

Change to Data Protection Laws

Katherine Hebditch

Baldwins Intellectual Property, PO Box 5999, Wellesley St, Auckland
(email: katherine.hebditch@baldwins.com)

Before agricultural or veterinary products are used and sold in New Zealand they must be granted approval by the regulatory authorities. They are the Ministry for Primary Industry (MPI) and the Environmental Protection Authority (EPA).

If it is a new active ingredient or there is a significant change from an existing product, the approval process can involve significant costs in obtaining data to prove there is minimal risk to public health and the environment and that the products are effective.

If the product is the same as an existing product that is registered (i.e., it is a generic product), it is possible to cross reference the data which supported the registration for the original innovative product, rather than obtain new data. This can be a very significant shortcut which will save on costs and time to bring a generic product to market. In fact, many generic products would not be on the market were it not for this shortcut. While it is possible for a generic manufacturer to generate the data themselves to support a registration application, in practice this does not happen owing to the prohibitive cost and time involved. However, this cross referencing of data can only be done once the data for the original product become publically available.

Part of the law governing the registration of new products is that the government agency will keep data confidential for a certain period of time after the first registration. This is generally known as the "data protection period". This gives the innovative product registrant, i.e., the company that generated the data, a head start on the market. The investment in time and money to create the data package is often considerable. Data protection can be thought of as a reward for making this investment.

This data protection period can be considered a form of intellectual property protection, which if handled strategically can complement patent protection. As New Zealand is a small market, patent applications are not always filed in New Zealand. In these cases one of the main intellectual property options is data protection. However, many believe the data protection provisions are not comprehensive enough to encourage the registering of new products in New Zealand, particularly in cases where there is no patent protection.

Government review of data protection periods

The Government recently indicated that it intends to make some amendments to the data protection provisions in the Agricultural Compounds and Veterinary Medicines Act (the law that governs the registration of products). Officials are working on the necessary amendments, with a view to the changes taking effect from late 2013. How-

ever, the timing of bringing changes of law through parliament is often slower than anticipated.

As part of the announcement of the changes that would be made there was also a note of what will not be changing, notably the data protection period for new active chemical ingredients that have not been previously registered in New Zealand. The review found that the current five year period of protection was appropriate. To put this in context; Australia gives eight years, Europe eight and the United States ten, with provisions for extending this time where further data are provided for various reasons. However the Government believes five years strikes the appropriate balance between encouraging the introduction of new products into New Zealand and the time before generic products can enter the market. In comparison other countries this data protection period is relatively generic manufacturer friendly.

New uses

In order to encourage the registration of additional uses for products, it will be possible to seek an extension of the five-year period of protection by one year for each additional use that is registered within three years of initial product registration, up to a maximum of three extra years. This would give a potential maximum of eight years of protection for the original data.

This change is being introduced because the Government review found that a number of important New Zealand horticultural crops and commercially farmed animals are considered "minor" commercial crops or species internationally, so products are not registered for use on them. The change is intended to encourage the registration of these additional "minor" uses in the New Zealand market. Examples of some of the agricultural uses which are relatively major in New Zealand in comparison to other countries are related to apples, kiwifruit, deer, goats and ostriches.

It has been pointed out this approach could encourage daisy-chaining of applications for new uses, rather than including all uses in the first application for registration. It is therefore possible that this provision could actually delay products becoming available for multiple uses.

New uses and reformulations of non-innovative compounds

Currently there is no data protection provided for new uses or reformulations of products that contain active ingredients that have been previously registered in New Zealand. The review found that the lack of data protection in this area may be inhibiting the registration and development of uses and products for the New Zealand market. As a result, a three-year period of data protection will be

introduced for new uses and reformulations. This is intended to provide an incentive to register additional uses and reformulations of existing products in the New Zealand market.

How large a change will need to be made in order to trigger data protection for a new use will need to be clarified.

We are sure that the above issues in relation to the extension of data protection provisions will be addressed in the upcoming legislation. The extension provisions are a welcome addition to the data protection available in New Zealand and should encourage registration of new products in New Zealand.

If you have any queries regarding intellectual property related matters (including patents, trademarks, copyright or licensing), please contact:

katherine.hebditch@baldwins.com and *tim.stirrup@baldwins.com* Patent Proze, Baldwins Intellectual Property, PO Box 5999, Wellesley Street, Auckland

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Katherine Hebditch and Tim Stirrup of Baldwins Intellectual Property in Auckland specialise in chemistry and biotechnology patents. Katherine obtained her PhD in organic chemistry from the University of Manchester in the UK in 2004. She is currently working towards registration as a patent attorney. Tim obtained his PhD in molecular biology from the University of Southampton in the UK in 2007. He is also working towards registration as a patent attorney.

