

Pharmaceutical Extensions

The topic of pharmaceutical patent term extensions has again recently been the subject of consideration before the Patent Office and the Federal Court. In two separate proceedings, the issue of whether the Commissioner is entitled to amend the Register to reflect a new (shorter) extension period was considered by the Federal Court. The issue arose when it came to light that the actual first regulatory approval date was earlier than the first regulatory approval date supplied by the patentee in the original application for extension. This also raises the question of whether the identification of an earlier first regulatory approval date can lead to a finding that the application for extension was filed out of time and that the extension was therefore invalidly granted in the first place. The latter is yet to be determined.

18 September 2006

DECISION OF A DELEGATE OF THE COMMISSIONER OF PATENTS

PFIZER CORP, PFIZER LTD, PFIZER INC. AND PFIZER RESEARCH AND DEVELOPMENT COMPANY, N.V./S.A (“PFIZER”) (RE PFIZER CORPORATION (2005) 67 IPR 201)

AND

DECISION OF THE FEDERAL COURT OF AUSTRALIA
PFIZER CORP V COMMISSIONER OF PATENTS (NO 2)
[2006] FCA 1176

Australian Patent Nos 540769 and 573123, relating to Norvasc (amlodipine) and 651637 and 691005, relating to Replax (eletriptan hydrobromide), (“the patents”) had all been granted an extension of the patent term under the pharmaceutical extension provisions of the Patents Act 1990 (Cth) (“the Act”). The extensions varied from about 5 months to almost 5 years and were recorded in the patent Register.

On 23 March 2005, amendments were made to the Patents Regulations, with effect on both new and existing entries on the patent Register, that if the Commissioner becomes aware that the first regulatory approval date in relation to the pharmaceutical substance is earlier than that supplied with the application for extension, then the Commissioner must amend the Register to insert the correct extension of the term of the patent (reg 10.7(7)).

Each of the patents had been extended on the basis of registration in the Australian Register of Therapeutic Goods (ARTG). However, it subsequently came to the Commissioner’s attention that earlier “export only” listings were included in the ARTG. The Commissioner accordingly notified Pfizer that she intended to amend the Register to reflect extensions of term calculated on these earlier dates. This would have the effect of reducing the currently recorded extensions by some ten or thirteen months, and in the case of AU 691005, reducing the five month term to zero.

Section 70(3) of the Act sets out that in order for a patent to qualify for an extension:

- (a) goods containing or consisting of the pharmaceutical substance (as disclosed and claimed in the patent) must be included in the ARTG; and
- (b) the period beginning on the date of the patent (usually the filing date) and ending on the first regulatory approval date for the substance must be at least 5 years.

The first regulatory approval date, as given by s 70(5), is the date of commencement of the *first inclusion* in the ARTG of goods that contain, or consist of, the substance.

The extension of term is calculated according to s 77 and is the period beginning on the date of the patent and ending on the *earliest* first



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regulatory approval date (as defined by s 70); reduced by five years (but not below zero). The maximum term of an extension is five years.

Pfizer contended that the relevant first regulatory approval date for calculating the extension of term is limited to the first such date for the purpose of marketing in, or importing into, Australia for general marketing of the pharmaceutical substance, and does not include the regulatory approval date for export purposes only.

The Hearing Officer noted that the Therapeutic Goods Act 1989 (“the TGA”) provided for the ARTG to contain two parts, one relating to goods to be known as registered goods and the other relating to goods to be known as listed goods. In this context the Hearing Officer concluded that the meaning of the “first inclusion in the Australian Register of Therapeutic Goods” must take into account the plain meaning of “inclusion” or “include” (“to contain, embrace or comprise”) and the nature of the ARTG and the inclusions provided for under the TGA. It was therefore clear that at all relevant times goods included on the ARTG have encompassed both registered and listed goods. As a result, export listings in the ARTG are to be taken into account when determining the first regulatory approval date. It was also noted that although most extensions have in the past been based on registered goods included in the ARTG, a small but significant number have been based on ARTG listings. On this basis it was assumed that the requirements of the TGA are clear and the concept of inclusion in the ARTG well understood.

When the relevant export listings were taken into account, the dates of commencement of the first inclusion in the ARTG that were supplied with the applications for the extension of term were found to be later than the actual first regulatory approval date as determined under s 70(5). In such circumstances, the Register must be amended in accordance with reg 10.7(7).

