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Life Sciences Update

In this update

From the Editors

Welcome to the May 2015 edition of *Life Sciences Update.*

First in this edition, Stevie Gough and Andrew Rankine discuss a number of developments concerning the regulation of biosimilars in Australia. In particular, the TGA is in the process of reviewing its policy regarding the naming and regulatory evaluation of biosimilars. The Pharmaceutical Benefits Advisory Committee has also recently announced that it will consider marking biosimilars as equivalent and therefore substitutable with the reference medicine on a case by case basis. We will continue to monitor and report on developments in this area.

Cecillia Suatan provides an update on Yvonne D'Arcy's appeal from the Full Federal Court's decision in *D'Arcy v Myriad Genetics & Anor* [2014] FCAFC 115 to the High Court. After granting special leave earlier this year, the High Court will hear the appeal in June this year.

Andrew Sutherland reports on the latest instalment on the proceedings concerning the term extension for the LEXAPRO patent (*Alphapharm Pty Ltd v H Lundbeck A/S and Others* (2014) 108 IPR 459). In dismissing Alphapharm's appeal from the Full Federal Court, the High Court confirmed the power of the Commissioner of Patents to extend the time for making an application to extend the term of a patent, with the result that Lundbeck's application for an extension of time was properly granted.

Andrew Sutherland also reviews a report published by IP Australia's Patent Analytics Hub in relation to innovation in the medical devices field in Australia. The high proportion of patent applications concerning medical device technologies filed in Australia means that Australia is ranked higher than many other developed nations in this area. The report identifies three key areas of innovation in the medical device field disclosed in Australian patent applications, namely sleep apnoea, hearing implants and stents. Fortunately for Australia's economy, the report forecasts that medical device innovation in Australia is expected to increase in the coming years.

David Watson examines recent amendments to the *Patents Act 1990* (Cth) to implement the TRIPS Protocol - a procedure to compel a patentee of a pharmaceutical patent to grant a licence for the manufacture and export of a generic to address public health issues in eligible countries. A patentee is to be paid an adequate remuneration for such a compulsory licence, which takes into account the economic value to the eligible country.

Mary Papadopoulos and Christina Forsyth provide an overview of a guidance document issued by the International Medical Device Regulators Forum that aims to provide a framework for risk categorisation and corresponding considerations for software used for medical purposes that is developed independent of a particular hardware platform. The document is intended to be used by regulators when developing the regulatory framework for such software in order to provide consistency across jurisdictions.

Julie Chan reports on the Commissioner of Patent's decision in *Mars, Incorporated v Hill's Pet Nutrition, Inc.* [2014] APO 67, where a computer-implemented method of selecting or determining appropriate nutrition for animals based on the genetic make-up of the animal was found to be patentable.

Stuart D'Aloisio reports on the interlocutory decision in *GlaxoSmithKline Consumer Healthcare Investments (Ireland) (No.2) Limited v Apotex Pty Ltd* [2014] FCA 1398, in which Justice Beach dismissed an application by Apotex and Generic Partners to be released from their undertakings not to launch a generic version of GlaxoSmithKline's Panadol Osteo product. While the Court considered the relevance of the loss of "first generic mover advantage" to the legal test for granting interlocutory injunctions, the Court held it was not decisive in this case.

Christina Forsyth discusses two recent cases dealing with applications for preliminary discovery, each with different outcomes and each with consequential costs orders. In *Gordagen Pharmaceuticals Pty Ltd v Commonwealth Scientific and Industrial Research Organisation* [2014] FCA 1058, Justice Middleton dismissed Gordagen's application based on the finding that it did not make reasonable enquiries before applying to the court and ordered Gordaden to pay CSIRO's costs. In *GlaxoSmithKline Australia Pty Ltd v Pharmacor Pty Ltd* [2014] FCA 1202, GSK was successful in its application but after receiving discovery did not commence proceedings against Pharmacor and was therefore ordered to pay Pharmacor's costs of the application and giving discovery.

Other news in brief

- **Product safety and accurate marketing claims in the cosmetics industry an ACCC priority**

  In October 2014, the ACCC announced that as part of this year's surveillance activities it is focusing on reducing injuries caused by cosmetics. In particular, its focus is on cosmetic products which have no ingredient labelling and where ingredient labelling is in a language other than English. The ACCC also outlined activities aimed at ensuring safe products and accurate marketing claims in the cosmetics industry. See: https://www.accc.gov.au/media-release/accc-looks-to-reduce-injuries-caused-by-cosmetics.

- **TGA overview of complementary medicines regulation**

  On 25 March 2015, the TGA presented an overview of complementary medicines regulation. The detailed and comprehensive presentation covered topics such as the types of medicines that fall under the banner of complementary medicines, listing eligibility requirements and regulatory framework, post-listing compliance, guidelines for evidence to support indications and claims, and safety, efficacy and quality data for registered complementary medicines. A video of the presentation and the slides are available at https://www.tga.gov.au/tga-presentation-given-capsig-nsw-complementary-medicines-revival-25-march-2015.

Other news in brief continued

- **Reports on regulation of autologous stem cell therapies.**

  Earlier this year, the TGA sought comments from interested parties on the regulation of autologous stem cell therapies. The Discussion Papers are available here: https://www.tga.gov.au/consultation/consultation-regulation-autologous-stem-cell-therapies. The consultation period closed in March 2015 and the TGA has now published all submissions that were not marked confidential. A total of 80 submissions were received. The TGA is now considering the submissions and will provide an update when it is available. See: https://www.tga.gov.au/submissions-received-regulation-autologous-stem-cell-therapies.

- **Medicines Australia Code of Conduct - changes to public reporting of gifts and benefits**

  The Medicines Australia Code of Conduct sets standards for the marketing and promotion of prescription pharmaceutical products in Australia by member pharmaceutical companies. On 24 April 2015, the ACCC granted authorisation of Edition 18 of the Code provided that Medicines Australia strengthen the public reporting of gifts and benefits made to individual healthcare professionals (referred to as "transfers of value"), such as speaking fees, advisory board fees, or sponsorships to attend a conference. Medicines Australia is considering the conditions imposed by the ACCC and if accepted Edition 18 will come into effect on 16 May 2015. Until then, Edition 17 remains the effective Code. See: https://www.accc.gov.au/media-release/accc-authorises-medicines-australia-code-subject-to-strengthening-individual-reporting and https://medicinesaustralia.com.au/media-release/pharmaceutical-industry-moves-closer-to-improved-transparency-with-accc-code-authorisation/.

