA, for the treatment of schizophrenia.

Apotex Pty Ltd (**Apotex**) obtained registration on the Australian Register of Therapeutic Goods to market generic olanzapine products in Australia. The Eli Lilly parties (together, **Lilly**) contended that Apotex, by obtaining such registration, threatened to infringe certain claims of the Patent. By way of cross-claim, Apotex asserted that the Patent was invalid.

The case required the application of both the *Patents Act 1952* (Cth) (**1952 Act**) and the *Patents Act 1990* (Cth) (**1990 Act**). The 1952 Act applied to the grounds of invalidity relied on by Apotex, while the 1990 Act applied to the issue of infringement.

Following the hearing of the matter in October 2011, Justice Middleton upheld the validity of the Patent as well as Lilly's claims of infringement against Apotex. The Patent expired in March 2012, prior to the date of Justice Middleton's decision.

Infringement

Lilly contended that Apotex's proposed products infringed claims 1 to 4 of the Patent.

Although Apotex admitted that its products contained olanzapine, it asserted that they did not contain the compound referred to in the relevant claims of the Patent, being "2-methyl-10-(4-methyl-1-piperazinyl)-4H-thieno[2,3-b][1,5]benzodiazepine". Apotex asserted that the correct chemical name for olanzapine is "2-methyl-***4-***(4-methyl-1-piperazinyl)-***10H-***thieno[2,3-b][1,5]benzodiazepine" (*emphasis* added), which is consistent with the naming convention used by the International Union of Pure and Applied Chemistry (**IUPAC**).

Thus, the key difference between the parties' respective positions on the issue of infringement was the proper chemical name to be ascribed to the structure depicted in the Patent.

The evidence showed that non-IUPAC-compliant numbering could legitimately have been used by the skilled addressee at the priority date. Justice Middleton held, on the basis of the evidence, that the name used by Lilly in the Patent would be understood by the skilled addressee to be olanzapine. Accordingly, Lilly's claims of infringement against Apotex were upheld.

Validity

Apotex asserted that the Patent was invalid on the grounds of lack of novelty, lack of inventive step and absence of manner of manufacture and failure to meet the requirements in section 40 of the 1952 Act. Apotex's arguments on these issues were rejected by Justice Middleton.

Novelty and the principles of selection
Apotex argued that the Patent lacked novelty on the basis of earlier patents filed by Lilly, which covered a vast number of thieno[1,5] benzodiazepine compounds, and one of which was British Patent No 1 533 235 (**235 Patent**). Justice Middleton held

that a skilled person would need to make "a significant number of choices" when reading the 235 Patent to arrive at olanzapine, and that "without considerable hindsight", there was no way to assume that a skilled person would arrive at olanzapine following a review of the 235 Patent. Accordingly, the 235 Patent (and related patents asserted by Apotex) were found not to disclose olanzapine.

Apotex also argued that the Patent lacked novelty based on a short "note" from the East German journal *Die Pharmazie* in 1983 (**Schauzu**). His Honour rejected this argument. Schauzu contained an apparent contradiction between the title and the structure depicted, and was therefore open to "multiple interpretations".

Justice Middleton considered the principles of "selection patents", and held that it was unsettled as to whether the concept of selection patents forms part of Australian law. His Honour ultimately applied established novelty principles to find that the claimed invention was novel. The claimed invention was also found to be valid under the principles of selection (if applicable under Australian law), due to the many advantages of olanzapine over other members of the class of compounds to which it belongs.

Inventive step

Justice Middleton accepted expert evidence which demonstrated a clear preference for electron-withdrawing groups in antipsychotic compounds. His Honour also noted that small changes to molecular structure were known to lead to potentially unexpected and unpredictable changes in a compound's activity and side effects. Justice Middleton held that the skilled team would *not* have been directly led to try olanzapine (which does not contain an electron-withdrawing group) as a matter of course to treat schizophrenia, with any expectation of success.

Other grounds

Justice Middleton did not accept Apotex's arguments relating to the manner of manufacture and section 40 grounds. The Patent was thus upheld as valid.

Next steps

Justice Middleton's decision, which was in Lilly's favour in relation to both infringement and validity, is currently the subject of an appeal by Apotex to the Full Court of the Federal Court. The appeal is due to be heard in November 2013.

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Australia to the rescue: New bill to introduce patent export provision to help countries in need

WHAT YOU NEED TO KNOW

- The *Intellectual Property Laws Amendment Bill 2013* (**Bill**) seeks to implement a number of changes in the intellectual property sphere. Two significant changes concern crown use provisions and the incorporation of Article 31 of the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property and the related TRIPS protocol (collectively, **TRIPS**) as discussed below. The Bill was introduced into Parliament on 30 May 2013.
- Under the Bill, Australian manufacturers could apply for a compulsory licence under the pharmaceutical patent of another company to provide aid to eligible countries in need.
- The Bill also aims to clarify the scope of authorities able to rely on 'crown use' provisions, as well as to strengthen transparency and accountability.
- While the Bill was passed by the House of Representatives in June 2013, its progress was stalled by the calling of the recent Federal election and as a result, its future is currently uncertain.

The Bill incorporates provisions set out in TRIPS which allow Australian manufacturers to supply eligible importing countries with generic versions of patented medicines in order to respond to public health problems.

TRIPS

The current compulsory licence provisions set out in the *Patents Act 1990* (Cth) (**Act**) are designed to address the needs of the Australian public, but do not allow Australia to export pharmaceuticals under compulsory licence to meet the needs of other countries. The Bill seeks to incorporate provisions set out in TRIPS, which will allow Australia to export pharmaceutical patented products under compulsory licence to a country that is experiencing a serious epidemic under specific circumstances. This licence will be limited to that which is necessary to address the public health problem concerned. Despite being a signatory to TRIPS, Australia is only now implementing legislation to give effect to certain obligations which have been in place since 2007.

It is well recognised that patent protection in the pharmaceutical industry is vital to ensure continued investment and innovation. Such protection counters the high costs and risks associated with developing new products. It is this high cost of production and at point of sale that limits access of affordable medicines for the developing world. This is a pressing issue as the United Nations (**UN**) estimate nearly two billion people lack access to essential medicines.

This Bill introduces a system that is open to eligible importing countries that are able to demonstrate that there is a public health problem that can be addressed by the use of a particular pharmaceutical product, and that the country has insufficient manufacturing capacity to produce the product. The Explanatory Memorandum to the Bill specifies that developing countries with an established aid relationship with Australia will not be able to use the system.

"The Bill seeks to allow Australia to export pharmaceutical patented products under compulsory licence to a country that is experiencing a serious epidemic under specific circumstances. It remains to be seen whether the system is a practical or only a theoretical solution to the problem facing developing countries."

