

Life Sciences Update

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From the Editors

Welcome to the April 2014 edition of *Life Sciences Update*.

In this edition, Ross Zaurrini discusses the Australian Competition and Consumer Commission proceedings against Pfizer Australia, commenced in the Federal Court this year. The ACCC is arguing that Pfizer Australia's conduct leading up to the expiry of its atorvastatin patent for blockbuster drug Lipitor was anti-competitive. This is the first attempt by the ACCC to discipline the conduct of an originator pharmaceutical company attempting to protect market share following the loss of patent exclusivity.

Paula Iannitti, Marcus Fleming and Bruce Hardy report on the decision of the High Court of Australia in *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd* [2013] HCA 50, in which it was held that Apotex did not infringe a patent claiming a method of treating psoriasis by administering leflunomide. The High Court for the first time considered whether claims to methods of medical treatment are patentable, and examined infringement of method of treatment claims directed at new therapeutic uses of known substances.

Andrew Sutherland reports on the decision of the Full Court of the Federal Court in *Aspen Pharma Pty Ltd v H Lundbeck A/S* [2013] FCAFC 129. The Court found no error of law in the decision of the Administrative Appeals Tribunal to grant an extension of time of around 10 years to Lundbeck to file an application for

an extension of term for its patent covering escitalopram (Lexapro).

Stuart D'Aloisio discusses AstraZeneca's success in obtaining an order that Alphapharm give preliminary discovery of extracts from its regulatory dossier submitted when seeking registration of its generic esomeprazole magnesium products on the Australian Register of Therapeutic Goods (*AstraZeneca AB v Alphapharm Pty Ltd* [2014] FCA 9). This case reflects the increasing trend of originator pharmaceutical companies seeking to use the Federal Court's preliminary discovery procedure to obtain information about generic products to assess potential patent infringement.

Phoebe Vertigan reviews the decision in *CSL Limited v Novo Nordisk Pharmaceuticals Pty Ltd* [2013] FCA 1307, which concerned an application by CSL for release of confidential research and development documents discovered by Novo Nordisk during patent litigation proceedings for use in proceedings before the Technical Board of Appeal of the European Patent Office. The court found that there were no "special circumstances" to justify the release of the documents for use outside the proceeding. This case highlights the relative sanctity of the rule against the use of discovered documents for a purpose not connected to the proceedings in which they were discovered.

Katherine Payne provides an update on the revised and updated *Australian Regulatory Guidelines for Complementary Medicines*, which is now available from the TGA website. In December last year the TGA published its response to submissions received as part of the consultation process on the guidelines, which commenced in 2012. The revised guidelines do not introduce any new procedures or procedural changes, but aim to ensure consistency with current legislation and practices and to increase their usability.

David Watson reports on the decision of the Federal Court of Canada in *AbbVie Corporation, AbbVie Deutschland GmbH & Co. KG and AbbVie Biotechnology Ltd. v Janssen Inc.* 2014 FC 55. This case is the first biologics patent infringement case in Canada and concerns infringement of certain claims of AbbVie's patent directed to the use of human antibodies that bind interleukin-12 to treat psoriasis. In the decision handed down earlier this year, the court found that Janssen had infringed certain claims of AbbVie's patent. The court rejected Janssen's challenge to the validity of the claims on the grounds of breadth of claiming and obviousness. This case is also the first Canadian case in which the validity of "functional claims" for biologics (namely, claims directed at classes of biologics defined by functional characteristics) has been considered. The court found such claims permissible in certain circumstances.

Mark Straton reviews the decision of the Federal Court in *Apotex Pty Ltd v Servier Laboratories (Aust) Pty Ltd* [2013] FCA 1426, in which the court found that Servier's patent for perindopril arginine (marketed by Servier under the brand COVERSYL) failed to disclose the best method of performing the invention known to the patentee. The decision illustrates that the level of detail disclosed by a patentee in its specification is relevant not only to the requirement of sufficiency

under Australian patent law, but also to the requirement that the best method be disclosed. Interestingly, it appears that revocation of Servier's patent may not automatically follow from the finding of invalidity on this ground and Servier has since applied to amend its specification to correct the deficiency.

Amber Dalrymple reviews the decision of the Federal Court in *Eli Lilly and Company v Generic Health Pty Ltd* [2013] FCA 1254, in which the court granted an interlocutory injunction to Eli Lilly to prevent Generic Health Pty Ltd from launching a generic version of its raloxifene product, EVISTA in Australia pending final hearing. The decision highlights the tendency for interlocutory injunctions to be granted in Australia to prevent generic products from entering the market and listing on the PBS pending final hearing, particularly where there is evidence of multiple generic products registered and any delay can be attributed to the respondent.

Andrew Rankine and Stevie Gough report on the recent decision of the Federal Court in *Warner-Lambert Company LLC v Apotex Pty Ltd* [2014] FCA 241, in which the court refused to grant an interlocutory injunction to Warner Lambert to restrain Apotex from supplying its generic pregabalin product. This patent in issue in this case claimed methods of treatment and Apotex's product was registered for an indication that was not claimed in the patent. The court found Warner-Lambert failed to establish a prima facie case of infringement and the balance of convenience favoured Apotex. This is the first case to apply the High Court's decision regarding infringement of method of treatment claims in *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd* [2013] HCA 50 (also discussed in this issue). Warner-Lambert has since been granted leave to appeal to the Full Federal Court.

Other news in brief

Intellectual Property Laws Amendment Bill 2014 - implementing the TRIPS Protocol

The *Intellectual Property Laws Amendment Bill 2014* was introduced into the Australian House of Representatives on 19 March 2014. Amongst other things, the Bill amends the *Patents Act 1990* (Cth) to implement the TRIPS Protocol. The amendments include the introduction of compulsory licensing provisions for patented pharmaceutical inventions under which the court may order a compulsory licence to be granted for the manufacture and export of a pharmaceutical product to an eligible importing country if the proposed use of the pharmaceutical product is to address a public health issue in that country. In the Second Reading Speech for the Bill, the Hon Bob Baldwin MP stated that:

"the Bill will enable Australian pharmaceutical manufacturers to obtain a licence from the Federal Court to make generic versions of patented medicines and to export these medicines to countries with a demonstrated need. The scheme will ensure that patents can only be used under strict conditions and that patent owners are fairly compensated. The scheme is also designed to be as easy to use as possible, while ensuring appropriate safeguards are in place and consistency with Australia's broader international obligations."

Amendments to the *Therapeutic Goods Act 1989* (Cth)

On 28 February 2014, amendments to the *Therapeutic Goods Act 1989* (Cth) (**TG Act**) made by the *Therapeutic Goods Amendment (2013 Measures No. 1) Act 2014* (Cth) took effect. The amendments are aimed at improving the operation of the regulatory scheme for therapeutic goods and to increase consistency in the regulation of different types of therapeutic goods.

They include, amongst other things:

- a provision enabling the Minister to make a determination to exclude goods from regulation under the TG Act (new section 7AA);
- a provision enabling the Secretary to remove products from the ARTG if satisfied that they are not "therapeutic goods" (new section 9F);
- new offences and civil penalties where a person gives false or misleading information to the TGA when seeking approval to make changes to goods that are on the ARTG;
- new offences and civil penalties where a sponsor gives false or misleading information to the TGA in response to a notice from the TGA;
- new powers of the TGA to cancel the registration or listing of therapeutic goods if it appears that the presentation of listed therapeutic goods is unacceptable or the presentation of registered therapeutic goods is not acceptable. In this context, 'presentation' of therapeutic goods means the way in which the goods are presented for supply and includes matters relating to the name, labelling and packaging and any advertising or other informational material associated with the goods.

Discussion paper on an "IP Toolkit for Collaboration"

The Department of Industry and IP Australia have prepared a discussion paper on an "IP Toolkit for Collaboration" in response to recommendations for overcoming various barriers identified by the Chief Scientist and the Advisory Council on Intellectual Property to collaboration between Australia's publicly funded research organisations and the private sector. The purpose of the IP Toolkit is to develop practical resources to assist universities and publicly funded research organisations in collaborations with industry. The IP Toolkit can be accessed at <http://www.industry.gov.au/industry/IPtoolkit/Pages/default.aspx> and interested parties are invited to make written submissions and response to questions posed in the discussion paper by 23 May 2014.

Final report on the Pharmaceutical Patents Review now available

On 11 February 2014, the Minister for Industry, Ian Macfarlane announced that the government has no plans to release the final report on the Pharmaceutical Patents Review. This announcement was a response to a 'Question in Writing' from Western Australian MP Melissa Parke.