We hope you enjoy this edition of *Life Sciences Update*.

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Recent developments in the regulation of biosimilars in Australia

WHAT YOU NEED TO KNOW

- In January this year, the Therapeutic Goods Administration (TGA) announced a review of its policy regarding the naming of similar biological medicinal products ("biosimilars"), following recent international developments in this area.
- The TGA has now announced that its policy review has been expanded to encompass the evaluation of biosimilars generally, noting that "the understanding of biosimilar medicines is evolving".
- In a parallel development, the Pharmaceutical Benefits Advisory Committee (PBAC) announced at its March 2015 meeting that it will give case-by-case consideration to "a" flagging of biosimilars, suggesting that substitutability of biosimilars for their reference products may be permitted when supported by appropriate evidence.

Review of biosimilars naming

The TGA's guideline titled "Evaluation of Biosimilars" (version 1.0), published in July 2013, proposed a naming convention under which biosimilars would be assigned an Australian Biological Name ("ABN") comprising the ABN for the reference product, followed by a biosimilar identifier, made up of the prefix "sim" plus a three letter code to be issued by the WHO International Non-proprietary name ("INN") Committee (eg, "infliximab simfam").

However, on 21 January 2015, the TGA announced a review of biosimilars naming and stated that, in light of recent international developments, it would not be continuing with the naming convention outlined above.

Biosimilars nomenclature is currently being considered, at an international level, by the WHO's INN Expert Group, which aims to establish a uniform international approach. In July 2014, the Expert Group published a draft "Biological Qualifier" proposal.

Under the scheme proposed by the INN Expert Group, each biological active substance manufactured at a distinct site would be assigned a randomly selected, four letter alphabetic code, termed a "biological qualifier" or "BQ", which would form a suffix to the product's non-proprietary name. Under the proposed scheme, biological qualifiers would be assigned to all biological medicinal products (not only to biosimilars), including existing products.

The Biological Qualifier proposal was the subject of further debate at INN Expert Group's 60th consultation, held on 13-15 April 2015, and a final policy has not yet been issued.

In the interim, the TGA has indicated that biosimilars granted marketing approval in Australia will use the relevant ABN without a biosimilar identifier suffix (eg, a biosimilar to the reference product Neupogen® filgrastim would be named "[TRADE NAME]" filgrastim).

Review of biosimilars regulation

On 20 April 2015, the TGA announced that, in addition to undertaking a review of its policy regarding the naming convention for biosimilars, the TGA will conduct a review of the remainder of its guideline on the "Evaluation of Biosimilars".

In making this announcement, the TGA noted that the "understanding of biosimilars is evolving".

At the time of writing, the TGA was yet to indicate the expected timeline for its review or whether it proposed seeking submissions from relevant stakeholders. However, the TGA has indicated that those seeking additional information may email their query to streamlinedsubmission@tga.gov.au.

The TGA's announcement of a review of its biosimilars guidance follows calls by some industry bodies for a review of Australia's policy regarding the

substitutability of biosimilars and their reference products.

For example, the Generic Medicines Industry Association recently launched a "Guide to Biosimilars" (http://www.gmia.com.au/biosimilars/) noting that, while substitution of small molecule originator brands with generic alternatives is well established, "a clear process has yet to be developed to establish a suitable pathway for substitution of biosimilars".

Substitutability

In the Schedule of Pharmaceutical Benefits, the letter "a" located immediately before the brand names of small molecule pharmaceutical items (generally referred to as "a" flagging) indicates that the sponsors of those brands have submitted evidence demonstrating bioequivalence or therapeutic equivalence, leading to the expectation that those brands could be interchanged without differences in clinical effect.

In a "Discussion paper on Similar Biological Medicinal Products" published in July 2010, the Department of Health stated that "the current practice of 'a' flagging in the Schedule of Pharmaceutical Benefits, denoting that brand substitution may be undertaken by pharmacists at the point of dispensing, will not be applied to [biosimilars] at this time".

Consistently with that approach, in November 2010 the PBAC declined a request for "a" flagging made by the sponsor of the biosimilar filgrastim product Nivestim®, noting "the absence of a TGA issued statement, at the time of consideration, that would support 'a' flagging" (see http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd).

However, PBS-subsidies for biosimilars have now been given further consideration by the PBAC at its March 2015 meeting, and at a further meeting of the PBAC held on 17 April 2015. Notably, at its March meeting, the PBAC indicated that it would "consider the marking of equivalent (ie, "a" flagging) in the Schedule of Pharmaceutical Benefits of biosimilar medicines with their reference medicine on a case by case basis, taking into account the evidence presented in each submission to list a biosimilar medicine". At the time of writing, the outcome of the PBAC's April 17th meeting had not yet been published.

Given the PBAC's intention to consider "a" flagging for biosimilars on a case by case basis, and the role of the TGA in determining whether brand substitution is supported by available evidence, any statement by the TGA concerning "a" flagging arising from its current review of biosimilars evaluation will be eagerly awaited.

Biosimilars pipeline

At its March 2015 meeting, the PBAC recommended PBS listing for Eli Lilly's Basaglar®, an insulin glargine granted marketing approval on the basis of biosimilarity to Sanofi-Aventis's Lantus®. PBAC outcome documents record that the Minister for Health has requested the advice of the PBAC concerning "a" flagging of these products in the Schedule of Pharmaceutical Benefits. At the time of writing, the PBAC's advice had not yet been published.

The agenda for the PBAC's July 2015 meeting includes an application by Hospira for PBS listing of its biosimilar infliximab product, Inflectra®, covering the same indications as Janssen-Cilag's Remicade®. If that application is successful, this would represent the first PBS-listing for a biosimilar monoclonal antibody product in Australia.