The Bill identifies steps for relevant parties. Firstly, the 'in-need' country must identify a suitable Australian manufacturer which can make the product and identify the relevant patent. For countries with a serious epidemic, the manufacturer must make a reasonable effort to obtain authorisation in the form of a voluntary licence from the patent owner to produce the product. The patent owner has the onus to give consent within a reasonable period of time, otherwise the patented product may be manufactured and exported without authorisation of the owner. If a country is experiencing a national emergency or extreme emergency then the manufacturer may bypass the initial negotiation step. In either case, the manufacturer must then notify the TRIPS Council of its intent to use the system.

The manufacturer may then apply to the Federal Court of Australia for a Patented Pharmaceutical Invention Compulsory Licence (**Licence**). The application must include a statement on behalf of the eligible importing country declaring that it will endeavour to prevent re-exportation and a statement on behalf of the importer that it will take reasonable measures within its means to prevent the pharmaceutical product from being used or sold other than in accordance with the licence. The Court may grant a compulsory licence, grant a compulsory licence on restricted terms or deny the application. If the Federal Court grants the compulsory licence, the licensee must notify the Commissioner of Patents, who will then notify the TRIPS Council. The TRIPS Council conducts an annual review of the system to seek to ensure effective operation.

The patent holder is entitled reasonable remuneration by the Australian manufacturer for its loss of exclusive use of the patent. In the first instance, the amount will be as agreed between the manufacturer and patent holder. However, in the absence of an agreement, the Federal Court will determine adequate remuneration by taking into account the "economic value" to the eligible importing country of the use authorised by the licence. The Productivity Commission recently completed a review of compulsory licensing under the Act which assessed factors to be taken into account when determining "adequate" remuneration. The Bill provides no practical guidance about how such determinations should be made. Other jurisdictions that have introduced the system have implemented a specific formula for calculating remuneration which caps it at 4% of the total price paid by the importing country. The licensee would then manufacture and export the goods at a reduced price to the eligible importing country.

Practical effect of the Bill

While the Bill aims to balance the rights of patent holders by providing remuneration and limiting circumstances when compulsory licences will be granted, it appears there may still be significant costs to the patent holder. These costs include obtaining legal advice and representation, loss of potential royalty income, loss of control over manufactured products and the cost of monitoring compliance with any licences granted. This system encourages patent holders to grant voluntary licences in an effort to avoid these costs.

Several jurisdictions have already implemented similar exporting provisions, but to date only one licence has been granted under such provisions. A significant hurdle appears to be that the system relies on eligible countries to be aware of their rights to rely on this system. Further, the onus to undertake certain steps shifts throughout the process, which may cause confusion amongst applying parties. It remains to be seen whether the system is a practical or only a theoretical solution to the problem facing developing countries.

New IP Bill introduced regarding crown use

By allowing the government access to patented inventions under exceptional circumstances, the crown use provisions are intended to provide a safeguard to the public to ensure that the patent system does not impede governments from acting in the public interest. The current crown use provisions however have been criticised as being unclear. One particular criticism is whether the phrase 'for the services of the Commonwealth or State' applies to non-government bodies that deliver goods or services in areas where the Commonwealth has primary jurisdiction. There have also been concerns surrounding the transparency and accountability of the bodies using the crown use provisions. The Bill seeks to clarify the scope of 'crown use' by defining the entities which can use the provisions and by strengthening transparency and accountability.

"The Bill seeks to clarify the scope of 'crown use' by defining the entities which can use the provisions and strengthening transparency and accountability."

The Act currently provides that the Commonwealth Government or a State or Territory Government or a person authorised by these bodies can rely upon the crown use provisions. The Bill clarifies that crown use can be invoked for the provision of a service that any Australian, State or Territory Government has the primary responsibility for providing or funding. The intention is that the primary responsibility test will take account of all providers of similar services to those provided or funded by a government, including non-government providers. It is yet to be seen whether this amendment provides the clarity the Government require to rely upon the provision.

In order to improve transparency and accountability, the Bill provides that governments are required to first seek a negotiated outcome (such as a voluntary licence) with the patent owner. If negotiation is unsuccessful, the Minister must then approve the crown use by instrument and provide at least 14 days' notice to the patentee of the approved use, together with reasons for the use. In cases of an emergency, the requirement of negotiation and 14 days' notification is waived, although notification must be provided as soon as practicable. The patent holder will be remunerated by the Government on terms either agreed by the parties, or in the absence of agreement, as designated by the Court in accordance with an amount that is just and reasonable, having regard to the economic value of the exploitation of the invention. There is no further explanation of how the Court will practically determine the "economic value" of the licence.

"It will be interesting to see whether the Bill will provide enough clarity, protection and compensation to satisfy industry concerns."

Practical effect of the Bill

The Bill seeks to rectify ambiguities and may thereby result in an increased use of the crown use provisions. Practically, it will be interesting to see whether the Bill will provide enough clarity, protection and compensation to satisfy industry concerns in light of the express expansion in the class of potential applicants for crown use.

Status of the Bill

The Bill was introduced into Parliament on 30 May 2013 and passed by the House of Representatives on 25 June 2013. On 28 June 2013, it received its first and second reading speeches in the Senate when the Federal Election was called. Caretaker Conventions, a practice where parliament avoids making major policy decisions prior to an upcoming election that would commit the incoming Government, prevented the Bill from being passed. At the time of writing, there have been no post-election developments so the future of the Bill is somewhat uncertain.

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US Supreme Court decision on gene patents – what does it mean for Australia?

Association for Molecular Pathology, et al v Myriad Genetics, Inc, et al (2013) Case No 12-398

WHAT YOU NEED TO KNOW

- In an unanimous ruling in *Association for Molecular Pathology, et al v Myriad Genetics, Inc, et al* (2013) Case No 12-398, the US Supreme Court overturned the decision of a US Federal Appeals Court that isolated gene sequences of the BRCA 1 and BRCA 2 breast cancer genes were patentable subject matter, but upheld that court's unanimous decision that synthesised cDNA sequences were patent eligible.
- The judgment of the Full Court of the Federal Court of Australia in the parallel Australian proceeding is presently reserved. While there are significant differences between the respective tests for patentable subject matter, the attention given to the issue by the US Supreme Court is likely to figure heavily in the next round – an application to the High Court of Australia to endeavour to settle this area of law in Australia.

History of the proceedings

In the 12 May 2010 edition of the LSU we reported on the decision in *Association for Molecular Pathology, et al v US Patent and Trademark Office, et al* (2010) SDNY No 09 Civ 4515 in which Judge Sweet of the New York District Court invalidated 15 composition and method claims contained in seven gene patents co-owned by Myriad Genetics, Inc. and the University of Utah Research Foundation (together **Myriad**) over the BRCA 1 and BRCA 2 genes implicated in hereditary breast and ovarian cancer. Our full report on the decision at first instance is available here.

