JONES DAY

COMMENTARY

JUNE 2018


## IN SHORT

**The Situation:** Pfizer, a pharmaceutical manufacturer, brought an application for preliminary discovery of certain confidential documents belonging to Samsung Bioepis ("SB"), a competitor, believing those documents would enable Pfizer to decide whether or not to commence proceedings for patent infringement against SB.

**The Result:** On 18 May 2018, the Australian High Court refused SB's application for special leave to appeal and let stand the Full Court of the Federal Court's decision ordering SB to give Pfizer preliminary discovery.

**Looking Ahead:** It is now settled law in Australia that preliminary discovery is available where the prospective applicant reasonably believes that it may have (rather than has) the right to obtain relief for infringement.

### Background

Pfizer manufactures and supplies the biological medicine Enbrel (etanercept), used in the treatment of autoimmune diseases. Pfizer brought an application pursuant to rule 7.23 of the *Federal Court Rules 2011* for preliminary discovery of certain SB confidential documents that Pfizer believed would enable it to decide whether or not to commence proceedings for patent infringement against SB. The patents in suit concerned processes relating to one of the phases in the development of biological medicines.

Pfizer's assistant general counsel, Mr Silvestri, gave evidence, as the mind of Pfizer, about his belief that Pfizer may have the right to obtain relief for patent infringement. Mr Silvestri based his belief on the evidence of Pfizer's expert witness, Dr Ibarra, regarding: (i) the biosimilarity of Enbrel and Brenzys and the close similarity of the glycosylation profile of the two products; (ii) the likelihood of that similarity deriving from the similarity in the process used by both companies; and (iii) Pfizer's process being in accordance with the patents.

SB argued that the close similarity in the glycosylation profile of Enbrel and Brenzys was a feature of biosimilarity that could have been brought about by matters concerned with other phases in the development of the biological medicines or a combination of the phases and it was insufficient to lead one reasonably to believe that SB may be infringing the patents.

> The foundation of any application is that the prospective applicant reasonably believes that it may have a right to relief; that is, the belief must be reasonable and about something that "may be", not "is", the case.

### Decisions of the Court

Pfizer's application was refused at first instance: *Pfizer Ireland Pharmaceuticals v Samsung Bioepis AU Pty Ltd* [2017] FCA 285. The primary judge resolved the issue by reference to the expert witnesses' competing views and by rejecting the views of Dr Ibarra as not "persuasive".

On appeal, the Full Court allowed Pfizer's appeal: *Pfizer Ireland Pharmaceuticals v Samsung Bioepis AU Pty Ltd* [2017] FCAFC 193, holding that preliminary discovery applications are not intended to be mini-trials. The essence of rule 7.23 focuses on what "may" be the position. The foundation of any application is that the prospective applicant reasonably believes that it may have a right to relief; that is, the belief must be reasonable and about something that "may be", not "is", the case.

In practice, to defeat such a claim, it will be necessary either to show that the subjectively held belief does not exist or, if it does, there is no reasonable basis for thinking that there may be such a case. Showing that some aspect of the material on which the belief is based is contestable, or even arguably wrong, will rarely come close to making good such a contention. Many views may be held with which others disagree, but that does not make the views necessarily unreasonably held.

Therefore, the relevant question was not whether one scientific view was more or less persuasive than another but, rather, whether Dr Ibarra's views so lacked foundation that Mr Silvestri's reliance on them did not demonstrate that he reasonably believed that Pfizer may have a right to obtain relief. As Dr Ibarra's views were not criticised as ones that could not reasonably be held by anyone in her position, this question was answered in the negative.

In its special leave application to the High Court, SB argued, *inter alia*, that the Full Court shifted focus away from an objective assessment of the facts as to whether a reasonable basis was provided for the prospective applicant believing it may have the right to relief to an assessment of the subjective state of mind of the particular deponents who asserted the relevant belief. However, the High Court was not persuaded to grant special leave to appeal.

## TWO KEY TAKEAWAYS

1. The foundation of any preliminary discovery application is that the prospective applicant reasonably believes that it may have a right to relief; that is, the belief must be reasonable and about something that "may be", not "is", the case.
2. To defeat such a claim, it will be necessary either to show that the subjectively held belief does not exist or, if it does, there is no reasonable basis for thinking that there may be such a case.

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