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UPDATE: Myriad gene patent case goes to the High Court of Australia

D'Arcy v Myriad Genetics Inc & Anor (S251/2014)

WHAT YOU NEED TO KNOW

- In 2013, the Federal Court of Australia upheld the patent eligibility of isolated genes coding for a mutant breast cancer protein (BRCA1) in the recent case of *Cancer Voices Australia v Myriad Genetics Inc* [2013] FCA 65. In 2014, this decision was unanimously upheld on appeal by 5 judges of the Full Court (*D'Arcy v Myriad Genetics Inc & Anor* [2014] FCAFC 115).
- The approach of the Australian court is not in line with parallel litigation in the United States, in which it was held that DNA sequences were not patent-eligible subject matter.
- Earlier this year, the High Court of Australia granted special leave to appeal the decision in *D'Arcy v Myriad Genetics & Anor*.

On Friday, 13 February 2015, the High Court of Australia granted special leave to appeal the decision in *D'Arcy v Myriad Genetics & Anor* [2014] FCAFC 115, ensuring that the gene patent debate in Australia isn't over just yet.

A total of six Federal Court judges in Australia have so far upheld the patent eligibility of isolated genes coding for a mutant breast cancer protein (BRCA1) now the subject of the appeal to the High Court. The first instance decision by Justice Nicholas in February 2013 in *Cancer Voices Australia v Myriad Genetics Inc* [2013] FCA 65 that isolated DNA sequences were relevantly a "manner of manufacture" in satisfaction of section 18(1) of the *Patents Act 1990* (Cth) was unanimously upheld by a rare five-member bench of the Full Court (Allsop CJ, Howsett, Kenny, Bennett and Middleton JJ) in *D'Arcy v Myriad Genetics Inc & Anor* in September 2014.

The Australian decisions are, however, at odds with parallel litigation in the United States, where the US Supreme Court unanimously concluded that DNA sequences, even when isolated from the human body, were "products of nature" and not patent-eligible subject matter.

Given this inconsistent outcome, and the wide-spread interest in the gene patent debate in Australia, it is perhaps not surprising that the High Court granted special leave to hear the matter. The Institute of Patent and Trade Mark Attorneys of Australia has also filed a summons seeking leave to intervene as amicus curiae.

The case is now in the High Court listings for the period commencing 10 June 2015. We will cover the High Court's decision in an upcoming edition of *Life Sciences Update*.

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The LEXAPRO patent term extension saga comes to an end

Alphapharm Pty Ltd v H Lundbeck A/S and Others (2014) 108 IPR 459

WHAT YOU NEED TO KNOW

- As we reported in our April 2014 edition of *Life Sciences Update*, the Full Court of the Federal Court of Australia found no error in a decision of the AAT to grant an extension of time of around 10 years to Lundbeck to apply to extend the term of its LEXAPRO patent.
- By a 3:2 majority, the High Court of Australia dismissed an appeal against the Full Court's decision. The High Court confirmed that the power to extend the time for making an application to extend the term of a patent describing and claiming one or more pharmaceutical substances per se is available to the Commissioner of Patents.

The primary issue before the High Court was whether or not the Commissioner of Patents had the power to extend the time within which Lundbeck could apply for an extension of term.

Under sections 70(1), 71(2) and 223 of the *Patents Act 1990* (Cth) (**Act**) and regulation 22.11(4)(b) of the *Patents Regulations 1991* (Cth) (**Regulations**), two "timing requirements" applied to Lundbeck's extension of term application.

(a) First, Lundbeck had to file the extension of term application during the patent term.

(b) Secondly, Lundbeck had to file the application within 6 months of the first date that its product CIPRAMIL (a mixture of enantiomers including LEXAPRO) was included in the ARTG.

Section 223 of the Act provides that the Commissioner has the power to extend the time for doing "a relevant act" (other than a "prescribed action") that is not done by the required time due to, for example, an error or omission on the part of the applicant's attorney or agent. Reg 22.11(4)(b) provides that a prescribed action includes "filing, during the term of a standard patent" an extension of term application.

The generic parties argued that the effect of reg 22.11(4)(b) was that both timing requirements applying to Lundbeck's extension of term application were non-extendable. Conversely, Lundbeck argued that only the first timing requirement (requiring Lundbeck to file the extension of term application during the patent term) was non-extendable.

Justices Crennan, Bell and Gageler preferred Lundbeck's construction. Their Honours held that the generic parties' position "misapprehend[ed] the real purpose" of the relevant provision of section 223, which was to "confer a general remedial power to extend time" and "the derivative power of reg 22.11(4) [is] to exclude a limited number of times from that general power to extend time."

Their Honours referred to the origin of the more limited carve out propounded by Lundbeck and the consequences that would flow from the uncertainty which would arise if a patentee was entitled to extend the time for making an extension of term application following the expiry of the patent term. Their Honours held that reg 22.11(4)(b) addressed that uncertainty and there was no evidence to suggest the scope of the regulation also included the second timing requirement.

Their Honours held the second timing requirement had an "entirely different and unrelated purpose", which was linked to a patentee satisfying all pre-conditions relating to an extension of term application and the decision by a patentee about whether or not it would apply for an extension of term.

Justices Kiefel and Keane reached a different conclusion. Their Honours held that the "relevant act" for the purposes of section 223 of the Act was the making of an extension of term application and reg 22.11(4)(b) limited the Commissioner's power to grant an extension of time for the filing of an application of that kind. Their Honours noted that section 71(2) of the Act only refers to one action (ie, the making of an extension of term application, which has to occur at a

time that satisfies the two timing requirements) and it could not "reasonably be read as referring to two actions".

Their Honours held that under section 223(2) of the Act, the Commissioner has power to extend the time for "all acts to be done in connection with an extension of a patent term, other than the making of the application for extension itself".

The result of the majority's decision in this case is that Lundbeck's application for an extension of time to make an extension of term application was properly granted by the Commissioner.

Their Honours held that the real purpose of the relevant provision of section 223 was to "*confer a general remedial power to extend time*" and "*the derivative power of reg 22.11(4) [is] to exclude a limited number of times from that general power to extend time*".

