PREGABALIN PATENT DODGES PAINFUL REVOCATION

22 December 2016 | Australia
Legal Briefings – By **Helen Macpherson** and **Rachelle Downie**

On 21 October 2016, Justice Nicholas of the Federal Court handed down his decision, in the much anticipated case over the pregabalin drug (*Apotex Pty Ltd v Warner-Lambert Company LLC (No 2)* [2016] FCA 1238).

Pregabalin is used to treat neuropathic pain, epilepsy, fibromyalgia, and neuralgia.

Pregabalin is sold by Pfizer under the brand name Lyrica and is their second highest product by revenue in Australia.

The case considered both the validity of the pregabalin patent as well as whether generic versions of this drug (marketed by Apotex and Generic Partners) infringed the pregabalin patent.

Justice Nicholas' decision is highly relevant to companies operating in the pharmaceutical industry. On the question of validity, the decision illustrates:

- the high bar that must be met in order to invalidate a patent on the grounds of false suggestion and inutility; and
- how, even where the skilled addressee must engage in complex, time-consuming and expensive work in order to produce something within the claimed invention, a patent may still be able to survive an insufficiency challenge.

This article considers Justice Nicholas' findings on false suggestion, inutility and sufficiency. Click here to read our article on Justice Nicholas' infringement decision.

As yet, no appeal has been filed from Justice Nicholas' decision, with the patent due to expire in July 2017.

FALSE SUGGESTION

To succeed on this ground, there has to be both a false suggestion or a misrepresentation AND this suggestion or representation must have materially contributed to the Commissioner's decision to grant the patent.

False suggestions or misrepresentations can arise in one of two ways:

- In what is written in the patent specification; and/or
- In correspondence between the patentee and the Patent Office during the course of the prosecution of the patent.

Most of the successful cases on this ground have involved misrepresentations in correspondence between the patentee and Office. Here, however, the alleged misrepresentation was said to arise out of statements made in the specification of the Patent that were carried through into the Patent as granted.

Apotex alleged that Pfizer had misrepresented in the specification that the racemic compound had been tested for the treatment of pain as described in the patent. Justice Nicholas found that the patent had made this representation, which the patentee had accepted was false. However, the Judge did not consider that this misrepresentation had materially contributed to the Commissioner's decision to grant the patent. Justice Nicholas considered that the main focus of the patent was the (S)-enantiomer, and so it seemed unlikely that the Commissioner gave any consideration to the test results other than to notice that the most preferred embodiment (the (S)-enantiomer) may be effective in the treatment of pain.

So, the ground of false suggestion failed.

INUTILITY

To succeed on this ground, it must be shown that the patent was not “useful”. This doesn’t mean that the invention must be useful or even practicable in the commercial sense, unless that is a promise of the invention. The bar for proving inutility is set quite low: all that needs to be proven is that there are products or methods within the scope of a claim that are not useful. However, whether such products or methods fall within the scope of the claim will depend on the construction given to the claim. Here, the Courts have said that claims are not to be read through the eyes of a skilled addressee purposefully seeking to perform the claimed invention in a manner that would not provide a useful result or in a manner that the skilled addressee would appreciate would lead to unworkability, if there is another construction that is equally open that avoids that result.

Apotex alleged lack of utility on two bases:

1. That claim 1 was inutile as the (S)-enantiomer was not effective in any patient in the treatment of pain conditions that do not involve neuropathic pain or central sensitisation. The expert evidence indicated that, while pregabalin was an effective treatment of neuropathic pain, there would be some patients for whom it would provide no pain relief even from neuropathic pain. In the case of central sensitisation, the expert evidence indicated that all clinically relevant pain states involved some degree of central sensitisation. On this basis, the Judge found that this part of the inutility case failed. The patent did not convey any promise as to the degree to which the claimed method of treatment would relieve pain. So, claim 1 did not lack utility, as the method of treatment defined in claim 1 was capable of providing some measure of pain relief to a substantial number of patients in need of pain treatment.

2. That all of the claims (except two) were inutile because the (R)-enantiomer was not effective in the treatment of pain. For this part of the case, Apotex relied on a series of scientific papers and the Lyrica PI which reported the results of pre-clinical *in vitro* studies or pre-clinical *in vivo* rodent studies. The Judge considered that these studies might have some value as predictive tools, but did not provide a reliable basis for inferring that the (R)-enantiomer was not useful in the treatment for pain in humans. The Judge also noted that none of the experts stated that the (R)-enantiomer would not be effective if given at an appropriate dose. The Judge was therefore not persuaded that the (R)-enantiomer would be ineffective in the treatment of pain if administered at high doses.

SUFFICIENCY

Apotex’s sufficiency case was premised on the argument that the patent did not describe any safe and effective dosage regimes which the skilled addressee may use for the purpose of treating patients. The test for insufficiency is whether the patent will enable the skilled addressee to produce something within each claim without new inventions or additions or prolonged study of matters presenting initial difficulty. So the question was what was the nature of the work involved in determining a safe and effective dosage regime for the use of pregabalin in humans.

The Judge recognised that this work would involve pre-clinical studies and phase 1, 2 and 3 studies, and that this work was complex, time-consuming and expensive. However, the Judge considered that this work would nevertheless be routine, and that on the evidence before him there was no indication that the skilled addressee would be confronted with any problems when conducting these studies. As a general principle, the Judge stated that the description of the invention will not be insufficient merely because the skilled addressee is expected to apply considerable skill, effort and resources to make it work. If the steps required to be taken to work the invention are readily apparent to the notional skilled addressee, and they are standard or routine steps within the competence of the skilled addressee, then the test for sufficiency will be satisfied.

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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