In the 30 August 2011 edition of the LSU we reported on the appeal from that decision in *Association for Molecular Pathology, et al v US Patent and Trademark Office, et al* (2011) Case No 2010 Civ 1406, in which Judges Lourie, Bryson and Moore of the US Federal Circuit handed down a 2-1 judgment affirming in part and reversing in part the lower court's decision. Our full report on the appeal decision is available here.

Of present relevance:

- All three judges in the Federal Circuit appeal were in favour of the patentability of cDNA sequences, which are artificially created sequences from which introns (non-coding portions of a gene) have been removed, leaving only the exons (coding portions of a gene).
- Judges Lourie and Moore were in favour of the patentability of isolated DNA sequences on the basis that they were "markedly different" to naturally occurring genes, but the judges differed in their rationale. In particular:
  - Lourie J was of the view that the breaking of covalent chemical bonds in the isolation process was dispositive as it led to "a distinctive chemical identity" even though the alteration did not change the "information-transmitting quality of the DNA"; and

"The US Supreme Court held that: *"a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but that cDNA is patent eligible because it is not naturally occurring."* "

- Moore J did not consider the cleaving of covalent bonds to be sufficient, but relied on the past practice of the USPTO in granting gene patents and the "settled expectations of the inventing community".

- Bryson J dissented from the majority opinion on the issue of isolated DNA, as "there is no magic to a chemical bond" since "the nucleotide sequences of the claimed molecules are the same as the nucleotide sequences found in naturally occurring human genes". He also gave no weight to past USPTO practices because "the PTO lacks substantive rulemaking authority as to issues such as patentability".

The US Supreme Court decision

On appeal, oral arguments were heard in the US Supreme Court on 15 April 2013. On 13 June 2013, the Court handed down an unanimous judgment which affirmed in part and reversed in part the US Federal Appeal Court decision.

In a brief 18-page judgment delivered by Justice Thomas, a large portion of which was dedicated to (as Justice Scalia described it) the "fine details of molecular biology", the Supreme Court held that:

> *"a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but that cDNA is patent eligible because it is not naturally occurring."*

In arriving at its decision, the Supreme Court drew an important distinction between discovery and invention. In particular:

- The Supreme Court distinguished its decision in *Chakrabarty* 447 U.S. 303 (1980), which concerned the introduction of plasmids to a bacterium which gave it "markedly different characteristics" by allowing it to break down components of crude oil, on the basis that:

  > *"Myriad did not create anything. To be sure, it found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention. Groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the [patent eligibility] enquiry".*

- The Supreme Court followed the Court's decision in *Funk Brothers* 333 U.S. 127 (1948), which denied patentability to a mixture of naturally occurring strains of bacteria that helped leguminous plants fix nitrogen to the soil, on the basis that:

  > *"Myriad found the location of the BRCA 1 and BRCA 2 genes, but that discovery, by itself, does not render the BRCA genes 'new … composition[s] of matter' … that are patent eligible".*

- The Supreme Court noted that:

  > *"Many of Myriad's patent descriptions simply detail the 'iterative process' of discovery by which Myriad narrowed the possible locations for the gene sequences that it sought … But extensive effort alone is insufficient to satisfy the demands of [patent eligibility]."*

As to the 2-1 decision of the Federal Appeals Court, the Supreme Court preferred Judge Bryson's analysis to that of Judges Lourie or Moore, stating that:

> *"Nor are Myriad's claims saved by the fact that isolating DNA from the human genome severs chemical bonds and thereby creates a non-naturally occurring molecule. Myriad's claims are simply not expressed in terms of chemical composition, nor do they rely in any way on the chemical changes that result from the isolation of a particular section of DNA. Instead, the claims understandably focus on the genetic information encoded in the BRCA1 and BRCA2 genes."*

The Supreme Court also refused to pay deference to the USPTO's past practice of granting gene patents, since Congress had not endorsed the views of the USPTO in subsequent legislation. To the contrary, the United States Government argued in the Federal Circuit and in the Supreme Court that isolated DNA was *not* patent eligible subject matter.

Importantly, however, the Supreme Court upheld the patent eligibility of cDNA sequences, on the basis that:

> *"creation of a cDNA sequence from mRNA results in an exons-only molecule that is not naturally occurring … the lab technician unquestionably creates something new when cDNA is made. cDNA retains the naturally occurring exons of DNA, but it is distinct from the DNA from which it was derived."*

The Supreme Court was also quick to point out that its decision was limited to the issue of patent eligibility of isolated DNA sequence, and did not implicate the potential validity of any method claims of the patents-

in-suit. It also expressly left open the patentability of innovative methods of isolating DNA, new applications of knowledge about the BRCA genes and DNA in which the order of naturally occurring nucleotides has been altered.

Implications for the Australian proceeding

On 15 February 2013, Justice Nicholas of the Federal Court of Australia delivered judgment in *Cancer Voices Australia v Myriad Genetic Inc* [2013] FCA 65 in a challege to the validity of Australian Patent No 686004 for BRCA 1 and BRCA 2. Like the US Myriad litigation, this was essentially a test case in Australia over the patentability of "isolated" nucleic acids.

Like the US Supreme Court case, the only issue before Nicholas J was that of patentable subject matter (ie, "manner of manufacture").

Unlike the US Supreme Court decision, however:

- Nicholas J held that both "isolated" DNA and cDNA claimed were a manner of manufacture within s 18(1)(a) of the *Patents Act 1990* (Cth), on the basis that it was an "artificially created state of affairs" in the "field of economic endeavour" (applying the principles established by *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252);
- While not convinced that the breaking of covalent bonds was itself something that differentiated naturally occurring DNA from isolated DNA, Nicholas J considered the claims to be directed to a "chemical composition" rather than the informational content of the genetic material, stating (at [76]):

  "the disputed claims are not to genetic information per se. They claim tangible materials. But the disputed claims are not to information as such. They could never be infringed by someone who merely reproduced a DNA sequence in written or digitised form"

- Nicholas J paid a degree of deference to past decisions of the Australian Patent Office on the patentability of isolated DNA sequences.

Nicholas J did not consider the US Myriad litigation to provide any direct assistance to the Australian proceedings, on the basis of differences in the law (and constitutional setting) under which the issue arises in the two countries, and on the basis that different evidence was presented in each case.