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Australia – a world leader in medical devices

WHAT YOU NEED TO KNOW

- Australia is one of the few countries that has developed a technological specialisation within the medical devices field. Australia ranks:
    - 8th in the world (ahead of Canada, Sweden and the United Kingdom), in terms of the relative proportion of medical device patents to total PCT applications of national origin; and
    - 13th in the world (ahead of the Netherlands, Denmark and Spain), in terms of the total number of PCT patent applications filed concerning innovations within that field.
- Australia has three well-established areas of medical device specialisation: stents, respiratory and hearing.
- The levels of innovation in Australia are expected to continue to increase in the following emerging "hot spot" areas of activity: medical devices for surgical applications, implantable devices, electromedical and diagnostics, and vision.

IP Australia's Patent Analytics Hub recently released a report concerning innovation in Australia in the medical devices field. The report considered patent applications filed under the PCT system between 1 January 2001 and 31 May 2012 concerning inventions within the medical devices field.

The report defines "medical devices" consistently with the *Therapeutic Goods Act 1989* (Cth) and treats applications naming an Australian inventor as being of Australia origin, regardless of whether inventors of other nationalities are also named.

The report describes the following three areas of innovation within the medical devices field as being particularly well-established in Australia: innovations relating to treatments for sleep apnoea, hearing implants for conductive and sensorineural hearing loss and stents and methods for their delivery. The most prolific patent applicants during the study period were ResMed, Cochlear and Cook. The applications filed by those entities represented around 19% of the total number of applications filed in the medical devices field which named an Australian inventor.

The report suggests that while the respiratory and hearing areas will continue to grow, the level of innovation relating to stents experienced a noticeable decline from around 2010 to the end of the study period, which may indicate that the area is contracting.

The report highlights that the surgical, implantable devices, electromedical and diagnostics and visual fields are emerging "hot spot" areas of specialisation in Australia.

The reports used the number of forward citations for an application (ie, the number of times an application has been cited against other patent applications) to assess the economic value and significance or technological impact of the underlying invention. The application naming an Australian inventor with the greatest number of forward citations identified during the study, concerns the discovery by Australian scientists of an association between breast cancer and molecular alterations to the structure of hair.

By comparison to the rest of the world, applications naming an Australian inventor, had a greater than average numbers of forward citations five years post-publication, in the electromedical, implantable joints, respiratory and stents areas within the medical devices field.

A number of networks of collaborative activity were identified during the study in various areas within medical devices, which are illustrated in detail in the report. The report identifies that a significant level of collaboration occurred between Australian and foreign inventors and found that up to 24% of all applications naming an Australian inventor also named a foreign inventor. The report suggests that this was due in

part to the levels of collaboration between the most active Australian patent filers (ie, ResMed, Cochlear and Cook) and foreign entities. The greatest levels of collaboration involving Australian inventors occurred with inventors from the United States, United Kingdom, Germany, Switzerland and New Zealand.

The report points out that interestingly, of the 1,441 distinct applicants identified during the study, only 360 applicants filed more than one application. Approximately 40% of all applications identified during the study were filed by single filers.

In addition to the CSIRO, the most active publicly-funded patent filers identified during the study included the Bionics Institute, HEARing CRC, Lions Eye Institute, NICTA, NewSouth Innovations and VisionCRC. The most active patent filing universities identified during the study were the University of Queensland, the University of Sydney and the Queensland University of Technology.

The report concludes by noting that the established and emerging areas of specialisation in Australia based on the data considered from the study period may be valuable targets for private and public investment in the future.

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"The report concludes by noting that the established and emerging areas of specialisation in Australia based on the data considered from the study period may be valuable targets for private and public investment in the future."

Compulsory patent licences to address public health problems faced by least-developed countries

Intellectual Property Laws Amendment Act 2015 (Cth)

WHAT YOU NEED TO KNOW

- The *Intellectual Property Laws Amendment Act 2015* (Cth) was assented to on 25 February 2015. The Amendment Act implements Australia's obligations under the TRIPS Protocol.
- The Amendment Act enables Australian pharmaceutical manufacturers to apply to the Federal Court of Australia to obtain compulsory licences to manufacture and export generic versions of patented pharmaceutical products to particular countries for the purpose of addressing public health problems. Compulsory licences may only be granted in certain circumstances, and are subject to terms prescribed by the Amendment Act, in order to protect the rights of patentees.
- The Amendment Act makes a number of other changes to Australia's intellectual property system, the most notable of which is the creation of a single patent application and examination process for Australia and New Zealand.

Background

Australia is a member state of the World Trade Organisation (**WTO**) and a signatory to the Agreement on Trade-Related Aspects of Intellectual Property Rights (**TRIPS Agreement**).

Prior to 2003, Article 31 of the TRIPS Agreement restricted courts of WTO members from granting compulsory licences to third parties to manufacture and supply pharmaceuticals to respond to epidemics, to situations where the supply was predominately for the domestic market.

Article 31 created an obvious problem for WTO members that lack the capability to manufacture pharmaceuticals themselves. Recognising this issue, on 30 August 2003 members agreed to an interim waiver of the relevant paragraphs of Article 31 to enable the export of pharmaceuticals under compulsory licence (**Interim Waiver**).

On 8 December 2005, the TRIPS Protocol was drafted to give permanent effect to the Interim Waiver. The TRIPS Protocol enables least-developed WTO members and any other member that notifies the Council for TRIPS of its intention to use the system, to import pharmaceuticals under a compulsory licence for public health purposes, if certain conditions are satisfied.

Australia accepted the TRIPS Protocol on 12 September 2007. The TRIPS Protocol enters into force when two-thirds of WTO members accept it. The current deadline for acceptance is 31 December 2015.

Schedules 1 and 2 of the Amendment Act

Schedule 1 of the *Intellectual Property Laws Amendment Act 2015* (Cth) (**Amendment Act**) (which commences on 25 August 2015) amends the *Patents Act 1990* (Cth) (**Patents Act**) to implement the Interim Waiver.

Under the Patents Act as amended a person will be able to apply to the Federal Court for an order requiring the patentee of a patented pharmaceutical invention to grant the applicant a licence to exploit the invention to enable the manufacturing of a pharmaceutical product in Australia for export to an eligible importing country (new section 136D of the Patents Act).

