

# PBS Listing Injunction Refused by Australian Court

Hexal Australia Pty Ltd v Roche Therapeutics Inc [2005] FCA 1218, 5 August 2005  
**The Federal Court has declined to grant Roche Therapeutics Pty Ltd (Roche) an interlocutory injunction to stop two generic companies from seeking PBS listing for a drug which allegedly infringed Roche's patent rights.**

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*The decision is significant as it is the first time that the Court has considered two important aspects of the particular mechanism by which drugs are listed under the PBS – the strict listing timetable and the supply commitment which applicants are required to provide.*

## THE PROCEEDINGS

Roche is the exclusive licensee of an Australian patent owned by Roche Therapeutics, Inc and F.Hoffman-La Roche AG. The Patent has a priority date in February 1993 and is concerned with the use of compounds, which are dual non-selective [beta]-adrenoreceptor and alpha-1-adrenoreceptor antagonists for the treatment of congestive heart failure. Details of the relevant claims are set out later in this article.

Roche markets in Australia a product known as Dilatrend and claimed in evidence to have invested, in reliance on its statutory monopoly, substantial sums in promoting and marketing that product.

Hexal brought proceedings seeking to revoke the Patent for lack of validity. Roche filed a cross claim seeking an interlocutory injunction alleging that Hexal intended to apply to register a generic version on the PBS.

Roche also brought separate proceedings, with the same allegation, seeking interlocutory relief against Alphapharm Pty Ltd (*Alphapharm*).

The Court combined both of Roche's applications into a single hearing

## THE PBS

The PBS is a scheme under which the Federal Government agrees to subsidise the cost of medicines to the public. It is not essential to list on the PBS in order to market a drug. So long as the drug is registered with the Therapeutics Goods Administration (*TGA*), the drug can be marketed. However, PBS listing significantly reduces the cost of a drug to the public such that drugs not listed on the PBS tend to be prohibitively expensive and uncompetitive as compared to an equivalent drug listed on the PBS.

The PBS listing process contains three key features relevant to this matter, one of which does not seem to have been considered by Her Honour.

First, the PBS operates under a rigid timetable. Only three opportunities for listing exist each year, namely 1 April, 1 August and 1 December with applications having to be filed by 1 January,



1 May and 1 September respectively. Accordingly, if a listing application deadline is missed, the applicant must wait a further three months. Where the applicant is seeking to register a generic version, the originator will be able to enjoy its statutory monopoly for a further three month period. In this case the judge expedited her reasons and handed down her decision on 31 August 2005 in order to allow the respondents to file applications on 1 September 2005.

Secondly, the PBS requires each applicant to agree in its application that, if PBS listing is granted, it will be able to supply the drug on the listing date. In this case this meant that, if Hexal and Alphapharm were to apply on 1 September 2005, each was admitting that, were the application to succeed, it would have the generic product in Australia and available for purchase on and from 1 December 2005. Accordingly, this invites an inference that the product will have been imported into, or made in, Australia on (or, in reality, shortly before) 1 December 2005.

Thirdly, when the first generic version of a drug is listed on the PBS, the price of the drug is automatically reduced by 12.5%. As a result the reimbursement price of the originator drug is reduced effective from first listing of a generic version. Her Honour does not appear to have considered the relevance of this issue specifically in assessing whether interlocutory relief ought to be granted.

#### **THE PRINCIPLES OF INTERLOCUTORY RELIEF**

It is well established that, to obtain interlocutory relief, an applicant must establish three factors:

1. that there is a serious question to be tried (in that if the evidence remained the same, there is a probability at the final trial that it would be entitled to final relief);

2. that if relief is not granted it will suffer irreparable harm for which damages will not be an appropriate remedy; and
3. that the balance of convenience favours the relief.

The judge found that Roche failed on the second of these factors.

#### **SERIOUS QUESTION TO BE TRIED**

Her Honour considered whether there were serious questions on the issue of infringement and validity.

##### **(a) Infringement**

Two independent claims were relevant to the infringement allegations in these proceedings.

Claim 1 is a "Swiss-style" claim which claims use of carvedilol for manufacture of a medicament for decreasing mortality resulting from congestive heart failure. To establish infringement of this claim Roche sought to establish that Hexal or Alphapharm intended to manufacture the generic versions in Australia. However the evidence as to the place of manufacture of Hexal and Alphapharm was unclear and Her Honour was not satisfied that there was a serious question to be tried on infringement of this claim. It is not stated in the decision why Roche did not argue that importation into Australia of the generic versions infringed claim 1. However, because the validity and scope of a Swiss-style claim has not previously been considered by an Australian court, Roche may not have wished to have to establish, in an interlocutory proceeding, that a Swiss-style claim can be infringed by importation.

Claim 14 claims a method for decreasing mortality resulting from congestive heart failure in mammals comprising the administration



of carvedilol alone or in combination with other specified therapeutic agents. Because these claims cover a method of use and not a product per se, Roche was required to allege infringement under section 117 of the Patents Act (so-called *indirect infringement*). That section provides:

117 *Infringement by supply of products*

- (1) *If the use of a product by a person would infringe a patent, the supply of that product by one person to another is an infringement of the patent by the supplier unless the supplier is the patentee or licensee of the patent.*
- (2) *A reference in subsection (1) to the use of a product by a person is a reference to:*
- (a) *if the product is capable of only one reasonable use, having regard to its nature or design - that use; or*
  - (b) *if the product is not a staple commercial product - any use of the product, if the supplier had reason to believe that the person would put it to that use; or*
  - (c) *in any case - the use of the product in accordance with any instructions for the use of the product, or any inducement to use the product, given to the person by the supplier or contained in an advertisement published by or with the authority of the supplier.*

Accordingly, section 117 renders a person liable for infringement by supplying a product, if use of that product by another person, would infringe the patent.

