The Squeeze on US Applicants

By Blair Hesp and Helen Palmer

Over the past ten years the policies and practices adopted by the United States Patent and Trade Marks Office (USPTO) have changed markedly for pharmaceutical and biotechnology related patent applications. These changes have proved to be somewhat frustrating for patent applicants.

A patent application can be filed first in New Zealand and then in the course of time may come to be filed at the USPTO. The policies and procedures that applied in the US at the time of filing the New Zealand application are often markedly different from those that apply when the US application is examined. Generally, the timeframe between the original New Zealand filing and examination of the US application is around 5 years.

The changes adopted by the USPTO have had the effect of narrowing the type of protection available for a particular invention. In the case of pharmaceutical inventions, often protection will now only be achievable for a reasonably narrow and tightly defined set of compounds that have been well described and exemplified. Gone are the days of applicants being able to have claims to a reasonably broad generic class of compounds granted in a single patent with minimal supporting experimental data.

We have also noticed in recent times that it is becoming much more difficult to make a general claim as to the suitable indications for the pharmaceutical compounds. It is best practice to show some in vitro and preferably in vivo utility of the compounds or compositions, but the actual types of trials and supporting experimental details can also be important. It would now be difficult to argue before the USPTO that a class of compounds shows utility for treating cancer in general if in vitro trials have been carried out using only one cancer cell line. The approach taken by the USPTO now is that protection is likely to be limited to the particular cancer exhibited by the cell line, possibly extended to some very closely related cancers. Another thing that makes this more frustrating is that 12 months outside of the original New Zealand filing there is little opportunity to add experimental material which could support more general patent claims, unless the applicant is prepared to look at other (costly) options such as filing continuation-in-part applications.

Another factor that is being raised more often by US examiners is the issue of restriction requirements. A restriction requirement identifies different aspects of an invention and requires an applicant to limit its application to one of the identified aspects. It is then necessary to file a divisional application if the applicant wishes to pursue patent protection for the other aspects of the invention. The aspects of the invention are often closely related. In the case of a pharmaceutical invention, these may even be groups of closely related compounds that show similar utility and have the same general structural features. Such closely related classes of compounds are often, in our view, quite fairly incorporated into the same specification. Where a number of different aspects are identified in the specification and an applicant is required to file one or more divisional applications, this adds significantly to the cost of achieving patent protection covering each of the identified aspects.

To add to the overall climate, the US courts are also issuing decisions that have made it more difficult for US patent holders to assert a broad interpretation of their patent claims.

With the goal posts being moved in this way by the USPTO and the US courts - and we can see no likelihood of let up on the positions being taken - it is vitally important that patent applications are not filed on the skinniest of experimental data. We recommend that substantial exemplification of compounds/compositions, along with a multitude of in vitro and in vivo tests, is the best position to take. Of course applicants need to balance the importance of filing an application to obtain an early priority date and perhaps allow publication of the invention, against the need to include strong supporting data in a patent application.

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

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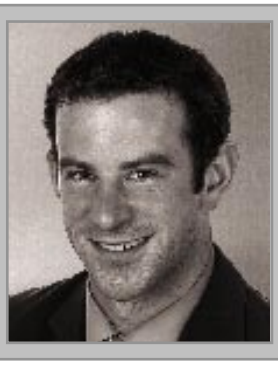

Helen Palmer and Blair Hesp of Baldwins specialise in chemistry and biotechnology patents. Helen joined Baldwins in 2000. She has a PhD in chemistry from The University of Auckland. Helen is a registered patent attorney in New Zealand and Australia. Blair joined Baldwins in 2006. He has a PhD in pharmacology 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.