

# Rights Holders Rearmed with Preliminary Discovery Powers by Full Federal Court

Richard Hoad, Partner, and Sarah Martine, Lawyer, at Clayton Utz consider the recent Federal Court decision, which should ensure that the preliminary discovery process remains a real weapon in the armoury of rights holders who suspect that their rights are being infringed.

How can a party assess if litigation is worth the cost before launching it? Preliminary discovery is a mechanism by which a prospective applicant, which considers that it might have a legal claim against another party, can obtain relevant documents prior to the commencement of substantive proceedings, in order to assess the merits of its potential claim. But what must the applicant show?

The Full Federal Court decision of *Pfizer Ireland Pharmaceuticals v Samsung Bioepis AU Pty Ltd* [2017] FCAFC 193 makes it clear that a prospective applicant seeking an order for preliminary discovery only needs to have a reasonable belief that it **may** have the right to obtain relief from a prospective respondent.

## Pfizer is concerned about potential patent infringement

The applicants (**Pfizer**) manufacture ENBREL, which is a biological medicine that is used in the treatment of autoimmune diseases such as rheumatoid arthritis, juvenile rheumatoid arthritis and psoriatic arthritis. The active ingredient in ENBREL is etanercept.

In July 2016, Samsung Bioepis AU Pty Ltd (**SBA**) obtained registration on the Australian Register of Therapeutic Goods of two pharmaceutical products containing etanercept as their active ingredient under the name BRENZYS. Pfizer was concerned that the manufacture of

BRENZYS might infringe one or more of Pfizer's process patents. However, it did not have sufficient information to decide whether to commence patent infringement proceedings.

Faced with this dilemma, Pfizer utilised the Federal Court's preliminary discovery procedure. Pfizer sought preliminary discovery of certain documents that SBA lodged with the Therapeutic Goods Administration regarding the processes used to manufacture BRENZYS. Pfizer believed that these documents would enable it to decide whether or not to commence proceedings against SBA for patent infringement.

## Preliminary discovery in the Federal Court

The relevant preliminary discovery procedure in the Federal Court is governed by Rule 7.23 of the Federal Court Rules 2011 (Cth), which allows a prospective applicant to apply to the Court for an order for discovery by a prospective respondent if the prospective applicant:

- has a reasonable belief that it has the right to obtain relief in the Court from a prospective respondent;
- after making reasonable inquiries, does not have sufficient information to decide whether to start proceedings to obtain such relief; and
- reasonably believes that the prospective respondent has, or is likely to have, in its control

documents directly relevant to the right to obtain the relief, and that inspection of the documents would assist in making the decision.

## How the Court assessed Pfizer's evidence to support its application for preliminary discovery

The key issue before the Federal Court was whether the expert evidence that Pfizer put forward in support of its application showed that Pfizer reasonably believed that SBA might be infringing its patents. Dr Ibarra (Pfizer's Director and Group Leader of Process Development, Manufacturing Science and Technology) provided expert evidence relating to the technical aspects of the patents and the process dependence of biological medicines.

At first instance, Justice Burley refused Pfizer's application. He was not satisfied that Pfizer had demonstrated that it had a reasonable belief, as opposed to a "mere suspicion", that it may have the right to obtain relief from SBA for patent infringement, saying that the mere fact that BRENZYS and ENBREL are biosimilar products does not mean that the manufacturing processes for the products are the same.

On appeal, the Full Court considered the proper approach to be taken in relation to preliminary discovery applications and, in particular, the "reasonable belief" requirement.

Three separate judgments were delivered, however there was broad agreement on the principles and Pfizer's appeal was unanimously upheld. The Full Court held that the evidence presented by Pfizer was sufficient to establish that it had a reasonable belief that it **may** have a right to obtain relief from SBA for patent infringement. As such, SBA was ordered to provide the discovery sought by Pfizer.

### Requirements for preliminary discovery

Chief Justice Allsop observed that the language used in Rule 7.23 should be given its ordinary meaning and its wording used as the framework of analysis for deciding preliminary discovery applications. Any judicial guidance should not be elevated above this statutory formulation,

Bearing this in mind, Justice Perram provided the following useful guidance in relation to the requirements for seeking preliminary discovery:

- the prospective applicant must prove that it has a belief that it **may** (not **does**) have a right to relief;
- the prospective applicant must demonstrate that the belief is reasonable, either by reference to material known to the person holding the belief, or by other material subsequently placed before the Court;
- a person deposing to the belief need not give evidence of the belief a second time, to the extent that additional material is placed before the Court on the issue of the reasonableness of the belief;
- the question of whether the belief is reasonable requires asking whether a person apprised of all of the relevant material could reasonably believe that they **may** have a right to obtain relief;
- one may believe that a person may have a case on certain material without one's mind being in any way inclined to the notion that they do have such a case; and
- in practice, in order to defeat a claim for preliminary discovery, it will be necessary either to show that the 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.

Chief Justice Allsop noted, with apparent disapproval, that the application at first instance involved two days of hearings, and the application for leave and the appeal took a further two days. As the Chief Justice observed, the level of fact finding that took place was well beyond what was required by the language used in Rule 7.23.

### Why this decision on preliminary discovery is good news for rights holders

The purpose of preliminary discovery is to enable a party to ascertain, in a reasonably efficient and cost-effective manner, whether the costs of substantive litigation are justified. As Chief Justice Allsop emphasised in this case, applications for preliminary discovery are summary in nature, and are not "mini-trials".

That purpose would be defeated if the process of applying for preliminary discovery was too burdensome or the hurdles were set too high – and, in particular, if the Court applied too rigorous a standard in the assessment of whether the applicant has a reasonable belief that it has the right to obtain relief. By definition, the prospective applicant has imperfect knowledge about the prospective respondent's conduct. The forming of the requisite belief will necessarily entail an element of speculation. The key question, as the Full Court recognises, is

whether the belief which is formed is a reasonable one.

The Full Court's decision should ensure that the preliminary discovery process remains a real weapon in the armoury of rights holders who suspect that their rights are being infringed. It should also put a brake on the tendency for applications of this kind to become unnecessarily drawn out and costly.