An appeal from the judgment of Nicholas J was heard by a Full Court of the Federal Court of Australia on 7 and 8 August 2013, in *Yvonne D'Arcy v Myriad Genetics Inc & Anor* and judgment is reserved. In apparent recognition of the significance of the principle at stake, the Full Court took the unusual step of having 5 justices hear the appeal, including the Chief Justice.

While s 14(2) of the *Federal Court of Australia Act 1976* (Cth) provides that a Full Court "consists of 3 or more judges sitting together", the Full Court is very rarely constituted by more than 3 judges. While an unanimous judgment of 5 judges of the Full Court would go a long way toward settling the issue under Australian law, the expression by the Full Court of a divergence of views should (given clear public interest) attract the attention of the High Court of Australia in due course. The case seems destined to go another round.

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An overview of the Pharmaceutical Patents Review draft report

WHAT YOU NEED TO KNOW

- The Draft Report of the Pharmaceutical Patents Review was published in April this year.
- The Draft Report makes a number of recommendations which aim to secure timely access to competitively priced pharmaceuticals, including reducing extensions of term, introducing an exception for manufacture for export and reducing the cost of the Pharmaceutical Benefits Scheme.
- Although the Final Report on the Pharmaceutical Patents Review was provided to the Government in May 2013, a Final Report has not been released.

On 15 October 2012, the then Parliamentary Secretary for Industry and Innovation, the Honourable Mark Dreyfus QC MP, announced a review of the pharmaceutical patents regime in Australia. The panel in charge of the review is chaired by Tony Harris (Parliamentary Budget Officer), and includes Professor Dianne Nicol (Associate Dean, University of Tasmania) and Dr Nicholas Gruen (CEO of Lateral Economics) (**Panel**). The draft report of the pharmaceutical patents review (**Draft Report**) was released on 2 April 2013.

The key objectives of the review is to determine whether the current system for pharmaceutical patents effectively balances the objectives of securing timely access to competitively priced pharmaceuticals, fostering innovation and supporting employment in research and industry. The contentious nature of a number of recommendations means that this review should be monitored by all involved in the pharmaceutical industry. This article will highlight some of the key recommendations made in the Draft Report.

Extensions of term

A key recommendation of the Draft Report is to reduce extensions of term for pharmaceutical patents from the present 5 years, and use the savings to Government to provide a direct subsidy to fund R&D. The Draft Report cites economic analysis to support the argument that extensions of term do not improve investment in R&D in Australia. Unfortunately, the draft recommendation does not quantify the amount of subsidy to be paid, nor how the amount will be distributed.

Another recommendation in the Draft Report is that patents that receive an extension of term in Australia should not expire later than their equivalent patents in other jurisdictions. The Panel observed that patents in Australia tend to expire later than their overseas counterparts because term extensions are calculated from the date on which regulatory approval is granted in Australia, rather than on earlier approval overseas.

These recommendations have the potential to significantly shorten the effective life of pharmaceutical patents in Australia and bring significant savings to Australia's PBS. If progressed it is likely they will meet significant opposition by innovator interests.

Manufacture for export

Under the *Patents Act 1990* (Cth) a patentee has the exclusive right to exploit the patented invention, which includes making, hiring, selling or otherwise disposing, using or importing the invention. This is consistent with Australia's international agreements, such as the TRIPS Agreement and the AUSFTA.

The Draft Report contemplates a situation where manufacture for export (**MFE**) is permitted to allow manufacture of a patented product for export to a non-patent country without the patent owner's permission. As the definition of "exploit" suggests that MFE infringes a patentee's rights and Australia's international agreements, the Draft Report advances alternative options for the government to pursue.

The Draft Report suggests that as a preliminary measure the Government should introduce a limited MFE exception that is consistent with Australia's international obligations, while vigorously pursuing MFE exceptions in bilateral, plurilateral and international forums. As the AUSFTA is particularly influential it seems unlikely that the Government

would pursue a regime inconsistent with that Agreement or, in turn, US law.

Given these difficulties, the Draft Report's advances as an interim measure for the Government to seek agreement from patentees that they will not enforce their rights in respect of MFE, phrased in terms of Corporate Social Responsibility.

Other methods for managing PBS costs

The Draft Report recommends that the Government takes a more active role in managing the cost of the PBS where a patent relating to a PBS-listed pharmaceutical is successfully challenged in court. This could involve ensuring that the Government recoups more of the cost to the PBS arising from delayed generic entry, and implementing measures provide negotiated incentives for a party who successfully challenges a patent.

Given the focus of the Draft Report, these recommendations are unsurprising. The ultimate Government response to these recommendations (if they are included in a Final Review) will be of particular interest to pharmaceutical companies currently involved in patent litigation, as they touch on a number of policy issues such as the government's right to damages, and whether the government qualifies as a "person affected" for the purposes of the usual undertakings as to damages.

Watch this space

The Panel provided a Final Report to the Government in May 2013, however, at the time of publishing this had not been released. As the review was an initiative of the former Labor government, the future of the recommendations is now unclear. The new Coalition Government did not make any substantive policy announcements regarding patents in the lead up to the Federal election. Therefore, we have no indication of the new Government's appetite for change in this area, particularly with regards to the more controversial recommendations in the Draft Report. We will continue to watch this space.

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No fishing allowed

Otsuka Pharmaceutical Co., Ltd v Generic Health Pty Ltd (No 2) [2013] FCA 554 (7 June 2013)

WHAT YOU NEED TO KNOW

- Generic Health sought discovery to support its attack on the validity of the patent on the ground of inutility.
- The Court found that the allegation was speculative, not supported by the evidence already filed and was based on facts that were objectively contradicted by the respondent's own ARTG registration.
- The Court refused the application for discovery noting the request had all the hallmarks of a fishing expedition, finding that it was not satisfied that the requested documents would facilitate the just resolution of the proceeding as quickly, inexpensively and efficiently as possible.

WHAT YOU NEED TO DO

- When making applications for discovery it is important to ensure the request is grounded by reference to an arguable claim in the pleadings. It may be easier to argue such a connection before a party has the opportunity to file evidence.
- Given the current approach in patent proceedings is to limit discovery prior to the completion of evidence, it is also prudent to ensure as a matter of strategy that the evidence filed provides some support for a later discovery request.
- If the discovery sought is extensive, and, as was the case here, requires translation of documents, such that the provision of discovery could delay the hearing for several months, attention should be given to making the request as soon as feasible in the proceedings.

Background

In *Otsuka Pharmaceutical Co Ltd & Anor v Generic Health Pty Ltd*, the respondent in a patent infringement action sought discovery from the applicants, Otsuka and Bristol-Meyers Squibb, for documents to support its cross claim for revocation of the patent and in particular its challenge to the utility of particular claims of the patent.