The Pharmaceutical Patents Review was commissioned by the Gillard Labor government in 2012. The Draft Report of the Pharmaceutical Patents Review was published in April 2013 and reported on by Phoebe Vertigan in the October 2013 edition of *Life Sciences Update*. The Draft Report included a number of proposed recommendations, including reducing extensions of term for pharmaceutical patents from the present 5 years, and using the savings to government to provide a direct subsidy to fund R&D. In March 2014, the final report was, however, made available online on IP Australia's website. The Minister for Industry, Ian Macfarlane has indicated he has no plans to respond to any of the recommendations of the report.

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

Editors



Ben Miller
Partner
Sydney
T: +61 2 9258 6431
E: ben.miller@ashurst.com



Paula Iannitti
Senior Associate
Sydney
T: +61 2 9258 5629
E: paula.iannitti@ashurst.com

Briefing note for the Australian Pharmaceutical Industry

ACCC v Pfizer Australia [2014]

WHAT YOU NEED TO KNOW

- On 13 January 2014, the Australian Competition and Consumer Commission (ACCC) brought proceedings against Pfizer Australia Pty Ltd (Pfizer) in the Federal Court of Australia in relation to Pfizer's conduct in the period leading up to, and shortly after, the expiry of its atorvastatin patent for "blockbuster" pharmaceutical Lipitor, which the ACCC says was to prevent or deter generic versions of atorvastatin from entering the market in Australia.
- The ACCC considers Pfizer's conduct was anti-competitive and in particular, that Pfizer misused its market power and sought to substantially lessen competition in breach of the *Competition and Consumer Act 2010* (Cth).
- This case represents the first attempt by the ACCC to discipline the conduct of originator pharmaceutical companies attempting to protect market share following the loss of patent exclusivity.

ACCC launches proceedings

On 13 January 2014, the Australian Competition and Consumer Commission (**ACCC**) brought proceedings against Pfizer Australia Pty Ltd (**Pfizer**) in the Federal Court.

The ACCC's case is that in the period leading up to, and shortly after, the expiry of its atorvastatin patent for blockbuster pharmaceutical Lipitor, Pfizer engaged in conduct to prevent or deter generic versions of atorvastatin from entering the market in Australia. The ACCC considers that Pfizer's conduct was anti-competitive and in particular, that Pfizer misused its market power and sought to substantially lessen competition in breach of the *Competition and Consumer Act 2010* (Cth) (**CCA**).

What did Pfizer do?

Pfizer's Australian patent for the atorvastatin molecule used in Lipitor was set to expire on 18 May 2012, and Pfizer (correctly) predicted that a number of generic versions of atorvastatin would enter the market shortly after that. In addition, as part of a 2008 patent settlement, Pfizer had agreed to let Ranbaxy launch a generic atorvastatin product from 18 February 2012 (ie 3 months before patent expiry and other generic products).

In anticipation of the upcoming loss of exclusivity Pfizer took the following steps.

1. **Direct sales.** In December 2010, Pfizer announced that it would cease supplying Lipitor and other prescription pharmaceuticals to community pharmacies through wholesalers, and would instead supply pharmacies directly through "Pfizer Direct".
2. **Accrual Fund Scheme.** In January 2011, Pfizer established an "Accrual Fund" for each community pharmacy to whom that it sold products. Pfizer began to credit each Accrual Fund with a notional sum equivalent to 5% of the pharmacy's purchases of Lipitor each month (the **Lipitor Rebate**). Similar rebates were also applied in relation to other Pfizer products (Aricept, Caduet, Celebrex, Effexor, Viagra, Xalacom and Xalatan).

Each pharmacy received a monthly statement showing the credits in its Accrual Fund, but Pfizer did not advise the pharmacies how to access or redeem those credits. As at 5 April 2012, Pfizer held Accrual Funds for more than 5,000 community pharmacies. The total value of the Lipitor Rebates was approximately \$35.6 million.
3. **Branded generic.** Pfizer developed its own generic version of atorvastatin (**Pfizer Atorvastatin**), and started supplying it in Australia in January 2012. Pfizer Atorvastatin was the same size, shape and colour as Lipitor, and had Pfizer's name on its packaging.

4. **Pfizer Atorvastatin Offer.** When Pfizer started supplying Pfizer Atorvastatin in January 2012, it made the following **Pfizer Atorvastatin Offer** to virtually all community pharmacies in Australia:

- a) Pfizer offered a range of "stepped" discounts ("Platinum", "Gold" or "Silver"), with the pharmacy receiving increasing proportions of Lipitor Rebates from the Accrual Fund and discounts on the purchase of both Lipitor and Pfizer Atorvastatin, depending on:
- the proportion of Lipitor sales it anticipated would be converted to sales of generic atorvastatin, once generic versions were available on the market (the Nominated Conversion Rate). The Nominated Conversion Rate determined the size of the discount that the pharmacy would receive on both Lipitor and Pfizer Atorvastatin purchases.
 - the pharmacy agreeing to purchase 75% of its anticipated generic atorvastatin requirements from Pfizer in the form of Pfizer Atorvastatin for 6, 9 or 12 months. The longer the minimum supply arrangement, the greater the amount of Lipitor Rebates that the pharmacy could access.
- b) Pfizer also made an "Alternate" offer, which provided for smaller discounts on Lipitor and Pfizer Atorvastatin purchases, but no access to the Lipitor Rebates.

In order to have the Lipitor Rebate amount released as a credit on its end of month statement for April 2012, a pharmacy was required to accept a Platinum, Gold or Silver Offer by 24 February 2012, and to accept the entire nominated volume of Pfizer Atorvastatin in a single shipment before 30 April 2012.

By 24 February 2012 (when Ranbaxy was able to enter the market), approximately 2346 pharmacies had accepted one of the three offers (with more than 2100 pharmacies accepting the Platinum Offer with the 12 month supply period). By 18 May 2012 (when all other generics were able to enter the market), more than 3300 pharmacies had accepted a Platinum, Gold or Silver Offer.

Why is the conduct allegedly anti-competitive?

The ACCC alleges that Pfizer's conduct was a misuse of market power (section 46, CCA) and amounted to exclusive dealing with a purpose of substantially lessening competition (section 47, CCA).

Each of those provisions carries a maximum penalty (per contravention) of the greater of \$10 million, or 3 times the financial gain from the conduct (if quantifiable), or 10% of group turnover. If the ACCC is successful in proving its allegations, it is likely to request the Court impose substantial financial penalties.

The table below is adapted from the ACCC's Statement of Claim.

Offer type	Proportion of the Accrual Fund released to the pharmacy	Required upfront purchase volume of Atorvastatin Pfizer	Nominated Conversion Rate	Atorvastatin Pfizer Discount	Lipitor Discount
Platinum	100%	75% of 12 months' total generic atorvastatin volume	<60%	60%	20%
			60-75%	70%	10%
			>75%	75%	5%
Gold	75%	75% of 9 months' total generic atorvastatin volume	<60%	60%	15%
			60-75%	65%	10%
			>75%	70%	5%
Silver	50%	75% of 6 months' total generic atorvastatin volume	<60%	55%	10%
			60-75%	60%	8%
			>75%	65%	5%
Alternate	0%	No minimum volume requirement	n/a	40%	5% until 1 June 2012, then 1.5%

Misuse of market power claim

The ACCC alleges that Pfizer had substantial **market power** in a market in Australia for the supply of atorvastatin. This is because until 18 February 2012, Pfizer was the only company that could legally supply atorvastatin in Australia and until 1 June 2012 only Pfizer Atorvastatin and Ranbaxy's Trovas could be supplied to the public through the PBS.

The ACCC says Pfizer **used** its market power to make the Pfizer Atorvastatin Offer (an offer it could not make without its privileged market position), and that it did so to **prevent or deter suppliers** of generic atorvastatin from competing in the atorvastatin market.

In particular, the ACCC alleges that the Pfizer Atorvastatin Offer incentivised pharmacies to purchase large stockpiles of Pfizer Atorvastatin before Lipitor lost exclusivity, thereby limiting the subsequent demand (and shelf space) for generic atorvastatin products and sought to secure Pfizer's market share by entrenching Pfizer Atorvastatin before Lipitor lost exclusivity.

The ACCC relies heavily on Pfizer's internal documents to make out its allegations as to what Pfizer intended would be the result of its conduct.

