Yes, No, Maybe: Is My Granted Patent Valid?

By Blair Hesp

Perhaps the most accurate answer is *definitely maybe*!

Many inventors view granted patents as the end of a successful patenting process. However, it is important to realise that a granted patent is still open to scrutiny by third parties. In addition, despite attempts to harmonise patent law internationally, universal validity of a granted patent is not guaranteed. The following case illustrates the unpredictability surrounding patent validity across borders.

Generic pharmaceutical company Arrow Pharmaceuticals has opposed the patenting of a weekly dosage form for the drug alendronate by Merck & Co Inc in various countries around the world. Alendronate is commonly used in the treatment of osteoporosis and generated US$2 billion in revenue for Merck in 2002, but is renowned for having unwanted gastric side effects if the strict directions relating to drug administration are not followed. Naturally, if a patient is required to take a pill on an empty stomach with a large glass of water while remaining upright for at least half an hour afterwards, daily dosing is not convenient, and patient concordance can be a problem.

Merck discovered that higher weekly doses are equally effective as a daily dose, but additionally resulted in fewer unwanted effects because of the reduction in the number of doses taken. Merck subsequently applied for global patent protection for this new dosing formulation and regime.

Arrow has opposed this patent application around the world, and New Zealand has been no exception. In New Zealand, and overseas, an invention must generally exhibit an inventive step, novelty and industrial applicability to be patentable. The initial pre-grant opposition in New Zealand succeeded on the basis that there is no inventive step in administering approximately seven-times the daily alendronate dose, once weekly. This decision was recently overturned on appeal to the New Zealand High Court on the basis that even though such a dosing paradigm had been known to be theoretically possible, Merck was the first to show that the weekly dosing regime was possible, and exhibited the benefit of fewer unwanted effects.

Meanwhile, Arrow has also been seeking the revocation of a number of claims in the corresponding Australian patent granted to Merck. However, in Australia Arrow succeeded in successfully having several claims of the corresponding Australian patent revoked on the grounds of lack of inventive step. The Australian Federal Court determined that there is no invention in asserting that a weekly dosing regime will result in greater patient concordance over a daily dosing regime. The Australian Federal Court further stated that there appeared to be no new substance, no new characteristics of a known substance, no new use and no new method, and therefore no new invention. This was a direct contradiction to the findings of the New Zealand High Court on the same matter.

To further cloud the issue, corresponding court battles have also been fought in the US Federal Court of Appeal and in the English High Court. The US case resulted in a narrow decision in favour of Merck (two Federal judges and the US Patent and Trademark Office versus two dissenting Federal Judges), while the English High Court decided to revoke the patent on the basis of lack of inventive step. The English High Court also went as far as revoking the original alendronate patent despite the patent being set to expire within a year of the decision.

This case demonstrates an important aspect of the patent process. Getting a granted patent is never the end of the road. While there have been efforts to harmonise international patent law, subtleties in the application of national laws within each jurisdiction remain. Most importantly, a granted patent is not necessarily a certificate of validity, and efforts should be made to maintain consistency between applications across borders, while also adapting specifications to meet local requirements.

A reminder: if you have any queries regarding patents, or indeed any form of intellectual property, please direct them to:

Patent Proze
Baldwins
PO Box 852, Wellington

Email: *email@baldwins.com*

Blair Hesp of Baldwins specialises in chemistry and biotechnology patents. Blair joined Baldwins in 2006. He has a PhD in pharmacology from the University of Otago as well as a NZDipBus with a management focus. Blair is currently studying towards a law degree and registration as a patent attorney.