The patent in question covered the use of a compound (Aripiprazole) in the treatment of depression (amongst other disorders). At an early stage of the proceeding, the parties had agreed that there should be no orders or timetable for discovery and both sides proceeded to prepare and file evidence in support of their respective claims.

Disputed discovery

After filing evidence in chief in support of its cross-claim and in answer on infringement, the respondent sought discovery including discovery of a category of documents that were:

"brought into existence before the date of grant of [the patent] which record any research, development, test or experimental work in respect of the alleged invention disclosed and claimed in [the patent] insofar as those documents relate to [depressive disorders] and the treatment of the "extended indication"… ".

"When making applications for discovery it is important to ensure the request is grounded by reference to an arguable claim in the pleadings. If the discovery sought is extensive, attention should be given to making the request as soon as feasible in the proceedings."

The "extended indication" was defined in the statement of claim and was taken from the Respondent's ARTG registration as follows: "Acute treatment of manic or mixed episodes associated with Bipolar 1 Disorder in adults…; Maintenance treatment of manic or mixed episodes in Bipolar 1 Disorder…"

The significance of the "extended indication" was that it also appeared to be central to the respondent's non-infringement argument (to be run at trial). The Court noted that the respondent will argue that the depressive symptoms associated with Bipolar 1 disorder are not a separate disorder, in and of themselves, but rather they are symptoms of the Bipolar 1 disorder and accordingly, the relevant claims of the patent do not cover the treatment of the depressive episodes of Bipolar 1 disorder.

The respondent argued that the disputed category of discovery was relevant to support its contention that the invention (as claimed in claim 8) lacks utility. It also argued that the disputed category of documents were relevant to the pleaded s 40 grounds of invalidity, namely, lack of best method, clarity and fair basis. Notably, his Honour Justice Yates made it clear that he would not make an order for discovery on the basis of the s 40 grounds, finding that no proper foundation for discovery had been established.

The opposing arguments

The applicants argued that there should be no order for discovery because the claim of inutility was speculative and the respondent was engaged in a "fishing expedition". In support of its opposition the applicant relied on the evidence in chief filed by the respondent which did not address or challenge the utility of the relevant claims. The applicant also argued that the discovery would be burdensome in that it would take some months and require the translation of documents.

The respondent sought to rely on some affidavit material that was filed in answer on infringement (not in support of its validity challenge). The evidence included scientific references that questioned the efficacy of Aripiprazole treatment for depressive episodes of bipolar disorder. Justice Yates noted that the respondent's reliance on this material sat "oddly" and was contradictory to its ARTG registration for Aripiprazole for the treatment of bipolar disorder. His honour noted that the ARTG registration objectively signified that Aripiprazole is an effective treatment for biopolar disorder. His Honour also struggled to reconcile the respondent's arguments with its non-infringement contention that the invention did not even cover the treatment of bipolar disorder.

Outcome

In considering the competing arguments and refusing the request for discovery, Justice Yates noted that the respondent "seeks discovery by reference to the disputed category of documents in the hope that it might find that which the evidence presently available to it apparently does not show … Such an application has all the hallmarks of "fishing" in the context of what appears to be a largely speculative allegation".

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Revised and restructured guidelines for complementary medicines coming soon

WHAT YOU NEED TO KNOW

- Submissions have now closed for the draft Australian Regulatory Guidelines for Complementary Medicines (**ARGCM**) Part D: Registered complementary medicines.
- As part of a broader package of reforms, the Therapeutic Goods Administration has been reviewing and restructuring the ARGCM to increase their usability and to ensure consistency with current regulations.
- The ARGCM Part D is the fourth and final section of the revised and updated guidelines. It replaces the current document "*ARGCM Part I: Registration of Complementary Medicines*" but does not introduce any new procedures.
- Submissions have separately been received on each of the other draft parts of the revised ARGCM and, once all submissions have been considered, the individual parts will be consolidated into the final document.

On 22 July 2013, submissions closed for the draft document *ARGCM Part D: Registered complementary medicines*. The ARGCM Part D is the fourth and final part of the revised and restructured guidelines, which are part of broader reforms to improve the regulation of complementary medicines in Australia. Part D replaces the current document "ARGCM Part I: Registration of Complementary Medicines", but does not introduce any new procedures. It rather makes formatting changes, corrections, and updates any outdated content.

The ARGCM provide guidance for sponsors, manufacturers, healthcare professionals and the general public on the regulatory requirements for the manufacture, supply and use of complementary medicines in Australia. The current guidelines were developed by the TGA in consultation with the Australian Self-Medication Industry (**ASMI**) and the Complementary Healthcare Council of Australia (**CHC**) in 2001. They are structured into five parts and cover the requirements for registering or listing complementary medicines and the application process.

The revised ARGCM are part of a broader package of reforms to the TGA and the regulation of complementary medicines in Australia. In August 2011, the Auditor-General released its report *Therapeutic Goods Regulation: Complementary Medicines*, which highlighted a number of issues with the effectiveness of the TGA's administration of complementary medicines regulation, including poor compliance with regulatory requirements and a lack of clarity and understanding of the regulatory requirements. In response to the Auditor General's report and a number of other major reviews, in December 2011 the Government announced plans to reform the TGA. As part of its implementation of these reforms, the TGA is reviewing and restructuring the ARGCM to make sure they are consistent with current legislation and practices and to increase their usability.

The revised ARGCM are structured into four parts, with Attachments containing technical information:

- Part A provides an overview of the regulatory framework for therapeutic goods in Australia. It includes information about different types of complementary medicines, the difference between active ingredients and excipients and the interface between foods and medicines.
- Part B covers the regulatory requirements for listed complementary medicines.
- Part C covers the evaluation process for new complementary substances to be approved.
- Part D covers the regulatory requirements for registered complementary medicines.

Each part has separately been released and been subject to a four week consultation process. Now that all submissions have been received, a public summary of submissions will be published on the TGA website.

Once the submissions have been considered, the parts will be consolidated into a final revised document. This will then be revised as required as new proposed reforms for complementary medicines are developed.

Complementary medicines

Complementary medicines, which are also sometimes referred to as "traditional" or "alternative" medicines, include vitamins, minerals and herbal, aromatherapy and homeopathic products. They are widely used in Australia and are often easily available (some popular examples include fish oil, St John's Wort and glucosamine). In Australia, complementary medicines are regulated under the *Therapeutic Goods Act 1989*. They either must be registered or listed on the ARTG, depending on their active ingredients and the health claims they make. In recent years, there has been steady growth in the use of complementary medicines. Following a large recall of products from a manufacturer of complementary medicines in 2003 and a report in late 2010 which found a significant number of complementary medicine products reviewed were not compliant with regulatory requirements, there has also been increased public attention directed towards the regulation of complementary medicines.