Exclusive dealing claim

The ACCC further alleges that the Pfizer Atorvastatin Offer amounted to anti-competitive exclusive dealing because Pfizer was supplying the Lipitor Rebates and the discounts on Lipitor and Pfizer Atorvastatin **on condition that** the pharmacies acquire not more than 25% of their anticipated generic atorvastatin requirements from other suppliers for the nominated period of time.

Contact



Ross Zaurrini
Partner
Sydney
T: +61 2 9258 6840
E: ross.zaurrini@ashurst.com

In this limb of its case, the ACCC says Pfizer, by providing discounts and rebates that were dependent on purchasing substantial volumes of generic atorvastatin from Pfizer, had the purpose of substantially lessening competition in the market for atorvastatin by seeking to prevent or deter other suppliers from engaging in competitive conduct in the market.

Next steps

This case is particularly interesting because:

- it represents the first attempt by the ACCC to discipline the conduct of originator pharmaceutical companies attempting to protect market share following the loss of patent exclusivity. Such attempts – which can take a number of forms, including the introduction of "follow-on" patented products and aggressive information campaigns against generic products – are often called "ever-greening", and have been the subject of recent investigation and successful prosecution by competition regulators in overseas jurisdictions;
- it is the ACCC's first allegation of misuse of market power in the health/pharmaceutical sector for many years, ie. since its prosecution of Baxter Healthcare for exclusive product bundling; and
- it comes at a time when the Government is preparing for a comprehensive "root and branch" review of competition law in Australia. That review is likely to include detailed consideration of the misuse of market power provisions, which are an area where the ACCC has traditionally had difficulty in proving contraventions.

Methods of treatment are patentable, but aren't infringed by accident

Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd & Ors [2013] HCA 50

WHAT YOU NEED TO KNOW

- The High Court of Australia has for the first time considered the issue of patentability of claims to methods of medical treatment. The High Court held by a majority of 4 (French CJ, Crennan, Kiefel and Gageler JJ) to 1 (Hayne J dissenting) that a method of medical treatment of the human body can be a "manner of manufacture", and, therefore, a patentable invention within s18(1)(a) of the *Patents Act 1990* (Cth).
- The High Court has also unanimously clarified that claims directed to treatment of a disease, being a hitherto unknown therapeutic use of a known pharmaceutical substance (having prior therapeutic uses) are limited in scope to the deliberate or conscious treatment of that disease. Notably, the High Court made it clear that a claim in this form is only infringed if the purpose of the administration is the use which is claimed. That is, there will be no incidental or accidental infringement by administration for the treatment of other diseases.
- The High Court's decision, therefore, provides some comfort to both innovator companies (by confirming that claims to methods of medical treatment can be patentable) and generic companies (by clarifying the scope of such claims and risks of infringement).

Background

Sanofi-Aventis Deutschland GmbH is the registered owner of Australian Patent No. 670491 entitled "Pharmaceutical for the treatment of skin disorders" (due to expire in March 2014) (the **Patent**). The Patent has one claim:

A method of preventing or treating a skin disorder, wherein the skin disorder is psoriasis, which comprises administering to a recipient an effective amount of a pharmaceutical composition containing ... [leflunomide].

Leflunomide has been registered on the Australian Register of Therapeutic Goods (**ARTG**) by Sanofi-Aventis Australia Pty Ltd under the names "Arava" and "Arablo" for the treatment of active rheumatoid arthritis (**RA**) and active psoriatic arthritis (**PsA**).

In July 2008, Apotex Pty Ltd (**Apotex**) successfully obtained registration of its generic version of leflunomide (**Apo-Leflunomide**) on the ARTG. Apotex's approved product information (**PI**) for Apo-Leflunomide stated that it is indicated for the treatment of active RA, active PsA and that it is not indicated for the treatment of psoriasis that is not associated with manifestations of arthritic disease.

Sanofi-Aventis Deutschland GmbH, Sanofi-Aventis Australia Pty Ltd and Aventisub II Incorporated (together, **Sanofi**) commenced proceedings against Apotex in October 2008, alleging, amongst other things, that Apotex's proposed supply of Apo-Leflunomide to treat PsA would infringe the Patent under s117 of the *Patents Act 1990* (Cth) (the **Act**).

Apotex denied infringement and filed a cross-claim seeking revocation of the Patent on a number of grounds, including that claim 1 is not a "manner of manufacture" within the meaning of section 6 of the Statute of Monopolies and, therefore, is not a patentable invention under s18(1)(a) of the Act.

At first instance, Jagot J held that the Patent was valid and found that Apotex's intended supply of its Apo-Leflunomide product for the treatment of PsA would infringe the Patent under sections 117(2)(b) and (c). In reaching that conclusion her Honour found that the claimed method is used where leflunomide is administered to a recipient so that the recipient's psoriasis **is in fact prevented or treated** (and that the purpose of the administration is not a requirement of the claim). Her Honour's conclusion as to infringement under sections 117(2)(b) and (c) was based on her finding that the evidence established that:

- Apotex knew that nearly every patient with PsA has or will develop psoriasis and if leflunomide is administered to a patient to treat PsA, leflunomide would be expected also to prevent or treat the patient's psoriasis (to some extent at least).
- Apotex's approved PI instructs a rheumatologist to use Apo-Leflunomide for the treatment of PsA and as almost all people with PsA have or will develop psoriasis the PI instructs rheumatologists to use leflunomide to treat psoriasis (irrespective of the exclusion of psoriasis in Apotex's PI).

The Full Federal Court dismissed Apotex's appeal. Although the majority (Bennett and Yates JJ) found that Jagot J erred in construing claim 1 and that the claim was directed to the object or purpose of preventing or treating psoriasis, their Honours went on to uphold Jagot J's finding on infringement under s117(2)(b) and (c).

Apotex's Appeal to the High Court

Apotex applied for, and was granted special leave to appeal to the High Court. The main issues before the High Court were:

- as regards validity, whether the subject matter of claim 1 is a "manner of manufacture" and hence a patentable invention within the meaning of s18(1)(a) of the Act (a narrower issue to be determined was whether claim 1 for a hitherto unknown therapeutic use of a pharmaceutical substance (having prior therapeutic uses) is a manner of manufacture);
- (if infringement remains to be determined) whether the proposed supply by Apotex of leflunomide to treat PsA would infringe the Patent under s117(1).

Patentability of methods of medical treatment for human beings

The High Court held by majority (Hayne J dissenting) that claims to methods of medical treatment of the human body can be a manner of manufacture and, therefore, a patentable invention within the meaning of s18(1)(a) of the Act. Crennan and Kiefel JJ (delivering a joint judgment) found that such claims are patentable assuming the other requirements of patentability are met and satisfies the *NRDC Case test*¹, namely the method is a contribution to a useful art having economic utility. In this regard their Honours noted a distinction between a method of medical treatment which involves a hitherto unknown

therapeutic use of a pharmaceutical (having prior therapeutic uses) and the activities or procedures of doctors and other medical staff when physically treating patients. Although not deciding the point, their Honours observed that the latter are, as a general matter, non-economic and not capable of industrial application.

Construction of claims to methods of treatment

Notably, the High Court (Crennan and Kiefel JJ with whom French CJ and Gageler J agreed) held that claim 1 of the Patent is a claim limited to the **specific purpose** of preventing and treating psoriasis. Their Honours found that because any novelty and inventive step is confined to a hitherto unknown therapeutic use of leflunomide (a substance having prior therapeutic uses), the monopoly granted in respect of claim 1 is limited to that hitherto unknown purpose. The High Court also clarified that a claim in this form is only infringed if the purpose of the administration is the use which is claimed. That is, there will be no "incidental" or "accidental" infringement because the specific purpose of administration is effectively an essential integer of the claim.

Indirect infringement under s 117 of the Act

Section 117 of the Act provides that, if use of a product by a person would infringe a patent, the supply of that product by a person is an infringement of the patent in certain circumstances. Sanofi was successful at first instance and on appeal to the Full Court in its claim of infringement under s117(2)(b) and (c) of the Act.

Section 117(2)(b) applies to any use of a product (which is not a staple commercial product) if the supplier had reason to believe that the person would put it to that use. Section 117(2)(c) applies in the case of use of the product in accordance with (amongst other things) any instructions for the use of the product, or any inducement to use the product, given to the person by the supplier.