The pharmaceutical product may be any "patented product, or product manufactured through a patented process, of the pharmaceutical sector". The eligible importing country, which will be prescribed by regulation as a least-developed country (as recognised by the United Nations) or country that has notified the Council for TRIPS of its intention to use the Interim

Waiver, may be a party to the proceedings between the applicant and patentee.

Under new section 136E, the Federal Court may make the order if it is satisfied of a number of matters, including:

(a) that the proposed use of the pharmaceutical product is to address a public health problem in the eligible importing country in circumstances of national emergency or extreme urgency, or by the public non-commercial use of the pharmaceutical product;

(b) that the applicant has attempted to obtain an authorisation from the patentee on reasonable terms and conditions, except in circumstances of national or extreme urgency; and

(c) that the applicant, eligible importing country and third party importer (if applicable) will take reasonable measures to prevent the pharmaceutical product from being used for a purpose other than addressing the public health problem in the eligible importing country.

If the order is granted, new section 136F prescribes licence terms, including quantity, labelling and notification requirements. The patentee is to be paid an amount as agreed or determined by the Federal Court to be adequate remuneration taking into account the economic value to the eligible importing country (new section 136J).

Schedule 2 of the Amendment Act commences when the TRIPS Protocol comes into force for Australia and makes minor amendments to refer to the TRIPS Agreement as amended by the TRIPS Protocol, rather than the Interim Waiver.

Other amendments made by the Act

The Amendment Act also:

(a) enables owners of plant breeder's rights to bring infringement proceedings in the Federal Circuit Court (Schedule 3);

(b) creates one regime for the regulation of patent attorneys in Australia and New Zealand (Schedule 4); and

(c) introduces a single patent application and examination process for Australia and New Zealand (Schedule 4). Under this process, an examiner in either country may consider applications for the grant of patents. The regime will take account of separate national laws and lead to separate patents being granted by the respective Patent Offices of Australia and New Zealand.

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Software as a Medical Device – A proposed regulatory framework

WHAT YOU NEED TO KNOW

- Existing regulation of medical devices may not cater adequately for software used for medical purposes that is developed independent of a particular hardware platform.
- There is a need to categorise software that functions as a medical device based on the level of risk of harm to patients or other users of the device.
- A possible international regulatory framework has been proposed to assist local regulators in incorporating a consistent approach to the regulation of software as a medical device.

As briefly discussed in our August 2014 edition of *Life Sciences Update*, the International Medical Device Regulators Forum (**IMDRF**), a voluntary, international group of medical device regulators is releasing a series of documents aimed at establishing a common framework for regulators to incorporate converged controls for the regulation of software as a medical device. The IMDRF working group has members from regulatory bodies in the USA, Australia, Japan, the EU, South America and Canada.

In May 2014, the Therapeutic Goods Administration (**TGA**) invited interested parties to comment on a proposed document setting out a possible framework for risk categorisation and corresponding considerations for software as a medical device. The IMDRF released a Final Document on this issue in September 2014.

Background

The use of software in healthcare is becoming more widespread and is now regarded essential to achieving not only administrative but clinical goals. The regulation of software that is used for making clinical decisions raises a number of interesting challenges.

Existing medical device regulations have tended to focus on software implemented in devices that rely on computer hardware to operate. Increasingly, however, software applications which are independent of hardware are becoming available, which can be implemented on a variety of different platforms, such as smartphones, tablets and the cloud, and transmitted over networks. The IMDRF draws the distinction between the former, as software in a medical device, and the latter, as software as a medical device (or SaMD).

The IMDRF defines SaMD as "*software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device*".

Unique challenges presented by SaMD

The IMDRF points to a number of new and unique challenges presented by the complexities of medical device software. For instance:

- SaMD may perform differently when implemented in different hardware platforms;
- Manufacturer updates often rely on the user of the medical device to install the software;
- The very nature of SaMD means that it can be duplicated and widely spread outside the control of the manufacturer; and
- Lifecycle aspects of SaMD involve rapid development cycles, frequent changes to software and updates delivered by mass distribution.

Objective of the IMDRF document

The global nature of healthcare providers and manufacturers calls for a harmonised and consistent approach to the regulation of medical device software.

The IMDRF has stated that the objective of the Final Document is not to replace or modify existing

regulatory classifications schemes. Rather, the document is to be used as a reference with the purpose of introducing "*a foundational approach, harmonised vocabulary and general and specific considerations for manufacturers, regulators, and users alike to address the unique challenges associated with the use of SaMD*". The IMDRF has sought to achieve this by setting out a common vocabulary, an approach for categorising software as a medical device and identifying considerations that arise from the technical or lifecycle aspects of SaMD.

Categorisation of SaMD

In Australia, the regulation of medical devices and medical device software depends on the classification of the device, which is risk-based. The classification of, and therefore the level of oversight the TGA will apply to, a medical device varies according to its intended use and the level of risk it presents to the patient or other user of the device.

In a similar vein, the Final Document sets out various criteria to categorise SaMD, using four categories based on the intended use of the software and levels of impact on the patient or public health. Category IV has the highest level of impact while Category I has the lowest.

The criteria for each category are as follows:

Category IV: SaMD that provides information to treat or diagnose a disease or conditions in a critical situation is considered to be very high impact. For example, software that implements diagnostic image analysis for making treatment decisions in patients with acute stroke where fast and accurate analysis is crucial to the choice of early treatment is considered Category IV.

Category III: SaMD that provides information to treat, diagnose or drive clinical management of a disease or conditions in a serious situation is considered to be high impact. An example of a Category III device is software that uses the microphone of a smart device to detect interrupted breathing during sleep and sounds a tone to wake the sleeper.

Category II: SaMD that provides information to treat, diagnose, drive clinical management of or inform clinical management for a disease or conditions in a non-serious situation is considered to be medium impact. For example, software that analyses heart rate data intended for a clinician to help diagnose arrhythmia is a Category II SaMD.

Category I: SaMD that provides information to drive clinical management of a disease or conditions in a non-serious situation or provides information to inform clinical management for a disease or conditions in a serious or non-serious situation is considered to be low impact. A Category I example is software that sends details of an exercise-based cardiac rehabilitation patient such as ECG rate, walking speed, heart rate, elapsed distance and location to a server for monitoring by a qualified professional.

