

# The Value of Dependent Claims

## H Lundbeck A/S v Alphapharm Pty Ltd

programs for viewing at a time more convenient to the viewer ("time shifting"), which of course would allow the viewer to skip through commercials during playback.

The majority of Nine's revenue is currently derived from advertisements broadcast during television programs and, during the litigation, Nine's counsel explained that Nine's commercial interest in the litigation was directly related to the loss of revenue that might be occasioned by the "skipping" of advertisements.

With Australia's migration to digital TV, personal video recorders, including Foxtel's IQ device and the TIVO device, are becoming more common.

As consumers increasingly engage in time shifting with the assistance of EPGs like IceTV's EPG, and skip through commercials when doing so, Nine and other free to air broadcasters are likely to find their major revenue stream under threat. This may see the increase of banner advertisements superimposed over the television programs or perhaps an increase in product placement advertisements in the broadcasters' own productions.



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The Full Court of the Federal Court of Australia has recently handed down its decision in the Australian round of litigation relating to Lundbeck's patent for the antidepressant Escitalopram (marketed as LEXAPRO and CIPRALEX).

Escitalopram is the (+)-enantiomer of the antidepressant drug known as Citalopram (marketed as CELEXA and CIPRAMIL), which was claimed and prior published in a patent also owned by Lundbeck. The patent-in-suit claims Escitalopram and its non-toxic acid addition salts, pharmaceutical compositions containing them, and a claim to two processes for preparing Escitalopram.

The decision relates to appeals and cross-appeals arising from three separate proceedings concerning the validity of the compound and pharmaceutical composition claims of Lundbeck's patent for Escitalopram, the alleged infringement of the process claim, and the validity of an extension of the term of the patent.

A detailed summary of the decision at first instance, which included a fourth proceeding that was not appealed, can be found at:

<http://www.sprusons.com.au/epublications/newsalerts/alphapharm.html>

### Importance of Dependent Claims

Ultimately, this Australian patent litigation demonstrates the value of including meaningful dependent claims during drafting, prosecution, or by amendment before litigating.

Much of the decision is concerned with the proper construction of claim 1, which is in the following terms:

1. (+)-1-(3-dimethylaminopropyl)-1-(4'-fluorophenyl)-1,3-dihydroisobenzofuran-5-carbonitrile and non-toxic acid addition salts thereof.

and specifically whether or not claim 1 encompasses "the purified or isolated (+)-enantiomer, or the (+)-enantiomer whether alone or as part of a mixture, or the

(+)-enantiomer as present in a racemate?" Bennett J found that "claim 1 is to the pure or isolated or separated (+)-enantiomer" (at [160]).

However, as commented on by Emmett J (at [66]), much of this argument might have been rendered academic by the inclusion of one or more dependent claims with a qualifying phrase such as, for example, "substantially pure"; "substantially free of the (-)-enantiomer"; or by the inclusion of an explicit level of purity.

A similar point can be observed in respect of claim 5, which was directed to a pharmaceutical composition in unit dosage form wherein the active ingredient is present in an amount from 0.1 to 100 mg per unit dose. Bennett and Middleton JJ affirmed the decision at first instance to revoke claim 5 for lack of utility (usefulness) as the primary judge had accepted evidence that the minimum useful dose of Escitalopram is 5mg, and the maximum is 40mg. However, a further dependent claim with a narrower range of unit dose might have been valid.

### Novelty

By 2:1 majority, the Full Court affirmed the decision at first instance that claim 1 to Escitalopram, and its non-toxic acid addition salts, is novel over both the earlier Lundbeck patent claiming Citalopram, and a journal article that predicted the R-enantiomer of Citalopram would be far more potent than the S-enantiomer<sup>1</sup>, as neither disclosure contained "clear and unmistakable directions to obtain the enantiomers" (at [194] per Bennett J).

It is important to note that whether or not a claim to any resolved enantiomer will be held to be novel in the light of a prior disclosure of its corresponding racemate will depend on the particular facts of the case.