The High Court (Crennan and Kiefel JJ with whom French CJ and Gageler J agreed) found that Apotex's proposed supply of Apo-Leflunomide did not infringe claim 1 of the Patent under s117(2)(b) or (c) of the Act. As regards s117(c), the High Court found that Apotex's approved PI for Apo-Leflunomide specifically excludes the method of claim 1 and does not instruct recipients to use the product for the treatment or prevention of psoriasis. The High Court gave

¹ (1959) 102 CLR 252 at 270.

consideration in this context to the regime under which therapeutic goods are registered by the Therapeutics Goods Administration (**TGA**) in the Australian Register of Therapeutic Goods (**ARTG**) and noted that the indication in the PI is an emphatic instruction to recipients to restrict use of Apo-Leflunomide to use it other than in accordance with claim 1.

As regards s117(b) the High Court found that it had not been shown, nor could it be inferred, that Apotex had reason to believe that Apo-Leflunomide would be used by recipients to deliberately treat psoriasis in accordance with the method of claim 1 contrary to the indications in Apotex's PI.

Contacts



Ben Miller
Partner
Sydney
T: +61 2 9258 6431
E: ben.miller@ashurst.com



Marcus Fleming
Senior Associate
Melbourne
T: +61 3 9679 3472
E: marcus.fleming@ashurst.com



Paula Iannitti
Senior Associate
Sydney
T: +61 2 9258 5629
E: paula.iannitti@ashurst.com



Bruce Hardy
Lawyer
Melbourne
T: +61 3 9679 3442
E: bruce.hardy@ashurst.com

Conclusion

The High Court's decision provides some comfort to both innovator and generic pharmaceutical companies. For the first time the High Court has confirmed that claims to methods of medical treatment of the human body can be patentable in Australia, a question which has raised doubts over a considerable period of time.

The High Court's decision on claim construction and infringement of method of treatment claims directed at new therapeutic uses of known substances will also provide clarity to generic companies in terms of the effect of carving out indications from product information documents and minimising the risks of indirect infringement under s117.

Lundbeck overcomes a delay of 10 years to extend the patent term for Lexapro

Aspen Pharma Pty Ltd v H Lundbeck A/S [2013] FCAFC 129

WHAT YOU NEED TO KNOW

- In *Aspen Pharma Pty Ltd v H Lundbeck A/S* [2013] FCAFC 129, the Full Court of the Federal Court of Australia found no error in a decision of the Administrative Appeal Tribunal which affirmed a decision of the Commissioner of Patents, to grant an extension of time of around 10 years to Lundbeck to file an application for an extension of term for its patent covering escitalopram, sold as LEXAPRO.

Background

An extension of term for a patent concerning a pharmaceutical substance is available under the *Patents Act 1990 (Cth) (Act)* if the patentee meets certain requirements, including applying for the extension within a particular time period. A product containing or consisting of the pharmaceutical substance must also be included in the Australian Register of Therapeutic Goods (**ARTG**). In some cases, a patentee is required to file the application within 6 months of the date that a product was first included in the ARTG.

Escitalopram is the (+) enantiomer of the compound, citalopram. Citalopram is a mixture of both (+) and (-) enantiomers. Citalopram was included in the ARTG on 9 December 1997 under the name CIPRAMIL (**CIPRAMIL date**). Escitalopram was included in the ARTG on 16 September 2003 under the name LEXAPRO (**LEXAPRO date**). On 22 December 2003, Lundbeck filed an application to extend the term of the Patent, based on the LEXAPRO date. The Commissioner of Patents granted the application.

On 6 July 2005, Alphapharm applied to revoke the Patent and argued that Lundbeck's extension of term application should have been based on the CIPRAMIL date, on the basis that CIPRAMIL contains escitalopram. Justice Lindgren held that Lundbeck's extension of term application was invalid because it had been filed out of time. On 12 June 2009, the Full Federal Court made final orders affirming Lindgren J's decision. On the same day, Lundbeck filed an application for an extension of time (of around 10 years) to file an extension of term application. The original term of the Patent expired on the following day, and a number of generic companies (the

Applicants) then launched generic products containing escitalopram.

The Applicants unsuccessfully opposed Lundbeck's extension of time application before both the Commissioner of Patents and the AAT, and subsequently appealed the AAT's decision. As with all cases of administrative review, the Court's role in this case was to consider if the AAT had made any errors of law in affirming the Commissioner's decision to grant an extension of time to Lundbeck, not to determine what the AAT should or should not have decided on the evidence before it.

Full Federal Court decision

A key issue that arose in the case related to a form of preliminary advice that Lundbeck had received on 14 July 2005 from its patent attorneys. That advice suggested that "one immediate action" open to Lundbeck at that time was to make an application for an extension of time to file an extension of term application. The Full Federal Court held that the AAT had made no error in finding that Lundbeck had not acted unreasonably in not filing the extension of time application until 12 June 2009. The AAT accepted that Lundbeck had preferred and had followed later legal advice it had received from another law firm, which had been to the effect that Lundbeck should proceed on the basis that the extension of term application had been correctly based on the LEXAPRO date.

The Full Court found that the AAT's decision was not unreasonable in the unusual circumstances of the case, which had included a number of years of complex patent litigation, during which it should have

been expected that Lundbeck would take all reasonable steps to legally open to it to protect its interests. The Full Court noted that the AAT had accepted the likelihood that commercial considerations were taken into account by Lundbeck in preferring the advice that it followed, and that the AAT had considered the evidence of the prejudice suffered by the Applicants as a result of Lundbeck's delay.

Application for special leave to appeal to the High Court

On 11 April 2014, the High Court of Australia granted Alphapharm special leave to appeal from the Full Court's decision. The grant of special leave was limited to the ground of whether the power to extend time for Lundbeck to make its application to extend the term of its patent was available to the Commissioner of Patents under s223 of the Act.

Contacts



Peter Chalk
Team Leader
Melbourne
T: +61 3 9679 3106
E: peter.chalk@ashurst.com



Andrew Sutherland
Lawyer
Melbourne
T: +61 3 9679 3018
E: andrew.sutherland@ashurst.com

Preliminary discovery of product information

AstraZeneca AB v Alphapharm Pty Ltd [2014] FCA 9

WHAT YOU NEED TO KNOW

- Originators are increasingly seeking to use the Federal Court's preliminary discovery procedure to obtain information about generic products and assess potential patent infringement.
- The requirements for preliminary discovery are strict and the Court retains a discretion to refuse preliminary discovery even when the requirements are met.
- In a recent case, AstraZeneca successfully obtained an order that Alphapharm give preliminary discovery of extracts from its regulatory dossier submitted when seeking registration of its generic products.

In *AstraZeneca AB v Alphapharm Pty Ltd* [2014] FCA 9, Justice Besanko ordered Alphapharm to give preliminary discovery of extracts from Alphapharm's application to register its generic esomeprazole magnesium products on the Australian Register of Therapeutic Goods (**ARTG**). The case reflects the increasing trend for originator pharmaceutical companies to rely on the Federal Court's preliminary discovery procedure to seek information about a generic product.

Aim: to assess the prospects of proving patent infringement

One of the challenges facing originators is how to obtain sufficient information to assess whether a generic product infringes their patents.

Pharmaceutical products in Australia are required to be registered on the ARTG. An originator will often only become aware of a new generic product when it is registered and published on the ARTG. At that time, the generic company will be free to import, market and sell the product, unless the originator obtains acceptable undertakings or commences patent infringement proceedings and obtains an interlocutory injunction.

Depending on the relevant patent, the information published on the ARTG, coupled with the fact that the generic product is bioequivalent to the originator's own product, may not be sufficient to prove infringement. The absence of publicly available information can make it difficult for the originator to build a prima facie case of infringement for the purpose of securing an interlocutory injunction.

Method: preliminary discovery

In a number of recent cases, originators have sought to use the Federal Court's preliminary discovery procedure to obtain additional information about a generic product. The purpose of the preliminary discovery procedure is to enable a party (a "prospective applicant") to obtain information so that it can make a properly informed decision about whether to commence proceedings.

In order to obtain an order for preliminary discovery, the prospective applicant must show that:

1. it reasonably believes that it may have the right to obtain relief from a party (the "prospective respondent");
2. it has made reasonable enquiries, but does not have sufficient information to decide whether to commence proceedings to obtain that relief; and
3. it reasonably believes that the prospective respondent has documents in its control that are directly relevant and would assist in making the decision.

The Court is strict about meeting each of these requirements due to the intrusive nature of an order for preliminary discovery. Even if the requirements for preliminary discovery are satisfied, the Court retains a discretion not to order preliminary discovery. If the information available to the prospective applicant is sufficient to enable it to make a properly informed decision about whether to commence proceedings, then preliminary discovery will not be available.