Technical considerations for SaMD

A further consideration in the development of SaMD is the critical functionality that is necessary to achieve the SaMD's intended medical purpose. Because adverse health consequences for patients may flow from problems with the design or implementation of SaMD, it is important to ensure that risk and quality management is dealt with early in the development of SaMD. Accordingly, the IMDRF recommends that manufacturers implement a procedure for the design, development, deployment and documenting of the software to ensure it is robust and reliable as appropriate given the level of risk in light of the SaMD's intended medical purpose.

In addition, the IMDRF recommends that SaMD manufacturers conduct post market surveillance by monitoring user feedback to understand any errors or failures and that they implement automatic detection of errors in the software. The IMDRF also recommends that manufacturers ensure that any risks associated with different versions on the market are addressed and mitigated.

Manufacturers should also provide users with instructions on how to verify appropriate installation and updates to the SaMD and any changes to other software or hardware. The fact that SaMD may be used on a multitude of platforms means that manufacturers should proactively address any issues arising from such hardware by for example designing robust and resilient software.

What next?

The Final Document is not enforceable in any jurisdiction but may provide some guidance to regulators developing the regulatory framework for SaMD. The TGA is a founding member of the IMDRF and an active participant of the working group tasked with developing and harmonising approaches to the regulation of standalone medical device software.

According to the TGA website, the TGA considers the appropriateness of the IMDRF's publications in the context of the Australian regulatory framework, but it appears that the TGA has not as yet published anything in light of the Final Document.

"The Final Document is not enforceable in any jurisdiction but may provide some guidance to regulators developing the regulatory framework for software as a medical device."

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In-gene-uity: nutrition is in the genes

Mars, Inc. v Hill's Pet Nutrition, Inc. [2014] APO 67

WHAT YOU NEED TO KNOW

- A computer-implemented method of selecting or determining appropriate nutrition for animals based on the genetic make-up of the animal was found to be patentable.
- The Delegate concluded that the "selection of a nutritionally appropriate food for an animal" is an artificially created state of affairs for the purposes of manner of manufacture under section 18 of the *Patents Act 1990* (Cth).
- This decision pre-dates the Full Federal Court's decision in relation to computer-implemented methods in *Research Affiliates LLC v Commissioner of Patents* [2014] FCAFC 150.

Background

On 21 October 2014, the Australian Patent Office dismissed an opposition by Mars, Inc. (**Mars**) to Australian Patent Application Number 2005280008 (**Patent**) titled "Genome-based diet design" in the name of Hill's Pet Nutrition, Inc. (**Hill's**). Mars opposed the Patent under section 59 of the *Patents Act 1990* (Cth) (**Act**) on the grounds that the claims of the Patent:

- do not define a manner of manufacture;
- are not novel; and
- lack inventiveness.

The claimed invention

The invention is for a computer-implemented method for determining nutrition or food which is appropriate for an animal based on the animal's genome (DNA or genetic make-up). Historic attempts at determining nutrition or food appropriate for an animal have focused on phenotypic characteristics (observable physical or behavioural traits such as size, physical activity or hair type). This invention, however, is directed towards defining groups within an animal species based on genomic traits, such that there is genetic similarity within a group and genetic diversity between groups. Importantly, the Patent refers to the resultant groups as "genome-based breed clusters".

One embodiment of this invention involves grouping canines into four different clusters. Once the clusters are defined on the basis of genetic similarity, the phenotype of each cluster is analysed, and the nutritional needs appropriate to these phenotypes are selected (eg a certain percentage of protein or minerals which should be consumed each day).

Manner of manufacture

The requirement that an invention be a manner of manufacture is contained in section 18 of the Act. Australian courts have interpreted this requirement to mean that an invention is patentable if it creates an artificial state of affairs and has value in the field of economic endeavour (*National Research Development Corporation* [1959] HCA 67).

Mars submitted that the invention does not create an artificially created state of affairs, and that the invention claimed merely uses a computer to look up existing information about an animal and the nutrition best suited to meet the needs of that animal. Mars further argued that claim 1 of the patent is a computer-implemented, theoretical scheme or abstract plan for "selecting food for an animal based on the genetic characteristics of the animal".

Hill's counter-argued that the artificial state of affairs which was created was either:

1. the "nutritional formulation or food with an improved formula that is more appropriate for an animal"; or
2. "a change in the state of the computer".

In *Grant v Commissioner of Patents* [2006] FCAFC 120 a Full Court of the Federal Court of Australia noted that in order to satisfy the requirement of an artificially created state of affairs, a "physical effect in the sense of a concrete effect or phenomenon or manifestation or transformation is required". This reasoning was followed by the Federal Court in

RPL Central Pty Ltd v Commissioner of Patents [2013] FCA 871. Hill's second contention presumably also followed this reasoning, in that there is always a physical change or effect in a part of a computer used to implement a method. Interestingly, the Full Court in *Research Affiliates LLC v Commissioner of Patents* [2014] FCAFC 150, which handed down its decision nearly three weeks after this Patent Office decision, rejected that a change in the state of the computer confers sufficient patentability for the purposes of manner of manufacture.

As the invention does not actually result in the animal consuming the food which is selected, the Delegate reasoned that no physical effect in the animal is created. However, the Delegate found that the physical effect is the "selection of a nutritionally appropriate food for an animal". The Delegate further justified this conclusion, stating that the invention is analogous to diagnostic or screening methods for humans, which are more than theoretical schemes or abstract plans: "the effect achieved by such methods has traditionally been considered to lie in the useful arts and be proper subject matter for a patent". The close alignment between the method of the present invention and the traditionally patentable methods of diagnosis and screening was enough to convince the Delegate of patentability.

Novelty and inventive step

Mars's grounds of opposition in relation to novelty and inventive step were also unsuccessful.

The Delegate's decision has not been appealed to the Federal Court.

