PRE-TRIAL DISCOVERY OF MANUFACTURING PROCESS INFORMATION FOR ETANERCEPT BIOSIMILAR ALLOWED

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Legal Briefings – By **Shaun McVicar, Alison Laughlin and Gabrielle Gutmann**

In this week's important decision of *Pfizer Ireland Pharmaceuticals v Samsung Bioepis AU Pty Ltd* [2017] FCAFC 193, the Full Court of the Federal Court of Australia clarified the approach in determining an application for pre-trial discovery of documents – in this specific instance relevant to determining whether a pharmaceutical manufacturing process might infringe claims of a pharmaceutical process patent relating to the biologic, Etanercept.

The decision confirms that the foundation of such an application is that the applicant must reasonably believe that they ***may have***, not that they in fact ***have***, the right to obtain relief.

KEY TAKE-AWAYS

1. An applicant with a reasonable belief that one or more of its manufacturing process patents **may be** being infringed can seek preliminary discovery of documents to confirm this belief.

2. A reasonable belief need not be based on primary material and may be based on inference.

3. The basis for a reasonable belief will be tested on a case by case basis, and the applicant must do everything it reasonably can to find out whether it may have a right to relief before making a pre-trial application, and should show the Court it has done so.

THE DECISION

At first instance Pfizer applied for preliminary discovery of documents relevant to determining whether Samsung Bioepis AU (**SBA**) was infringing one or more of its patents for manufacturing processes for producing Etanercept. The primary Judge refused Pfizer's application deciding that it failed to establish a reasonable belief, as opposed to a mere suspicion, that SBA was infringing its patents.

The Full Court overturned this finding, holding that Pfizer's evidence was sufficient to establish a 'reasonable belief' that it ***may have*** rights.

A few key points arise:

1. The three Judges (including Chief Justice Allsop) agreed that the primary Judge erred in his enquiry of competing expert evidence by asking whose evidence was more persuasive or preferable. The real question was whether Pfizer's evidence (whether contestable or even arguably wrong) was capable of giving a basis for a reasonable belief that SBA **may be** infringing one or more of Pfizer's patents. Allsop CJ was unable to conclude (at [70]) that Pfizer's evidence was "*unreasonable or untenable in a hearing such as took place*" where "*there was no trial of the issue, no cross-examination and no presentation of competing views*". The applications are not mini-trials but summary applications [at [2]).

2. Justice Perram of the Full Court emphasised that to defeat a claim for pre-trial discovery it must be shown that a "*subjectively held belief does not exist or, if it does, that there is no reasonable basis for thinking that there may be (not is) such a case*" (at [121]). A belief may involve a degree of speculation, as long as the belief based on speculation is reasonable.

3. The primary Judge indicated that even if the preconditions to grant preliminary discovery had been established, his Honour would have refused to exercise the discretion in favour of Pfizer because Pfizer failed to produce its own primary material showing that it employed its own patent to produce its product (a central tenant of Pfizer's reasonable belief), that is, Pfizer had not made full disclosure of the reasons for its application. Given the Full Court's findings on Pfizer's evidence being a sufficient basis to establish a reasonable belief, the Full Court found there was nothing discretionary to deny the grant of pre-trial discovery.

KEY CONTACTS

If you have any questions, or would like to know how this might affect your business, phone, or email these key contacts.

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