Results

In *AstraZeneca AB v Alphapharm Pty Ltd* [2014] FCA 9, AstraZeneca successfully obtained an order requiring Alphapharm to give preliminary discovery of extracts from Alphapharm's ARTG dossier. The extracts included copies of Common Technical Document Module 3: Quality and the Drug Master File for the active pharmaceutical ingredient in Alphapharm's products.

AstraZeneca based its preliminary discovery application on Australian Patent No. 722839, which relates to esomeprazole magnesium trihydrate and processes for preparing it. Alphapharm's ARTG registrations describe the active pharmaceutical ingredient in Alphapharm's products as "esomeprazole magnesium", without specifying whether or not it is the trihydrate.

Prior to the hearing of AstraZeneca's application, Alphapharm provided limited extracts from its ARTG dossier. These extracts were the subject of competing expert reports submitted by the parties. The dispute focused on whether the information provided by Alphapharm was sufficient to enable AstraZeneca to decide whether to commence proceedings.

Justice Besanko followed Full Court authority that preliminary discovery is not to be refused because a prospective applicant has a "bare pleadable case". The policy underlying the rule is to enable a prospective applicant to determine if the costs and risks of litigation are worthwhile. Justice Besanko accepted the opinion of AstraZeneca's expert that the information provided by Alphapharm was suggestive, but not determinative, of the question of infringement. His Honour considered that the documents sought would assist AstraZeneca to assess the costs and risks of litigation.

Contacts



Grant Fisher
Partner
Melbourne
T: +61 3 9679 3471
E: grant.fisher@ashurst.com



Stuart D'Aloisio
Senior Associate
Melbourne
T: +61 3 9679 3324
E: stuart.d'aloisio@ashurst.com

Collateral use of discovered documents – what constitutes special circumstances?

CSL Limited v Novo Nordisk Pharmaceuticals Pty Ltd [2013] FCA 1307

WHAT YOU NEED TO KNOW

- This proceeding concerned the release of confidential documents discovered during the course of patent litigation in 2008.
- CSL applied to have the discovered documents released for use before the Technical Board of Appeal of the European Patent Office.
- This case demonstrates the difficulties in establishing that special circumstances exist which justify the grant of leave to use discovered documents for a purpose not connected to the proceedings in which they were discovered.

Background

In 2008, CSL Limited (CSL) commenced proceedings against Novo Nordisk Pharmaceuticals Pty Ltd (**Novo Nordisk**) for infringement of Australian Patent No. 716747, which related to a method for the preparation of stabilised growth hormone formulation. The allegedly infringing conduct was Novo Nordisk's manufacture, supply and sale of liquid human growth hormone products called NORDITROPIN SIMPLEXX and NORDITROPIN NORDIFLEX. The dispute settled in 2012, with CSL surrendering its Australian Patent.

During the course of the proceedings, documents were discovered by Novo Nordisk subject to confidentiality undertakings, but because the matter settled they were not received into evidence.

Present application

As is commonly the case in patent litigation, CSL and Novo Nordisk were engaged in proceedings regarding equivalent patents and the Norditropin products in other jurisdictions. In the European Patent Office (**EPO**), this matter was the subject of a Technical Board of Appeal (**Technical Board**) hearing early in 2014.

Relevantly, the Technical Board does not allow discovery of documents or cross examination, which meant that Novo Nordisk's research and development documents regarding its Norditropin products, which had been discovered in the Australian proceeding,

could not be obtained by an order in the Technical Board proceeding.

In late 2013, CSL applied to the Federal Court for leave to permit the discovered documents to be used for a purpose other than a purpose connected to the now settled Australian proceeding, in an attempt to introduce them as evidence before the Technical Board.

Harman Undertaking

Where a party is compelled to disclose documents or information for discovery in proceedings in Australia, the party receiving the documents is subject to the Harman Undertaking, which requires them to not use the discovered documents for any purpose other than the purpose for which the documents were given, unless they are received in evidence subject to the court's orders. The Harman Undertaking works to safeguard a party from abuse of its discovered documents, and also covers the solicitors acting for a company which receives discovered documents during the course of proceedings.

Leave refused

Although the court has the power to grant leave to allow documents to be used outside a proceeding, the authorities indicate that this power "is not freely exercised, and will only be exercised where special circumstances appear".

Novo Nordisk opposed the application by CSL on the basis that there were no special circumstances that would justify the grant of leave, and that it would be prejudiced if CSL was permitted to introduce the documents to the Technical Board.

Both parties presented evidence from European patent attorneys regarding the practices and procedures of the Technical Board and summarising the steps in that proceeding to date. A key point of contention between the patent attorneys was whether or not the Technical Board would, irrespective of what occurred in the Australian court, exercise its discretion to admit the evidence at a late stage of proceedings. Besanko J considered the fact that the Opposition Division of the EPO had handed down its decision four years earlier would result in the applicant facing a "substantial hurdle" to persuade the Technical Board to admit the documents at such a late stage of the appeal.

In addition to the challenges that the applicant would face to get the evidence before the Technical Board, the fact that the EPO's procedures meant any

confidential documents would likely be accessible to the public weighed heavily in his Honour's rejection of the application. Although there was debate between the parties as to whether confidentiality still existed in the documents created between 1991 to 1998, his Honour considered that this was a substantial risk nonetheless.

His Honour also considered it highly relevant that the EPO does not allow for discovery. His Honour said:

It seems to me that I should assume that the EPO is satisfied that it can do justice ... without material of the kind presently in issue.

Overall the significance of the documents to the applicant's case before the Technical Board was outweighed by the stage of the proceedings, concerns about confidentiality and a reluctance to interfere with proceedings in a different legal system. The combination of these factors and challenges led Besanko J to conclude that there were no "special circumstances" to justify the release (collateral use) of the discovered documents.

Contacts



Kellech Smith
Partner
Melbourne
T: +61 3 9679 3864
E: kellech.smith@ashurst.com



Phoebe Vertigan
Lawyer
Melbourne
T: +61 3 9679 3370
E: phoebe.vertigan@ashurst.com

Revised and restructured guidelines for complementary medicines released

WHAT YOU NEED TO KNOW

- The revised *Australian Regulatory Guidelines for Complementary Medicines* are now available from the TGA website.
- The consolidated document incorporates comments received on Parts A, B, C and D through the Therapeutic Goods Administration's (TGA) consultation process. The TGA has also published its responses to the submissions received.
- The revised ARGCM do not introduce any new procedures or procedural changes, but rather have amended outdated information to reflect current regulatory practice.

On 16 December 2013, the TGA published its responses to submissions received as part of its consultation on the *Australian Regulatory Guidelines for Complementary Medicines (ARGCM)*.

The revised and updated ARGCM are now available on the TGA's website at <http://www.tga.gov.au/industry/cm-argcm.htm>.

Revised ARGCM

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

- *Part A: General guidance on complementary medicine regulation in Australia* 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: Listed complementary medicines* covers the regulatory requirements for listed complementary medicines.
- *Part C: New complementary medicine substance evaluation* covers the evaluation process for new complementary substances to be approved.
- *Part D: Registered complementary medicines* covers the regulatory requirements for registered complementary medicines.

The revised ARGCM are part of a broader package of reforms to the TGA and regulation of complementary

medicines in Australia following the Auditor-General's recommendations on the ANAO audit of TGA regulation of complementary medicines in August 2011. The purpose of the revised ARGCM is to make sure they are consistent with current legislation and practices and to increase their usability.

The consultation process began in October 2012, when the draft of Part A was released for comment. Drafts of Parts B, C and D were subsequently released and each section was subject to a four week consultation period. Submissions closed for Part D in July 2013.

Submissions

The TGA received submissions from organisations such as the Australian Self-Medication Industry, the Complimentary Healthcare Council of Australia, Consumers' Health Forum, the Pharmacy Guild of Australia and the Dieticians Association of Australia. All submissions not marked as confidential are now available at <http://www.tga.gov.au/newsroom/consult-cm-argcm-submissions.htm>. A total of 27 submissions were received.

Further revision

The TGA has reported that all submissions it received supported the revision and restructure of the ARGCM. Although the consolidated document is now available online, the TGA will continue to receive comments on any part of the document via its website. It has explained that further revision will occur as needed. Given that the revised ARGCM is a complete rewrite of

the original ARGCM, the TGA has advised that it will not produce a change log indicating what revisions have been made. Any further changes, however, will be indicated on the website.