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No "first mover advantage" for generic Panadol Osteo

GlaxoSmithKline Consumer Healthcare Investments (Ireland) (No.2) Limited v Apotex Pty Ltd [2014] FCA 1398

WHAT YOU NEED TO KNOW

- Generic pharmaceutical companies often resist an interlocutory injunction by arguing they will lose the advantage of being the first mover in the market for generic versions of the pharmaceutical product.
- In this case, the Court considered the relevance of the so-called "first mover advantage" to the legal test for granting interlocutory injunctions.
- While the Court accepted that the loss of first mover advantage was a relevant matter to consider, it was not sufficient on the facts of this case to prevent an injunction from being granted.

On 16 December 2014, Justice Beach of the Federal Court dismissed an application by Apotex and Generic Partners (the **generic parties**) to be released from their undertakings to the Court not to launch a generic version of GlaxoSmithKline (**GSK**)'s Panadol Osteo product. The application was treated by the Court in substance as though GSK were applying for an interlocutory injunction against the generic parties. Justice Beach concluded that the restraint upon the generic parties should remain in place, notwithstanding the generic parties' contention that the balance of convenience favoured lifting the restraint because they would lose their "first mover advantage".

Factual background

GSK markets sustained release paracetamol tablets under the brand names Panadol Osteo and Panadol Back & Neck Long-Lasting. Panadol Osteo has been listed under the Pharmaceutical Benefits Scheme (**PBS**) since 2005.

The generic parties obtained regulatory approval of generic versions of GSK's products. In October 2014, GSK commenced patent infringement proceedings against them. The generic parties admitted infringement and cross-claimed for revocation of GSK's patent. In October and November 2014, the generic parties gave undertakings to the Court not to launch their generic products, pending the determination of the issues in the proceeding. In exchange GSK gave the "usual undertaking as to damages", to compensate the generic parties if GSK's patent is ultimately revoked.

Circumstances changed on 1 December 2014 when another generic company Pharmacor launched a sustained release paracetamol tablet. Pharmacor's product was listed on the PBS and "a flagged", to indicate that it is bioequivalent to GSK's Panadol Osteo. GSK did not commence proceedings to prevent the launch of Pharmacor's product, presumably because after obtaining preliminary discovery (as discussed in the article "*A high price to pay: Lessons from recent cases on preliminary discovery*" in this edition on page 20), GSK did not consider that it could sue Pharmacor.

Confronted with Pharmacor's entry into the market, the generic parties applied for PBS listing and sought to lift their undertakings previously given to the Court not to launch their generic products.

Applicable legal principles

Justice Beach held that Pharmacor's entry into the market was a sufficiently material change in circumstances, which made it appropriate for the Court to reconsider the restraints upon the generic parties.

In substance, the matter was treated as though GSK had made a fresh application for an interlocutory injunction against the generic parties. Justice Beach applied the well-established principles for determining such applications, which involve considering the relative strengths of the parties' substantive cases and the balance of convenience for granting the injunction. The "balance" involves weighing the harm suffered by the patentee if the injunction were refused, against

the harm suffered by the alleged infringer if the injunction were granted.

The strengths of the parties' cases

Justice Beach found that GSK's *prima facie* case on patent infringement was strong, given the admissions made by the generic parties. On the other hand, Justice Beach was not persuaded that the generic parties had a strong *prima facie* case on patent invalidity.

The generic parties alleged that the patent was invalid for lack of inventive step, lack of fair basis, insufficiency, failure to disclose the best method of performing the invention and lack of utility. Justice Beach found the generic parties' case on lack of inventive step to have the most merit, but entertained real doubts as to whether two prior publications relied upon by the generic parties would have been "ascertained, understood and regarded as relevant" for the purposes of the inventive step enquiry.

The balance of convenience

Turning to the balance of convenience, the generic parties argued that if they were not released from their undertakings they would lose the possibility of being the first mover in the market for generic Panadol Osteo products, either to Pharmacor or other generics.

Justice Beach held that, while the first mover advantage was a matter to be weighed in the balance of convenience, it was not decisive in this case. His Honour reasoned that on the evidence Pharmacor was a small player in the market. His Honour was persuaded by evidence that Apotex, as a much larger generic pharmaceutical company, would still be able to obtain a substantial foothold in the market notwithstanding Pharmacor's presence in the market.

Justice Beach was fortified in his conclusion by the generic parties' ability to claim compensation under GSK's usual undertaking as to damages, if the generic parties are ultimately successful in the proceeding. The generic parties argued that the difficulty of calculating such compensation was itself a factor to be weighed in the balance of convenience. Justice Beach was not persuaded that this tipped the balance in the generic parties' favour, because it would be just as difficult to calculate GSK's losses if the undertakings were lifted and GSK ultimately succeeded.

In summary, Justice Beach was persuaded that the balance of convenience favoured leaving the restraints on the generic parties in place. GSK's strong case on infringement and its substantial and longstanding business in the supply of the relevant products outweighed the generic parties' arguments, including the potential loss of first mover advantage.

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A high price to pay: Lessons from recent cases on preliminary discovery

Gordagen Pharmaceuticals Pty Ltd v Commonwealth Scientific and Industrial Research Organisation [2014] FCA 1058

GlaxoSmithKline Australia Pty Ltd v Pharmacor Pty Ltd [2014] FCA 1202

WHAT YOU NEED TO KNOW

- Applications seeking preliminary discovery before action are fact dependant but there are key elements that a party must establish before a court will order such discovery.
- A party seeking preliminary discovery must satisfy the court that it has made reasonable enquiries before making such an application. This includes taking advantage of an offer of information made by the prospective respondent in negotiations. Failure to take up such an offer will likely result in the refusal of the application, and an adverse costs order.
- The prospective applicant must also satisfy the court it reasonably believes it *may* have a potential claim against the prospective respondent but it does not have to show it *does* have such a claim.
- Caution must, however, be exercised in bringing such an application, because if discovery is given, and no claim is then brought, the usual order is that the applicant pay the costs of the other party of the preliminary discovery application, as well as the costs of giving discovery.

Applications for preliminary discovery

Rule 7.23 of the *Federal Court Rules 2011* (Cth) (**FCR**) sets out the requirements for making an application to obtain discovery from a prospective respondent.