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Can a mobile app be a medical device in Australia?

WHAT YOU NEED TO KNOW

- Industry bodies in a number of countries have highlighted potential consequences and risk of harm if mobile medical "apps" do not work as intended and have called for increased scrutiny and clarification of existing laws to ensure adequate regulation of devices that are intended to cure, treat, monitor or diagnose a medical condition.
- The US Food and Drug Administration has released a guidance which defines a sub-set of medical apps that it has termed a "mobile medical app" to fall under regulatory oversight. The FDA has also helpfully provided a list of mobile apps that it does not consider to fall under the guidance and regulatory oversight. A number of medical apps have been classified as devices in the US and are subject to US regulation.
- Mobile medical apps have not yet been singled out for specific Australian regulation. While a recent guidance makes it clear that the Therapeutic Goods Administration will seek to regulate any apps that it regards as falling within the definition of a "medical device" under Australian law, there is uncertainty as to whether mobile medical apps *per se* fall within the legislative definition.

WHAT YOU NEED TO DO

- App developers should carefully consider the function of any 'medical' apps they create or supply, as well as the manner in which the app is marketed and supplied.
- Seek specific legal advice on whether any specific medical app requires approval for inclusion on the Australian Register of Therapeutic Goods in its own right.

Mobile medical applications (or "apps") downloaded for use on smartphones and other mobile platforms are becoming increasingly common. There are now thousands of apps available on the Apple® iTunes Store® alone under the category of 'medical'. Medical apps are also attracting the attention of regulators in other countries, including the United States, but in some respects their regulatory status in Australia remains uncertain.

The current Australian position

Under the *Therapeutic Goods Act 1989* (Cth) (the **TG Act**), therapeutic goods, including medical devices, for human use that are imported, manufactured, supplied in, or exported from Australia must be included in the ARTG (unless specifically exempted by the TG Act). The extent of regulation of medical devices depends on the class of the device, which is determined by the intended use, level of potential risk and harm, degree of invasiveness and duration of use.

At present, there is no specific regulation for medical apps in the TG Act but it is clear that the TGA will seek to regulate any apps that it regards as falling within the definition of "medical device" in the TG Act.

Indeed, the TGA provided some guidance on this topic on 13 September 2013, available here.

The definition of "medical device" is contained in s 41BD of the TG Act. In general, a medical device is any "instrument, apparatus, appliance, material or other article" intended by the supplier to be used for humans for a therapeutic purpose such as diagnosing, monitoring, treating or alleviating diseases, injuries or disabilities, or investigating, replacing or modifying the anatomy or of a physiological process.

Is a medical app a "medical device"?

The definition of a medical device under the TG Act also contains the words "and including any software necessary for its proper application". The phrase plainly covers software implemented in devices that rely on computer hardware to operate. The definition of medical device also includes "accessories" to things that otherwise fall within the definition of "medical device".

According to the Australian Regulatory Guidelines for Medical Devices[1] (the **ARGMD**), software is regulated

[1] Available from http://www.tga.gov.au/industry/devices-argmd.htm.

in different ways depending on the manufacturer's intended purpose for the software and how it is supplied. According to the ARGMD, software that is part of a device and supplied with a medical device is regulated as part of the device. By contrast, software (or an "accessory") to a device that is supplied separately from that device is regulated as a separate medical device. Similarly, software that is used as a diagnostic or therapeutic tool is regulated as a separate medical device. The ARGMD states that software that itself falls within the definition of a medical device needs to be approved on the ARTG as a separate registration from any related devices.

It is unclear, however, whether a mobile medical app purchased online and downloaded to a standard smartphone or tablet falls within the present definition of a medical device in the TG Act. A smartphone or tablet on which a medical app can be used is unlikely to itself fall within the definition of "medical device" because smartphones and tablets are not typically intended by the supplier to be used for a therapeutic purpose. It is, therefore, difficult to see how a mobile medical app purchased separately online can be described as an "accessory to" a medical device. In order to be regulated, therefore, it seems a mobile medical app needs to itself be a "medical device".

From a policy perspective, there is a good case to be made that any tool or application that is intended to be used on humans for a therapeutic purpose should be regulated, irrespective of how it is supplied, and irrespective of the particular medium or platform by which it is used. Recent decisions of the High Court of Australia, however, have emphasised the primacy of the particular text in statutory construction over broader notions of legislative intention. The expression in s 41BD of the TG Act "instrument, apparatus, appliance, material or other article" appears to limit the definition to physical "things", which arguably exclude software *per se*. When an app is purchased online, what "device" is supplied? Does a computer program (a set of machine-readable instructions) communicated by electromagnetic waves qualify as an "instrument, apparatus, appliance, material or other article"?

The term "apparatus" has received judicial consideration, albeit in a different context, and has been held to denote a "mechanical contrivance to achieve a particular purpose".[2] According to the *Macquarie Dictionary*, an "apparatus" is "an assemblage of instruments, machinery, appliances, materials, etc., for a particular use". The *Macquarie Dictionary* defines "instrument" as "a mechanical device or contrivance; a tool; an implement", "appliance" as "an instrument, apparatus, or device", and "material" as "the substance or substances of which a thing is made or composed". The definition of "article" includes "an individual piece or thing of a class" and "any thing". It is perhaps arguable that the scope of these words can include a computer program *per se* because it brings about a change in the state of a device such as a smartphone. There is, however, a strong argument that in the context of software, the definition requires a physical item (such as disk) to be supplied, and that by the words used the legislature simply did not contemplate computer programs with medical applications being supplied online for use with ubiquitous devices such as smartphones.

Although the TGA's recent guidance does not deal with this threshold question, the guidance states:

> "*… products that have a role in diagnosing or managing illness using software that analyses clinical data, such as the results of blood tests or ECGs, would, if they come within the definition above, be considered to be medical devices and would therefore be subject to TGA's regulatory oversight.*"

"There is a good case to be made that any tool or application that is intended to be used on humans for a therapeutic purpose should be regulated, irrespective of the particular medium. There is, however, a strong case argument that the present statutory definition requires a physical item to be supplied, and that the legislature simply did not contemplate computer programs with medical applications being supplied online for use with ubiquitous devices such as smartphones."

[2] *Thomas v Ferguson Transformers Pty Ltd* [1979] 1 NSWLR 216 per Hutley JA at 219-220 in *Thiele v Commonwealth* (1990) 22 FCR 342.

The guidance also states the TGA's view that apps that are "limited to managing and presenting information" or mere "sources of information" would not constitute a medical device unless the app also incorporates a therapeutic or diagnostic function.