Contacts



Grant Fisher
Partner
Melbourne
T: +61 3 9679 3471
E: grant.fisher@ashurst.com



Katherine Payne
Lawyer
Melbourne
T: +61 3 9679 3289
E: katherine.payne@ashurst.com

"Hair on bald men" insufficient for Janssen to invalidate Canadian patent

AbbVie Corporation, AbbVie Deutschland GmbH & Co. KG and AbbVie Biotechnology Ltd. v Janssen Inc. 2014 FC 55

WHAT YOU NEED TO KNOW

- On 17 January 2014, Justice Hughes of the Federal Court of Canada held that Janssen Inc. infringed certain claims of a patent owned by AbbVie Deutschland GmbH & Co. KG. The challenges by Janssen to the validity of the claims of the patent failed. The Canadian patent claims the use of human antibodies that bind interleukin-12, a cytokine that regulates immune reactions in the body, to treat psoriasis.
- This is the first biologics patent infringement case in Canada.
- The decision demonstrates that claiming a class of biologics defined by functional characteristics ("functional claiming") is permissible in Canada in certain circumstances. Janssen has filed a notice of appeal with the Federal Court of Appeal.

Background

The patent in issue was Canadian Letters Patent No. 2 365 281, which claims the use of human antibodies that bind interleukin-12 (**IL-12**) to treat psoriasis (the Patent). The binding neutralises some of the effects of IL-12, and thus is useful in the treatment of diseases.

Janssen sells injectable products containing ustekinumab for the treatment of psoriasis in Canada under the brand name STELARA. The AbbVie parties (together, **AbbVie**) do not market an anti-IL-12 antibody in Canada.

The Patent

The Patent contains 223 claims. The parties agreed to focus on two claims. Claim 143 relates to the use of a neutralising isolated human antibody that binds and dissociates to/from IL-12 with a particular score for affinity (as determined by an assay) and which inhibits IL-12 function with a particular score for potency (as determined by another assay), to treat psoriasis. Claim 222 is in similar terms but requires the antibody to bind to a human interleukin comprising a p40 subunit.

The Patent specification describes antibody J695 in detail, including its production using phage display. The specification also refers to the transgenic mouse method of antibody production. Janssen developed STELARA using transgenic mice. Both antibodies bind to human IL-12, but at different places.

Infringement

Tests conducted by AbbVie found that STELARA fell within the scores for affinity and potency as set out in claims 143 and 222. Janssen did not conduct tests on STELARA, but chose to criticise AbbVie's tests and argued it was not given notice and an opportunity to attend AbbVie's tests. Justice Hughes concluded that the evidence of the tests was admissible, given that Janssen had provided no test results and had an opportunity to cross-examine the academic that conducted the testing.

Justice Hughes held that Janssen infringed claims 143 and 222 despite the fact that STELARA is made using transgenic mice (claims 143 and 222 are not restricted to antibodies created by phage display, as is the case with some other claims).

Validity

Breadth of Claiming

Janssen argued that claims 143 and 222 were overly broad. The issue was whether, having claimed the invention without reference to the specific antibody described in the Patent, or even the specific method by which it was described to be made in the Patent (ie phage display), the claims can validly cover whatever antibody falls within the affinity and potency constraints.¹

¹ [141]-[144], [148]; *Patent Act*, RSC 1985, c. P-4, s 27(3).

Janssen cited *Free World Trust v Electro Santé Inc*, [2000] 2 SCR 1024 (Supreme Court of Canada):

The claims cannot be stretched to allow the patentee to monopolize anything that achieves the desirable result. It is not legitimate, for example, to obtain a patent for a particular method that grows hair on bald men and thereafter claim anything that grows hair on bald men infringes.

Justice Hughes applied *Monsanto Co v Canada (Commissioner of Patents)*, [1979] 2 SCR 1108 (**Monsanto**) and held that the claims in issue were not overly broad. In *Monsanto*, it was held that if the person skilled in the art would predict that all the compounds in the claimed class would have the same utility as the few example compounds detailed in the specification, it is valid to claim the class of compounds.

Justice Hughes stated that claims 143 and 222 are readily understandable by a person skilled in the art and that there was no evidence to indicate that antibodies falling within the parameters of the claims will not bind IL-12 and treat psoriasis.

Janssen argued, as a policy issue, that "functional claiming" should not be allowed, ie if the patentee discovers one antibody that binds to IL-12 to treat psoriasis, it cannot claim any antibody that binds to IL-12 and treats psoriasis. Justice Hughes noted:

AbbVie was the first to confirm that, if you want to treat psoriasis, you must get an antibody that binds to IL-12 and it must have a certain level of [affinity] and potency. That is very different from saying – we have a particular antibody (J695), and we put it into people, and it treats their psoriasis; therefore we want a patent claiming any antibody that does that.

This is the first Canadian case that deals with "functional claiming" for biologics. It demonstrates that claiming a class of biologics defined by functional characteristics is permissible where the claims do not cover antibodies that do not function as claimed and only cover antibodies that can be soundly predicted to work based on the work of the inventors.

Obviousness

Justice Hughes rejected a challenge to the Patent's validity on obviousness grounds. His Honour held that the difference between the prior art and the invention as claimed is "the difference ... between hope and certainty." Although there was a hope among persons skilled in the art that antigen binding to one or more cytokines might treat human diseases, the invention was that psoriasis would be treated when a particular cytokine was bound by an antigen having certain properties. This difference was not "more or less self-evident", as required for lack of inventive step under Canadian law.

Contacts



Ben Miller
Partner
Sydney
T: +61 2 9258 6431
E: ben.miller@ashurst.com



David Watson
Graduate
Sydney
T: +61 2 9258 6560
E: david.watson@ashurst.com

Running a risk: Servier's perindopril arginine patent found to lack best method

Apotex Pty Ltd v Servier Laboratories (Aust) Pty Ltd [2013] FCA 1426

WHAT YOU NEED TO KNOW

- The Federal Court of Australia has found that the patent for perindopril arginine, marketed by Servier under the brand name COVERSYL, failed to disclose the best method of performing the invention known to the patentee.
- Justice Rares found that two specific methods known to Servier were better than the "generalised and unspecific" method disclosed in the patent because they eliminated the risk that the skilled addressee would be put to expensive trial and error in ascertaining the details of the method for themselves.
- Although found invalid on this ground, however, it appears that revocation of the patent may not necessarily follow and Servier has applied to amend the patent to rectify the defect.

The Proceedings

Apotex Pty Ltd brought proceedings to challenge the validity of Australian Patent 2003200700 (the **Patent**), held by Les Laboratoires Servier and exclusively licensed to Servier Laboratories (Aust) Pty Ltd. The Patent claims the arginine salt of the drug perindopril, its hydrates, its pharmaceutical compositions and a method of treatment using those compositions. Perindopril is used in the treatment of hypertension and heart failure.

Servier possessed an earlier patent claiming the erbumine salt of perindopril and had marketed tablets containing perindopril erbumine under the brand name COVERSYL between 1992 and 2006. Following the expiry of the earlier patent, Servier marketed tablets containing perindopril arginine under the same brand name.

Apotex asserted invalidity of the Patent on the grounds of lack of novelty, lack of inventive step, lack of fair basis, lack of disclosure of best method and for false suggestion.

Justice Rares found Apotex had established that the Patent failed to disclose the best method of performing the invention known to Servier. Apotex was unsuccessful on the other four asserted grounds of invalidity.

Lack of best method

Section 40(2)(a) of the *Patents Act 1990* (Cth), as it applied to the Patent, required that a complete patent specification "describe the invention fully, including the best method known to the applicant of performing the invention". The requirement for disclosure of best method is a distinct requirement to that of sufficiency, which requires that the specification provide sufficient description to enable the skilled addressee to perform the invention without new inventiveness or prolonged study.

The evidence established that Servier had made perindopril arginine twice, first in 1986 and again in 1991, with the methods used on each occasion differing in their choice of various parameters, including solvent, heating rate, mixing rate and crystallisation vessel. Both of these methods were examples of "classical" methods of salification.

The Patent specification, however, did not disclose the detailed parameters of the salification method used by Servier, stating only that perindopril arginine had been prepared "according to a classical method of salification of organic chemistry".

In arguing for the validity of its patent, Servier contended that Apotex, to establish lack of best method, was required to prove that a skilled addressee following the general description of "a classical method of salification" would have achieved a

worse result than that achieved using Servier's 1986 or 1991 method, and that Apotex had failed to prove this.

Justice Rares rejected this argument. His Honour found that the specific methods known to Servier were better than the "generalised and unspecific" method disclosed in the Patent because they eliminated the risk that a worse result would be obtained and therefore saved the skilled addressee from potentially expensive trial and error. Referring to the inventor employed by Servier, his Honour said that "as a person skilled in the art, he knew that there were many alternatives available from which to choose and that some were likely not to be as good as others". In his Honour's opinion, the general method disclosed by Servier was "wholly inadequate to describe the best method, or any substantive content of any particular classical method that the patentee knew of performing the invention."

