

# Serious questions headed for a High Paced Verdict

*CSL Limited v GlaxoSmithKline Australia Pty Ltd [2006] FCA 1301 (3 October 2006, Weinberg J).* Also discussed in this case note are recent amendments to the Australian *Patents Act 1990*, to allow springboarding for purposes connected with obtaining regulatory approval.

23 October 2006

## **CSL LIMITED V GLAXOSMITHKLINE AUSTRALIA PTY LTD [2006] FCA 1301 (3 OCTOBER 2006, WEINBERG J)**

CSL Limited (**CSL**) has recently been denied an interlocutory injunction against GlaxoSmithKline Australia Pty Ltd (**GSK**) in relation to GSK's claims concerning the companies' competing human papilloma vaccine (**HPV**) vaccines. However the judge found that CSL had raised serious questions to be tried, and had it not been for GSK agreeing to a speedy hearing of the matter, he may have been inclined to grant some of the orders sought by CSL.

The case provides a useful reminder of the need for caution when making comparative product claims.

CSL's HPV vaccine is called Gardasil. It is the world's first cervical cancer vaccine and the only such vaccine approved in Australia.

GSK's HPV vaccine is called Cervarix. It is the subject of a pending application for marketing approval in Australia.

Each vaccine is based on work by Professor Ian Frazer, who is well-known for his groundbreaking research in this area, and was named Australian of the Year in 2006.

In June and July 2006, GSK engaged a market research organisation to undertake a "market research project". That activity consisted of contacting general practitioners by telephone to ascertain whether they were interested in participating, for a fee, in market research on cervical cancer vaccines, and if so sending by facsimile an information sheet containing comparative information on Gardasil and Cervarix.

The Information Sheet was a two page document containing some non-contentious background information describing the impact and cause of cervical cancer, and particularly its links with HPV. The Information Sheet went on to deal, in a comparative way, with Gardasil and Cervarix.

The Information Sheet was distributed to at least 300 GPs who were then interviewed by telephone. GPs were asked whether, on the basis of the Information Sheet, they would be prepared to prescribe one vaccine in preference to the other, and what price differential they would be prepared to pay in order to secure the benefits that one vaccine offered over the other.

CSL alleged that the comparative information was misleading or deceptive and that the interview questions "loaded" in such a way as to suggest that Cervarix offered clinical



benefits that Gardasil did not. The following were among the allegedly misleading or deceptive representations:

- Cervarix is registered under the Therapeutic Goods Act, has been approved by the TGA for protection against cervical cancer caused by HPV types 16 and 18 and is indicated for females of a wider age group than Gardasil.

*CSL alleged that Cervarix is not registered under the Therapeutic Goods Act and has not been approved by the TGA for sale and supply in Australia.*

- Cervarix has been proven to provide protection against cancer caused by HPV type infections 31 and 45 and is the only vaccine to have shown evidence of cervical cancer coverage additional to HPV type 16 and 18 infections.

*CSL alleged that there is no or insufficient evidence that Cervarix provides protection against cancer causing HPV infections types HPV 31 and 45 and, further, Cervarix is not the only vaccine to have shown evidence of potential cross-protection against other cancer causing HPV types such as HPV 31 and 45.*

- Cervarix, formulated with an AS04 adjuvant, induces longer lasting and stronger immune responses than Gardasil, formulated with an aluminium adjuvant.

*CSL alleged that there is no or insufficient evidence to show that Cervarix, formulated with adjuvant AS04, induces longer lasting and stronger immune responses than Gardasil.*

- Gardasil may offer further protection against some vaginal and vulval cancers caused by HPV types 16 and 18 and has not been approved by the TGA for the prevention of infection caused by HPV types 6, 11, 16 and 18 in males aged 9–15.

*CSL alleged that the Gardasil Product Information Sheet stated that it has been approved by the TGA for the prevention of vulval and vaginal cancers and for use in boys aged 9–15.*

GSK offered undertakings that until trial, or order of the Court, it will not make any representation in Australia in trade or commerce that Cervarix is registered under the Therapeutic Goods Act and approved by the TGA for sale and supply in Australia. As a result it was unnecessary to deal with those alleged representations.