### Infringement of the Process Claim

The Full Court reversed the controversial decision at first instance that process claim 6(b) for obtaining Escitalopram had been infringed by Alphapharm's importation

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of Escitalopram prepared according to the claimed process, but for the "evanescent substitution" of the cyano-diol appearing in structures (II) and (II)' of claim 6(b) with a bromo-diol, which is later replaced in the compound by a cyanation process.

Emmett J (with whom Bennett and Middleton JJ agreed) found that (at [93]):

*"The author of Claim 6(b) clearly had in mind the existence of a convention whereby a substitutable element could be represented by the symbol "R". The failure to use that symbol instead of the symbol "NC" signified that the cyano-diol was an essential integer of the method disclosed by Claim 6(b). It follows that a method that involves substitution of the bromo-diol for the cyano-diol does not infringe the method disclosed by Claim 6(b)."*

Accordingly, where a process or method claim includes one or more steps involving a chemical structure, any substituents that do not materially affect the way the process or method works should be kept as general as possible, with the inclusion of more specific dependent claims.

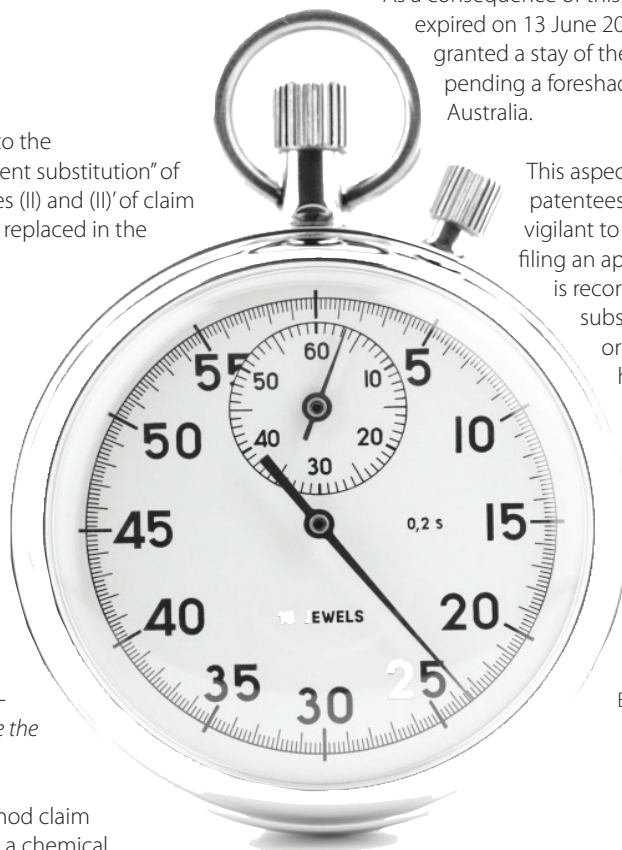
#### Extension of Patent Term

Bennett and Middleton JJ affirmed the decision at first instance that, for the purposes of obtaining an extension of patent term, the first inclusion on the Australian Register of Therapeutic Goods (ARTG) of goods that "contain" the (+)-enantiomer Escitalopram, was the earlier registration of its racemate, Citalopram.

As a consequence of this decision, the patent-in-suit should have expired on 13 June 2009. However, Lundbeck have been granted a stay of the order for removal of the extension pending a foreshadowed appeal to the High Court of Australia.

This aspect of the decision reiterates the need for patentees of pharmaceutical substances to be vigilant to ensure that the relevant deadline for filing an application for extension of patent term is recorded and acted on, and that any other substances, whether intended to be present or not, that are contained in goods which have been registered on the ARTG, do not also give rise to deadlines for making an application for extension of patent term.

<sup>1</sup> In fact, Escitalopram is the S-enantiomer of Citalopram, although this, of itself, was not the determining reason that the journal article did not constitute an anticipation of Escitalopram.



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