In summary, under Rule 7.23(1) a prospective applicant may apply to the Court if:

(a) it reasonably believes that it may have the right to obtain relief in the Court from a prospective respondent whose description has been ascertained;

(b) after making reasonable inquiries, it does not have sufficient information to decide whether to start a proceeding in the Court to obtain that relief; and

(c) it reasonably believes that:

(i) the prospective respondent has or is likely to have or has had or is likely to have had in the prospective respondent's control documents directly relevant to the question whether the prospective applicant has a right to obtain the relief; and

(ii) inspection of the documents by the prospective applicant would assist in making the decision.

The Federal Court recently considered two applications made under Rule 7.23 seeking preliminary discovery of documents, each with different outcomes.

Gordagen Pharmaceuticals Pty Ltd v Commonwealth Scientific and Industrial Research Organisation [2014] FCA 1058

In *Gordagen Pharmaceuticals Pty Ltd v Commonwealth Scientific and Industrial Research Organisation*, the issue considered by Justice Middleton was whether Gordagen had made reasonable enquiries as required by Rule 7.23(1)(b) of the FCR before making its application for preliminary discovery.

Gordagen sought preliminary discovery from CSIRO because it was concerned that confidential information it disclosed to CSIRO had been misused and the documents sought would enable Gordagen to determine whether to pursue allegations of misuse of the confidential information against CSIRO.

In correspondence between Gordagen and CSIRO leading up to Gordagen's application, CSIRO made an offer to provide two patent specifications in confidence in an attempt to resolve Gordagen's concerns. Gordagen did not avail itself of this offer and the Court held that Gordagen did not make reasonable enquiries because Gordagen did not engage in the possibility of taking the offered information to see where it may have led. This finding of fact was enough to dispose of Gordagen's application.

The Court nevertheless indicated there was no reason as a matter of principle or based on its reasons, why Gordagen could not bring another application on proper material, presumably if CSIRO's offered information did not resolve Gordagen's concerns. However, having lost its application for preliminary discovery, Gordagen was ordered to pay the legal costs of CSIRO of and incidental to the application.

GlaxoSmithKline Australia Pty Ltd v Pharmacor Pty Ltd [2014] FCA 1202

By contrast, in *GlaxoSmithKline Australia Pty Ltd v Pharmacor Pty Ltd*, Justice Beach found that GSK had made the requisite reasonable enquiries by making various requests to Pharmacor for the production of certain materials relating to Pharmacor's application to the Therapeutic Goods Administration (**TGA**) to include its modified release oral paracetamol products (**Pharmacor Products**) on the Australian Register of Therapeutic Goods (**ARTG**) and its application to the Pharmaceutical Evaluation Branch (**PEB**) to list these products on the Pharmaceutical Benefits Scheme. GSK had also made a Freedom of Information application to the TGA and a request of the Acting Secretary for the Department of Health seeking reasons for the decision to register Pharmacor's products on the ARTG.

The main issue to be decided in this case was whether GSK satisfied Rule 7.32(1)(a), namely, whether it reasonably believed it may have the right to obtain relief from Pharmacor.

GSK's primary case was that it had a reasonable belief that Pharmacor engaged in misleading and deceptive conduct and made false and misleading representations in contravention of sections 18 and 29 of the Australian Consumer Law by representing to the TGA and the PEB that the Pharmacor Products were bioequivalent to GSK's Panadol Osteo and Panadol Back & Neck products (**GSK Products**). GSK alleged that this arose from the fact that Pharmacor had stated that its products were differently formulated and had a dissolution profile in 0.1M HCl which was outside the claims of GSK's patent.

In the alternative, GSK argued that if the Pharmacor Products were bioequivalent to the GSK Products, then it is likely that GSK's patent was or would be infringed by the marketing of the Pharmacor Products.

In response, Pharmacor argued that the TGA had assessed its application for registration and approved the Pharmacor Products as bioequivalent to the GSK Products and there was no actual or threatened infringement of GSK's patent.

Justice Beach pointed out that Rule 7.32(1)(a) requires a "*reasonable belief*" that a party "*may*" have the right to obtain relief in court from a prospective respondent. The party does not have to show that it *would* have such a right to relief.

Importantly, Justice Beach accepted there was no evidence of any misrepresentation to the TGA or the PEB, and that there was no evidence that the Pharmacor Products were not bioequivalent to the GSK Products. Indeed his Honour accepted that was no basis for saying that GSK might have a claim against Pharmacor in relation to any representation made to the TGA or PEB. Any representation made by the TGA to the PEB was accurate. His Honour also held that any representation made to the TGA or to the PEB was not made "in trade or commerce" in the sense required by the Australian Consumer Law, according to the principles laid down by the High Court in *Concrete Constructions (NSW) Pty Ltd v Nelson* (1990) 169 CLR 594.

Justice Beach ultimately decided, however, that even if it were assumed the products were bioequivalent and that there was no patent infringement, Pharmacor's marketing and supply of the Pharmacor Products on the basis that the products were bioequivalent as approved by the TGA may give rise to a "half-truth" scenario or misleading or deceptive conduct by omission on the basis that such conduct did not refer to "key differences" between the Pharmacor Products and GSK Products. This was because, in his Honour's view, GSK had a reasonable belief that the GSK Products had different therapeutic effects from the Pharmacor Products.

These are, with respect, contradictory findings. His Honour proceeded on the understanding based on GSK's submissions that two products could be bioequivalent but each deliver "different therapeutic or other benefits". The definition of bioequivalence between products, however, requires that their

concentration-time profiles be sufficiently similar as to be taken not to produce clinically relevant differences in either therapeutic or adverse effects. Indeed bioequivalence is the basis on which both originator variation applications and generic drug applications are approved in Australia and most other developed countries.

Ultimately, his Honour held that GSK had a reasonable belief as to this potential claim against Pharmacor and ordered preliminary discovery in relation to this claim, as well as the production of samples for testing.

Having given discovery and samples, however, GSK did not then commence any proceeding against Pharmacor, presumably because GSK was satisfied that the products were indeed bioequivalent, as the TGA had assessed them.

As a result, GSK was ordered to pay Pharmacor's legal costs of the preliminary discovery application, as well as Pharmacor's costs of giving discovery – ultimately an expensive way to rule out a suspicion.

Editors' note: Ashurst Australia acted for Pharmacor in GlaxoSmithKline Australia Pty Ltd v Pharmacor Pty Ltd.

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