The judge analysed each of the remaining allegations and the intricate issues of interpretation of medical statements and the complex aetiology of HPV and prevention thereof. He found that CSL had raised a serious question to be tried in respect of each.

His Honour then went on to examine whether CSL had established the other requirements for interlocutory relief. In this regard he considered that there were two further and discrete requirements, namely:

- that the plaintiff is likely to suffer injury for which damages will not be an adequate remedy; and
- that the balance of convenience favours the granting of an injunction.

Until recently it was considered that inadequacy of damage was merely one factor to be considered in weighing the balance of convenience. However, his Honour found that the High Court had resolved this issue earlier this year and that this was now a separate and essential factor for the applicant to prove.

Each party submitted such strong arguments on these two issues that the judge considered each had overstated its case.



CSL contended that the harm that it would suffer fell into three categories:

- difficulty being encountered by its sales representatives in responding to GSK's claims about Cervarix;
- lost sales of Gardasil as a result of GPs' deferring the decision to prescribe HPV vaccine until Cervarix came onto the market; and
- lost tender sales through tender coordinators being unfairly prejudiced against Gardasil.

CSL expressly disavowed any intention of restraining GSK from communicating with the TGA about Cervarix in relation to matters that might arise during the prosecution of GSK's application for marketing approval.

GSK's response included:

- it would itself suffer irreparable harm if it were unable to carry out preparatory work leading up to the marketing of Cervarix while its application for marketing approval was pending (including corresponding with various regulatory bodies, such as the TGA, the PBAC and various State tender bodies for immunisation programs)
- members of the PBAC and members of the State tender bodies were not likely to be swayed in their decisions to fund/purchase Gardasil by a two page information sheet used in a telephone survey of GPs;
- only a handful of CSL sales representatives engaged in promoting Gardasil had had any contact with doctors who had spoken to GSK representatives about Cervarix;
- CSL's own publicity exercise including two separate mail-outs to almost 20,000 general practitioners in Australia, advertisements in various journals, presentations at conferences and press releases would not be irreparably harmed in the few weeks before the trial; and

- CSL had delayed 10 weeks to commence the proceeding.

His Honour was prepared to assume that CSL will suffer some harm and that damages may not be an adequate remedy. He also found that the same is probably true for GSK in relation to the utility of any undertaking as to damages given by CSL.

He found that the balance of convenience issue was finely balanced and the speedy trial and early resolution tilted the balance in favour of GSK. Had it not been for the fact that there will be a speedy trial of this matter, his Honour "might have been inclined to grant some, at least, of the orders sought by CSL."

### **SPRINGBOARDING AMENDMENTS**

The *Intellectual Property Laws Amendment Act 2006* has added a new section to the *Patents Act 1990* to provide an exemption to patent infringement for activities connected with obtaining marketing approval.

The amendments take effect on 25 October 2006 and provide a broader springboarding right in respect of patents in force on that date and any patents granted after that date (including patents granted on applications pending on that date).

Specifically, new section 119A provides that the rights of a patentee of a pharmaceutical patent are not infringed by a person exploiting an invention claimed in the patent if the exploitation is solely for purposes connected with obtaining regulatory approval in Australia or overseas.

The exemption does not allow export of goods from Australia unless solely for purposes connected with obtaining similar regulatory approval in a foreign country and those goods are covered by a patent whose term has been extended under the patent term extension provisions.



**Pharmaceutical patent** is defined as a patent claiming:

- a. a pharmaceutical substance; or
- b. a method, use or product relating to a pharmaceutical substance, including any of the following:
  - i. a method for producing a raw material needed to produce the substance;
  - ii. a product that is a raw material needed to produce the substance;
  - iii. a product that is a prodrug, metabolite or derivative of the substance.

Previously springboarding was only permitted under extended patents and only from the date the extension was granted. The amendments allow springboarding for the purposes of obtaining regulatory approval in Australia under all “pharmaceutical patents” (as defined). The amendments also allow a limited right to export pharmaceutical substances from Australia for the purposes of obtaining foreign regulatory approval.

## MORE INFORMATION

For further information or advice on any of the topics covered in this case note or any other intellectual property matters please contact:

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