This decision illustrates that the level of detail disclosed by a patentee in its specification is relevant not only to considerations of sufficiency, but also to the separate requirement under Australian law to disclose the best method known to the patentee of

performing the invention. In the present case, Apotex did not assert that Servier had disclosed insufficient detail to enable the skilled addressee to perform its invention, but rather that the generality of description constituted a failure to properly disclose the best method known to Servier of performing that invention. In His Honour's words, the requirement to disclose best method "is a fundamental aspect governing the grant of a patent" which "supplements the co-ordinate requirement in s 40(2)(a) that the complete specification also describe the invention fully".

Final orders

Justice Rares stated at the conclusion of his judgment that his finding as to lack of best method "raises the question of what relief should be granted under s 138(3) of the Act." This comment foreshadowed that orders for revocation of the Patent did not automatically follow. Servier has since applied to amend its specification to overcome the established ground of invalidity, and a timetable has been set for the progress of that amendment application.

Contacts



Ben Miller
Partner
Sydney
T: +61 2 9258 6431
E: ben.miller@ashurst.com



Mark Straton
Lawyer
Sydney
T: +61 2 9258 6525
E: mark.straton@ashurst.com

Generic EVISTA evicted

Eli Lilly and Company v Generic Health Pty Ltd [2013] FCA 1254

WHAT YOU NEED TO KNOW

- Eli Lilly has obtained an interlocutory injunction to prevent Generic Health from launching a generic version of raloxifene product 'EVISTA' in Australia pending the final hearing.
- In assessing the balance of convenience, Nicholas J gave primary weight to the detriment Eli Lilly would suffer, including as a result of price reduction on its product if the Generic Health products were listed on the Pharmaceutical Benefits Scheme, the difficulty presented by a number of other generic products then entering the market, the likelihood that the price would then never be reinstated, and the availability of an early final hearing.

Background

Eli Lilly and Company (**Eli Lilly**) is the owner of Australian Patent No. 723797 which is titled "Benzothiofenenes, formulations containing same, and methods" (the **Patent**). The invention the subject of the Patent relates to the use of raloxifene "in particulate form" in the preparation of formulations and compositions used in the treatment of various conditions, including osteoporosis. The commercial embodiment of the invention the subject of the Patent is marketed in Australia under the brand name 'EVISTA'. EVISTA is registered on the Australian Register of Therapeutic Goods (the **ARTG**) and has been listed on the PBS since 1 November 1999.

On or about 7 June 2013, Generic Health Pty Limited (**Generic Health**) obtained registration of three raloxifene hydrochloride products on the ARTG. Eli Lilly sought to restrain Generic Health from, amongst other things, manufacturing and selling products containing raloxifene hydrochloride in Australia.

Had interlocutory relief not been granted by the Court, the Generic Health products would have been listed on the PBS from 1 December 2013 and would have been available for sale in Australia thereafter, in competition with EVISTA.

The decision

On 26 November 2013, the Federal Court of Australia granted an interlocutory injunction restraining Generic Health from importing, manufacturing, supplying, offering to supply or agreeing to supply any raloxifene products. Justice Nicholas also ordered that Generic Health take all necessary steps to withdraw all applications for inclusion of any relevant raloxifene products on the PBS.

Although not satisfied on the basis of the expert evidence that Eli Lilly had a strong case, Nicholas J did not regard it as weak. Ultimately Nicholas J was satisfied that Eli Lilly had demonstrated a "prima facie" case of infringement, and turned to consider the balance of convenience.

Generic Health's expert evidence focused on the difficulties involved in quantifying the harm that it would suffer if it were deprived the "first mover advantage" in the market for generic raloxifene products (assuming that it would be the first supplier or one of the first suppliers of generic raloxifene in Australia). However, Justice Nicholas found that Generic Health was unlikely to obtain any significant first mover advantage.

One of Generic Health's major competitors, Apotex, was already the subject of an interlocutory injunction in favour of Eli Lilly, restraining it from supplying raloxifene products in Australia. In Nicholas J's view it was unlikely that Eli Lilly would be able to maintain its interlocutory injunction against Apotex in circumstances where there would be a material change in circumstances as a result of Generic Health entering the market. Eli Lilly had also made an application to list its own authorised generic on the PBS, which would become listed in the event Generic Health's product was listed.

In considering the balance of convenience, the Court considered how the market would likely be affected if the interlocutory relief was refused and the Generic Health products were included on the PBS.

First, there would be an immediate 16% price reduction to the Price to Pharmacists (**PTP**) for EVISTA pursuant to the *National Health Act 1953* (Cth). Secondly, the listing of the first generic product would

likely cause other generic products to be listed on the PBS, including Eli Lilly's authorised generic product, at a rapid pace. Thirdly, Nicholas J accepted Eli Lilly's evidence that EVISTA would suffer a substantial loss (up to 40%-60%) of its market share within 3 to 4 months of the price reduction taking effect. Once a number of generic products entered the market, calculation of that loss and damage and assessment of its causes would be difficult.

Perhaps most significantly, Nicholas J noted that if Eli Lilly successfully restrained Generic Health at a final hearing, reinstatement of the PTP for EVISTA would be in the discretion of the Minister for Health, and that it was unlikely in the circumstances that the PTP for EVISTA would ever recover if an interlocutory injunction was not granted and Eli Lilly successfully restrained Generic Health at a final hearing.

His Honour also inferred that Generic Health must have been aware of the parallel proceeding

commenced by Apotex more than 18 months ago, which raised substantially the same issues, and noted the delay by Generic Health in either commencing revocation proceedings or seeking a declaration of non-infringement, against the willingness of Eli Lilly to be ready for an early final hearing.

Conclusion/implications

Although questions of the balance of convenience are always weighed in the circumstances of the particular case, this decision highlights the tendency for interlocutory injunctions to be granted in Australia to prevent generic products from entering the market and listing on the PBS pending final hearing, particularly in circumstances in which there is evidence of multiple generic products registered, and any delay can be attributed to the respondent. The willingness of the applicant to proceed to an early final hearing, thus reducing the duration of an interlocutory injunction, may also tip the balance.

Contacts



Ben Miller
Partner
Sydney
T: +61 2 9258 6431
E: ben.miller@ashurst.com



Amber Dalrymple
Lawyer
Sydney
T: +61 2 9258 5928
E: amber.dalrymple@ashurst.com

No reason to believe: the Federal Court refuses interlocutory injunctive relief

Warner-Lambert Company LLC v Apotex Pty Ltd [2014] FCA 241

WHAT YOU NEED TO KNOW

- Warner-Lambert Company LLC applied to the Federal Court of Australia for an interlocutory injunction restraining supply of Apotex Pty Ltd's generic pregabalin product. Although registered for the treatment of seizures only, Warner argued Apotex had reason to believe that its product would be prescribed to treat pain, infringing a method of treatment patent owned by Warner.
- On 14 March 2014, Justice Griffiths dismissed Warner's application, finding that it had failed to establish a prima facie case of infringement under section 117 of the *Patents Act 1990* (Cth) and that the balance of convenience favoured Apotex.
- This case is the first to apply the High Court of Australia's decision in *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd* [2013] HCA 50, in which the High Court held that the registered indications for a generic pharmaceutical product operated as an "emphatic instruction" concerning the permissible use of that product.

Background

Warner-Lambert Company LLC (**Warner**) is a member of the Pfizer group of companies. Pfizer group companies hold two patents relating to the drug pregabalin, the first concerning the treatment of pain (**Pain Patent**) and the second concerning, relevantly, use of pregabalin to treat seizures (**Seizure Patent**).

In 2005, Warner obtained registration of pregabalin on the Australian Register of Therapeutic Goods (**ARTG**) under the name LYRICA for the treatment of neuropathic pain and seizures. In March 2013, LYRICA was listed on the Pharmaceutical Benefits Scheme (**PBS**), for the treatment of neuropathic pain only.

In September 2012, Apotex obtained ARTG registration of a generic pregabalin product. Originally, the registered indications for Apotex's product included both the treatment of neuropathic pain and seizures.

Apotex commenced Court proceedings in mid-2013 seeking revocation of the Pain Patent and of the Seizure Patent. However, the part of that proceeding relating to the Seizure Patent was discontinued, by consent, in October 2013. In that month, the registered indications for Apotex's pregabalin product

were narrowed: the neuropathic pain indication was deleted, leaving only the seizure indication. Apotex's product is not listed on the PBS.