Industry position

Industry both in Australia and abroad has queried the lack of, or uncertainty raised by, current regulations and stressed the need to minimise any potential risks of harm that may occur to patients or others using mobile medical apps.

In a submission to the Commonwealth Consumer Affairs Advisory Council in response to an issues paper titled "Apps purchased by Australian consumers on mobile and handheld devices",[3] the Medical Technology Association of Australia (**MTAA**) recommends that medical apps that are intended by the developer to cure, treat, monitor or diagnose a medical condition be regulated as medical devices.

The MTAA says use of medical apps is increasing, as is concern about the use of unregulated mobile medical apps, particularly by consumers. While medical apps should be differentiated from "wellness" apps (eg symptom checkers or calorie counters), sometimes the distinction may be unclear, particularly where preventative or self-monitoring activities are included in a diagnostic or treatment regime. Medical apps that fail to work as intended may of course have serious medical (and potentially legal) consequences. For instance, an app for monitoring glucose levels for diabetic patients may lead to serious complications for the patient if it does not work correctly. In addition to calling for appropriate regulatory oversight of medical apps based on level of risk, the MTAA stresses the importance for post market surveillance (eg acting on adverse reactions and consumer complaints) and highlights the inherent technical difficulties in recalling a potentially dangerous medical app.

The Groupe Spécial Mobile Association (**GSMA**), a European industry based association that represents the interests of the worldwide mobile communications industry, has issued a policy and position paper on the regulation of "mHealth" (or mobile heath), including mobile medical apps.[4] The GSMA submits that collaboration between industry and regulators is essential to providing clarity as to how medical device regulations apply to new and emerging mobile health solutions, ensuring safeguards to users of such solutions and also fostering continued innovation and progress. According to the GSMA, no additional regulation is required; rather clarification and possible extension of existing regulations is needed.

The International Medical Device Regulators Forum (**IMDRF**), a voluntary, international group of medical device regulators has established the Standalone Medical Device Software Working Group and released a consultation paper titled "Standalone Medical Device Software: Key Definitions"[5]. The paper defines "standalone software" as "software intended to be used for one or more medical purposes and is able to perform its medical purpose without being embedded in a hardware medical device or being dependent on specific or proprietary medical purpose hardware." In this paper, the IMDRF acknowledges that existing health regulations may not adequately address the health risks posed by "standalone software", particularly when such software is developed and distributed online. Comments on the paper, which sets out key definitions that are intended to help identify a risk framework, were sought and closed on 30 August 2013.

The position in the United States

The definition of "device" in the United States Food, Drug and Cosmetic Act includes any "contrivance" or "accessory" which is intended to be used in diagnosis or treatment, etc. The definition thus avoids the ambiguity that arises under the Australian legislation, discussed above.

In June 2012, the US Congress approved the FDA Safety and Innovation Act, which allows the FDA to regulate medical applications on smartphones and in September 2013, the US FDA released a guidance on mobile medical applications. The FDA's guidance defines a "mobile medical app" as a mobile app that meets the definition of a "device" under US legislation and:

a) is used as an accessory to a regulated medical device; or

b) transforms a mobile platform into a regulated device.

The intended use of a mobile app will determine whether it will meet the definition of a "device", which

[3] http://ccaac.gov.au/files/2013/02/MedicalTechnologyAssociationofAustralia.pdf.

[4] http://www.gsma.com/connectedliving/wp-content/uploads/2012/03/gsmamedicaldeviceregulationmhealthpolicyandposition.pdf. See also http://www.gsma.com/connectedliving/wp-content/uploads/2012/03/mHealth_Regulatory_medicaldevices_10_12.pdf.

[5] http://www.imdrf.org/docs/imdrf/final/consultations/imdrf-cons-sskd-130701.pdf.

may be shown by marketing materials or claims made about the app. The guidelines state that when "the intended use of a mobile app is for the diagnosis of disease or other conditions, or the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or function of the body", then the app is classified as a device and will be subject to regulation.

The FDA has helpfully set out examples of who will be considered a "mobile medical app manufacturer" and therefore subject to regulation as the "manufacturer" of the app. These include a person or entity that initiates specifications, designs or creates a mobile medial app software system in whole or from multiple software components. The FDA guidance makes it clear that manufacturers or suppliers of mobile platforms (eg smartphones and tablets) are excluded, provided that the platform is not marketed with a medical device intended use. Similarly, entities that distribute apps that do not engage in manufacturing (eg Apple® iTunes Store® or the "Android" market) are excluded from the definition of "mobile medical app manufacturer" although a creator of a mobile medical app that provides access to the app through a website subscription is a "mobile medical app manufacturer".

The FDA guidance also lists types of mobile apps that the FDA considers to be subject to regulation. For example, mobile apps that:

- connect to medical devices to control the device or display, store, analyse or transmit patient data;
- transform a platform into a regulated medical device by using certain methods, such as attachments, screens or sensors;
- perform patient-specific analysis, diagnosis or treatment recommendations,

are subject to the FDA's regulatory oversight.

Examples of medical apps that have been classified as devices in the US and are subject to US regulation include a mobile medical app that controls the delivery of insulin, one that acts as a stethoscope and another that allows doctors to view X-rays or other imaging on smart phones and tablets. Over the last ten years, the FDA has reportedly reviewed about 100 applications for regulatory approval of mobile medical apps.

The FDA's guidance also helpfully provides a list of mobile apps that the FDA does not consider to fall under the guidance and regulatory oversight, such as apps that contain medical reference materials, apps intended for health care providers as educational or training tools or for general patient education or access to commonly used reference information, and apps that automate general office operations in a health care setting and are not intended for use in the diagnosis of disease or other conditions, or the cure, mitigation, treatment, or prevention of disease.

It remains to be seen whether the developments in the US will prompt similar legislative action in Australia to clarify the regulatory status of mobile medical apps.

What are the risks of not registering a "medical device"

There are numerous offences and penalties set out in the TG Act for not registering a medical device on the ARTG. These are in addition to any claims which may arise in relation to the supply or manufacture of defective goods such as claims under the *Australian Consumer Law* or the general law of negligence.

The risks and penalties in the TG Act can be broadly summarised:

a) It is a criminal offence to manufacture, import or supply a medical device that is not included on the ARTG.

b) The penalties for these offences vary depending on the circumstances but can include imprisonment up to five years and fines varying from $170,000 up to $8,500,000.

c) In some circumstances, executive officers of corporations can also be found liable.

In the case of any uncertainty, it is best to seek specific legal advice and indeed engage with the TGA as to whether any specific medical device app requires approval for inclusion on the ARTG in its own right.

What does the future hold?