Roche argued that, having regard to the Product Information approved by the TGA in respect of each generic product, the supply of those products to pharmacists, doctors or patients would entail the use of those products for the purpose of reducing mortality from congestive heart failure. However, Hexal and Alphapharm argued that it is not possible to read the PIs as

evidence of infringement because the products are not claimed to reduce mortality from congestive heart failure. The PIs did state that the medical indications include hypertension and symptomatic mild to severe congestive heart failure but made no express reference to reducing mortality.

Roche's case would have been easier to establish if it could have shown that the product is not a 'staple commercial product'. However, the meaning of that phrase does not appear to have been considered by an Australian court and Her Honour considered that an interlocutory application was not the appropriate forum in which to decide this question.

Her Honour found that there was a serious question to be tried on the issue on infringement.

(b) *Validity*

Her Honour also considered evidence tendered in relation to validity, specifically on the issues of lack of novelty, lack of inventive step and lack of fair basis.

Lack of novelty and lack of inventive step was alleged to arise from a study (*Kelly Article*) of the effects of administering carvedilol to patients with chronic heart failure in which the author concluded 'These data suggest that carvedilol may have beneficial effects in patients with chronic heart failure secondary to coronary artery disease.'

However, Roche presented evidence from a senior staff cardiologist at St Vincent's Public Hospital that, until 1995, she regarded as counter-intuitive the use of beta-blockers to treat congestive heart failure. On the basis of this unchallenged evidence, Her Honour found that there was also a serious question to be tried on whether the patent was invalid for lack of novelty or for



obviousness. Her Honour also considered that a serious question was raised on whether certain claims lacked fair basis.

## **IRREPARABLE HARM**

Roche argued that the PBS listing would dilute its substantial investment in the promotion and marketing of Dilatrend.

Hexal and Alphapharm argued that any loss of market share by Roche (below its current 100%) would be easily identifiable, quantifiable and adequately compensable in damages. Hexal argued that, by contrast, were the injunction granted and the infringement case to subsequently fail, the loss it would suffer would not be easily quantifiable as it would be impossible to predict the sales it would have enjoyed had it been allowed to list on the PBS as planned.

Her Honour also noted that each of Hexal and Alphapharm had not disputed that if the patent is ultimately found to be valid and infringed each would be liable for damages or an account of profits.

Her Honour found that Roche had not established that it would suffer irreparable harm if the injunction were not granted. Her Honour considered Roche's harm could be adequately compensated in damages and also noted that if the Patent is found to be valid and to be infringed by Hexal and Alphapharm, then Roche would 'regain' its statutory monopoly.

## **BALANCE OF CONVENIENCE**

Roche argued that Hexal and Alphapharm had been on notice of the Patent since at least October 2003 and had begun the TGA and PBS processes prematurely and with a full appreciation of the risks involved. Roche also submitted that an early hearing date was

possible so the injunction would be in force for a short period only. Roche also argued that there was no evidence that the injunction would significantly disrupt existing plans or existing business relationships, there being no evidence that Hexal and Alphapharm had irretrievably proceeded down the path of marketing their respective generic versions.

Hexal and Alphapharm argued that Roche's case was weak and the public interest in access to cheaper medicines outweighed the serious harm that would ensue from granting an injunction in respect of a patent that was 'manifestly invalid'.

Her Honour did not need to come to a view on this issue but was inclined to refuse relief to Roche on this ground also.

## **COMMENT**

As noted above, Roche had, in reliance on its statutory monopoly, made a substantial investment in the marketing and promotion of its product, and most likely had done so in the expectation that its statutory monopoly would run full term (many years of which remain). There was no evidence of any urgent need to introduce generic versions in the market. It was not alleged that Roche was not meeting the market requirements for the product. Also, the evidence suggested that the full trial could be heard expeditiously.

Once a generic version is listed in the PBS, the price of the originator version is automatically reduced by 12.5%. There can be no guarantee that the price will automatically increase again if the generic versions are found to infringe and are therefore de-listed from the PBS. Accordingly, it is not clear that Roche would regain the full benefit of its statutory monopoly as suggested by Her Honour.



Further, if the generic versions are de-listed and the PBS price is not increased to the former level, it is arguable whether Roche's lost future profits would be recoverable as damages from Hexal and Alphapharm (nor how such damages would be apportioned between those respondents). An account of profits would not provide redress. As a result, it is not clear that the refusal to grant interlocutory relief could be adequately addressed by damages.

There was no evidence that the patent was due to expire shortly after the upcoming PBS deadlines, such that Roche could have obtained a de facto extension of its patent monopoly were it successful in forcing the PBS listing to be delayed for a further three months. On the contrary, the respondents were simply seeking entry to a market in the face of a granted patent with many years left to run. This is generally a legitimate tactic; it is always open to a party to enter a market during a patent term and to defend any consequent application for interlocutory relief.

However, in the heavily regulated pharmaceutical sector where market price is regulated by a government body rather than market forces, it is arguable whether Her Honour applied the tests appropriately. Her Honour states that her conclusion to refuse interlocutory relief 'is predicated on the assumption that all parties will move with the utmost expedition towards an

early hearing. A failure to do so might well justify reviewing this decision.' However, it is submitted that by the time such failure materialises, irreparable damage may already have been done through the irreversible reduction of the PBS price.

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