In February 2014, Apotex gave notice that it intended to commence marketing its pregabalin product for the treatment of seizures. Relying on the Pain Patent, Warner applied to the Court for an interlocutory injunction, which would restrain supply of Apotex's product until final hearing. Apotex consented to orders preventing marketing or supply of its product for the treatment of neuropathic pain, but argued that supply of its product for the treatment of seizures would not infringe the Pain Patent. For the purposes of the interlocutory proceedings, Apotex did not challenge the validity of the Pain Patent.

Prima facie case

Warner argued that, although Apotex's product was registered for the treatment of seizures only, Apotex nevertheless had reason to believe that its product would be used for the treatment of neuropathic pain. If Apotex were found to have reason to believe that its product would be used in that manner, then supply of the product in Australia would infringe the Pain Patent pursuant to section 117 of the *Patents Act 1990* (Cth) (**Act**).

Warner sought to establish that there is no market in Australia relating to the use of pregabalin in seizure management, so that Apotex's product would inevitably be supplied to treat pain. However, Justice Griffiths did not accept that submission. His Honour noted that, in 2005, Warner had itself applied (unsuccessfully) to have LYRICA's PBS listing extended to cover the treatment of seizures.

Warner also contended that pharmacists, being aware that Apotex's product was bioequivalent to LYRICA and had originally been registered for the treatment of both seizures and pain, would substitute Apotex's product for LYRICA, regardless of the condition for which pregabalin had been prescribed.

In assessing whether Apotex had reason to believe its product would be used to treat pain, Justice Griffiths considered the recent decision of the High Court of Australia in Sanofi-Aventis. In that case, the High Court explained that regard must be had to the regulatory regime for pharmaceuticals in Australia and held the registered indications for a generic pharmaceutical product operated as "emphatic instructions" to doctors and pharmacists concerning the manner in which the product could be used.

Justice Griffiths placed weight upon promotional materials and letters which Apotex proposed sending to doctors and pharmacists, highlighting that its product is not indicated for the treatment of neuropathic pain. His Honour found that, in the circumstances, those express instructions would displace pharmacists' more general understanding that Apotex's product was bioequivalent to LYRICA. Justice Griffiths concluded that Warner had not established a prima facie case (or had established only a weak case)

that Apotex had reason to believe its product would be used to treat neuropathic pain.

Balance of convenience

Justice Griffiths also found that the balance of convenience favoured Apotex. His Honour found that, if an injunction was refused and Warner was ultimately successful at trial, assessment of its damages would be more straightforward than would be the assessment of Apotex's damages if an injunction was granted and Apotex ultimately prevailed at trial.

In forming that view, Justice Griffiths had regard to evidence from a chartered accountant, highlighting the complexities involving in quantifying any compensation to which Apotex may ultimately be found entitled pursuant to an undertaking as to damages, including the difficulties involved in assessing a hypothetical market and price for Apotex's product.

In considering the balance of convenience, Justice Griffiths also had regard to evidence of Apotex's solicitor, relating to her experience in ongoing Federal Court proceedings relating to another pharmaceutical product. Apotex's solicitor described the prolonged delays and very substantial costs involved in an inquiry as to compensation payable pursuant to an undertaking as to damages given in that case.

Next steps

On 9 April 2014, Warner was granted leave to appeal to the Full Federal Court from the judgment of Justice Griffiths refusing interlocutory injunctive relief. The appeal is listed for hearing in early May.

Contacts



Ben Miller
Partner
Sydney
T: +61 2 9258 6431
E: ben.miller@ashurst.com



Andrew Rankine
Senior Associate
Sydney
T: +61 2 9258 6490
E: andrew.rankine@ashurst.com



Stevie Gough
Graduate
Sydney
T: +61 2 9258 6601
E: stevie.gough@ashurst.com

Abu Dhabi

Suite 101, Tower C2
Al Bateen Towers
Bainunah (34th) Street
Al Bateen
PO Box 93529
Abu Dhabi
United Arab Emirates
T: +971 (0)2 406 7200
F: +971 (0)2 406 7250

Adelaide

Level 3
70 Hindmarsh Square
Adelaide SA 5000
Australia
T: +61 8 8112 1000
F: +61 8 8112 1099

Beijing

Level 26, West Tower, Twin Towers
B12 Jianguomenwai Avenue
Chaoyang District
Beijing 100022
PRC
T: +86 10 5936 2800
F: +86 10 5936 2801

Brisbane

Level 38, Riverside Centre
123 Eagle Street
Brisbane QLD 4000
Australia
T: +61 7 3259 7000
F: +61 7 3259 7111

Brussels

Avenue Louise 489
1050 Brussels
Belgium
T: +32 (0)2 626 1900
F: +32 (0)2 626 1901

Canberra

Level 11
12 Moore Street
Canberra ACT 2601
Australia
T: +61 2 6234 4000
F: +61 2 6234 4111

Dubai

Level 5, Gate Precinct Building 3
Dubai International
Financial Centre
PO Box 119974
Dubai
United Arab Emirates
T: +971 (0)4 365 2000
F: +971 (0)4 365 2050

Frankfurt

Openturm
Bockenheimer Landstraße 2-4
60306 Frankfurt am Main
Germany
T: +49 (0)69 97 11 26
F: +49 (0)69 97 20 52 20

Hong Kong

11/F, Jardine House
1 Connaught Place
Central
Hong Kong
T: +852 2846 8989
F: +852 2868 0898

Jakarta (Associated Office)

Oentoeng Suria & Partners
Level 37, Equity Tower
Sudirman Central
Business District
JI. Jend. Sudirman Kav. 52-53
Jakarta Selatan 12190
Indonesia
T: +62 21 2996 9200
F: +62 21 2903 5360

Jeddah (Associated Office)

Alesayi Building
Madinah Road (South)
Al Andalus District/1
PO Box 55339
Jeddah 21534
Saudi Arabia
T: +966 (0)12 228 2700
F: +966 (0)12 228 2701

London

Broadwalk House
5 Appold Street
London EC2A 2HA
UK
T: +44 (0)20 7638 1111
F: +44 (0)20 7638 1112

Madrid

Alcalá, 44
28014 Madrid
Spain
T: +34 91 364 9800
F: +34 91 364 9801/02

Melbourne

Level 26
181 William Street
Melbourne VIC 3000
Australia
T: +61 3 9679 3000
F: +61 3 9679 3111

Milan

Via Sant'Orsola, 3
20123 Milan
Italy
T: +39 02 85 42 31
F: +39 02 85 42 34 44

Munich

Ludwigpalais
Ludwigstraße 8
80539 Munich
Germany
T: +49 (0)89 24 44 21 100
F: +49 (0)89 24 44 21 101

New York

Times Square Tower
7 Times Square
New York, NY 10036
USA
T: +1 212 205 7000
F: +1 212 205 7020

Paris

18, square Edouard VII
75009 Paris
France
T: +33 (0)1 53 53 53 53
F: +33 (0)1 53 53 53 54

Perth

Level 32, Exchange Plaza
2 The Esplanade
Perth WA 6000
Australia
T: +61 8 9366 8000
F: +61 8 9366 8111

Port Moresby

Level 4, Mogoru Moto Building
Champion Parade
PO Box 850
Port Moresby
Papua New Guinea
T: +675 309 2000
F: +675 309 2099

Rome

Via Sistina, 4
00187 Rome
Italy
T: +39 06 42 10 21
F: +39 06 42 10 22 22

Shanghai

Suite 3408-10
CITIC Square
1168 Nanjing Road West
Shanghai 200041
PRC
T: +86 21 6263 1888
F: +86 21 6263 1999

Singapore

12 Marina Boulevard
#24-01 Marina Bay
Financial Centre Tower 3
Singapore 018982
T: +65 6221 2214
F: +65 6221 5484

Stockholm

Jakobsgatan 6
PO Box 7124
SE-103 87 Stockholm
Sweden
T: +46 (0)8 407 24 00
F: +46 (0)8 407 24 40

Sydney

Level 36, Grosvenor Place
225 George Street
Sydney NSW 2000
Australia
T: +61 2 9258 6000
F: +61 2 9258 6999

Tokyo

Shiroyama Trust Tower
30th Floor
4-3-1 Toranomon, Minato-Ku
Tokyo 105-6030
Japan
T: +81 3 5405 6200
F: +81 3 5405 6222

Washington DC

1875 K Street NW
Washington, DC 20006
USA
T: +1 202 912 8000
F: +1 202 912 8050

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