There is little doubt that mobile medical apps will play an increasingly significant role in assisting medical practitioners and other health professionals, and in improving the quality of care and treatment of patients, but clear and effective regulation will be essential to delivering these benefits.

The ambiguities in the current drafting of Australian legislation raises questions as to whether such apps

are currently subject to TGA oversight. While the recent guidance from the TGA gives some assistance, time will tell whether Australia will follow the lead of the US and introduce specific legislative change and regulatory guidelines to clarify whether and which apps are subject to regulatory approval.

In the meantime, in light of the uncertainty in this area, app developers should carefully consider the function of any 'medical' apps they create or supply, as well as the manner in which the app is marketed and supplied. This may help reduce uncertainty as to whether the app falls within the definition of a medical device under Australian law. In addition, developers should also have careful regard to related aspects of Australian law, including:

a) the medical device standards in the TG Act and the Therapeutic Goods Advertising Code;

b) intellectual property laws, including regarding the branding of the app, copyright ownership and patent landscape;

c) privacy laws; and

d) the *Australian Consumer Law*, as enacted in Schedule 2 to the *Competition and Consumer Act 2010* (Cth) and equivalent Australian State and Territory fair trading legislation.

Apple and iTunes Store are trademarks of Apple Inc., registered in the U.S. and other countries.

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Validity of AstraZeneca's enantiomer and formulation patents over Nexium upheld

Ranbaxy Laboratories Limited v AstraZeneca AB
[2013] FCA 368 (23 April 2013)

WHAT YOU NEED TO KNOW

- The Federal Court has upheld the validity of two of AstraZeneca's patents over Nexium, thereby preventing market entry of Ranbaxy's generic esomeprazole products until June 2015.
- AstraZeneca's patent claiming an optically pure salt of a single enantiomer of omeprazole was held to be novel and inventive over the prior art.
- AstraZeneca relied upon two formulation patents: one patent was held to be valid and infringed while the other was construed in a manner which meant Ranbaxy's products did not infringe.
- Both parties have appealed parts of the decision to the Full Federal Court.

Background

On 23 April 2013, Justice Middleton of the Federal Court gave judgment for AstraZeneca in *Ranbaxy Laboratories Limited v AstraZeneca AB* [2013] FCA 368. The case concerns patents over AstraZeneca's blockbuster proton pump inhibitor (**PPI**) Nexium and pharmaceutical formulations thereof. The Court upheld the validity of two of AstraZeneca's patents, thereby preventing Ranbaxy's generic entry until June 2015. The case is notable for many reasons, including the Court's speedy judgment (less than a month after trial) and the facts being in contrast to previous enantiomer cases in Australia, notably *Apotex Pty Ltd v Sanofi-Aventis* (2009) 82 IPR 416 (***Apotex***).

Nexium

The active pharmaceutical ingredient in Nexium is esomeprazole magnesium trihydrate, which is the magnesium salt of the (*S*)-enantiomer of omeprazole. Omeprazole is AstraZeneca's first generation blockbuster PPI, marketed under the brand name Losec.

Nexium (like other PPIs) inhibits the secretion of gastric acid in the stomach and is indicated for the treatment of gastro-oesophageal reflux disease (**GORD**). Nexium has been proven to treat severe GORD much more effectively than other PPIs, including Losec.

Purity Patent

AstraZeneca's Australian Patent No. 676337 (**Purity Patent**) claims optically pure salts of the (-)-enantiomer (later confirmed to be the (S)-enantiomer) of omeprazole.

The Court rejected Ranbaxy's claim that the Purity Patent lacked novelty over a prior-published German patent application, which referred to "optically pure" (-)-omeprazole and its salts with bases. The Court held that properly understood with the aid of expert evidence, the prior publication did not convey to the skilled addressee any meaningful level of optical purity, nor disclose the optically pure salts of (-)-omeprazole that are the subject of the Purity Patent.

The Court also rejected Ranbaxy's case on obviousness, which was put in at least four different ways and from three different starting points. The Court found that, in May 1993, it was not obvious to make optically pure salts of enantiomers of omeprazole. Omeprazole was known at that time to be a safe and effective drug whose enantiomers had equal pharmacological activity. The Court also found that the skilled team would not have reasonably expected to obtain optically pure salts of (-)-omeprazole, even if it were motivated to do so.

These objective findings on inventive step were supported by evidence of AstraZeneca's inventive

journey. The Court accepted evidence that AstraZeneca's inventor, who successfully separated the enantiomers of omeprazole, did so purely for academic interest and despite his colleagues' disbelief that he would succeed.

The findings on inventive step were in contrast to the facts of *Apotex*, in which the Court held it was obvious to make salts of the (*d*)-enantiomer of clopidogrel, in circumstances where the idea of separating the enantiomers was not claimed to be part of the invention and the techniques for doing so were standard.

MUPS Patent

AstraZeneca's Australian Patent No. 695966 (**MUPS Patent**) claims a particular "Multiple Unit Pellet System" or "MUPS" formulation. The formulation consists of multiple units, being enteric coated pellets containing omeprazole or one of its enantiomers, compressed into a tablet. Enteric coatings delay the release of an active substance until after it has passed through the acidic environment of the stomach. The Court found that the invention of the MUPS Patent was a particular combination of integers that enabled the multiple units to be compressed without compromising their gastric acid resistance.

The Court rejected Ranbaxy's contention that the brief reference to "*pellets formulated into tablets*" in a prior US patent was sufficient to anticipate the MUPS Patent, finding that this does not amount to "*clear and unmistakable directions*".

The Court held that, in July 1994, it was not obvious to conceive of a multiunit tablet formulation of omeprazole or one of its enantiomers, let alone to try the invention claimed in the MUPS Patent from among the many possible variables and avenues of experimentation available to the inventor. Even if these matters were obvious, the Court held that the skilled person would not have tried the invention of the MUPS Patent with a reasonable expectation of success.

774 Patent

AstraZeneca's Australian Patent No. 695774 (**774 Patent**) claims formulations of acid sensitive PPIs in which a separating layer forms *in situ*. This separating layer has the function of reducing the extent of any reaction between the PPI and the enteric coating polymer(s) as part of a stable pharmaceutical formulation.

The Court found in Ranbaxy's favour on two principal construction issues, which meant that its generic esomeprazole products were held not to infringe the 774 Patent. In the interests of the expeditious disposal of the proceeding, the Court did not consider and determine the many other detailed technical infringement and validity issues raised by the parties' extensive evidence on the 774 Patent.

Appeals

Ranbaxy has appealed from the Court's judgment concerning the Purity Patent and the MUPS Patent. AstraZeneca has cross-appealed from the Court's judgment concerning the 774 Patent. The appeals are set down for hearing in November 2013.

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