In response, Pfizer also submitted that reg 10.7(7) is invalid because it is *ultra vires* and that under the circumstances amendment would be a restriction

of the Patentee’s rights and amount to a reduction in the term of the extension. The Hearing Officer pointed out that the Register was merely *prima facie* evidence concerning patent rights but that it does not establish those rights. Before granting an extension, the Commissioner only has to determine that ss 70 and 71 are satisfied. The term of the extension is calculated by s 77 and is not decided or set by the Commissioner. Accordingly, while the Commissioner may be *functus officio* on the decision to grant the extension, she is not so merely in amending particulars on the Register that are intended to correctly reflect the term of the extension provided for under s 77.

The decision was appealed to the Federal Court.

Before the Court, two issues were considered: the validity of reg 10.7(7); and the date from which an extension of term of a pharmaceutical patent is calculated.

With regard to the first point, Pfizer submitted that reg 10.7(7) is invalid but limited its submissions to that contention. It was accepted by all parties that for the purposes of the appeal, Bennett J would follow the Lundbeck decision (discussed below) that reg 10.7(7) is valid prior to any determination to the contrary by the Full Court.

In determining the second point, Her Honour first considered the structure of the ARTG, noting that inclusion of a patented pharmaceutical substance as a Listed Good or a Registered Good both allowed the patentee, albeit to a different extent, to exploit the substance. Pfizer acknowledged this but submitted that the provision of data for Registered Goods is more onerous and extensive, resulting in a delay in marketing in Australia and in full exploitation of the patent. However, it was held that the extent to which the provision of data for Registered Goods is more onerous than Listed Goods was not considered to be determinative of the issue. This turned on the construction of ss 70 and 77 of the Act.

On its face, the meaning of the expression “*first inclusion* in the ARTG” as used in s 70(5)(a) was found to be clear and unambiguous: “the entry, first in time, in a



part of the ARTG”.

With regard to the meaning of “*earliest* first regulatory approval date” as used in s 77, Pfizer contended that the meaning given by s 70(5)(a) to “no pre-TGA marketing approval” should be consistent with the meaning given to “pre-TGA marketing approval”, which is defined by s 70(5)(b) as the date of the “*first approval*”. Pfizer submitted that this referred to approval for marketing in Australia prior to the commencement of the Therapeutic Goods Act 1989 (Cth) (“the TG Act”). Therefore, where no pre-TGA marketing approval was given, the first regulatory approval date should be determined by the first inclusion in the ARTG which allows marketing in Australia, *i.e.* inclusion as Registered Goods.

Her Honour, noted that s 70(6), which defines “pre-TGA marketing approval” as an approval to market the substance or a product containing the substance in Australia; or import into Australia, for general marketing, the substance or a product containing the substance, is restricted to the scenario where there is an approval by the Minister or Secretary prior to the TG Act. However, it was also noted that the TG Act further makes provision for the Secretary to grant approvals for importation into or supply in Australia of specified therapeutic goods in certain circumstances before the substance is included as Registered Goods in the ARTG, which is outside the scope of s 70(5). Her Honour then went on to state that if “the intention were to define “first regulatory approval date” as the date of approval to market in Australia or the date of entry in the ARTG as Registered Goods, it would have been easy to do so”.

Her Honour also considered extrinsic materials which Pfizer contended evinced a clear legislative policy for granting the patentee at least 15 years of “unfettered exploitation rights” commencing on the date of approval enabling marketing in Australia and which should be relied upon to interpret the provisions of the Act. However, it was held that the words “first inclusion in the ARTG” were neither ambiguous nor obscure and did not lead to a manifestly absurd or unreasonable result, and thus the provisions of the Acts Interpretation Act 1901 (Cth) did not apply.

In conclusion it was held that an export only listing in the ARTG is an inclusion in the ARTG for the purpose of s 70 of the Act and that where that inclusion precedes registration that permits marketing in Australia and no pre-TGA marketing approval was given, it is the first inclusion in the ARTG and the first regulatory approval date for the purpose of s 77.

The appeal was dismissed.

**DECISION OF THE FEDERAL COURT OF AUSTRALIA
H LUNDBECK A/S V COMMISSIONER OF PATENTS [2005]
FCA 1718**

Australian Patent No 623144 relates to the (S)-enantiomer of citalopram (escitalopram). The patentee, H Lundbeck A/S (“Lundbeck”), applied for and was granted an extension of term on the basis of the registration of escitalopram oxalate in the ARTG on 16 September 2003. Alphapharm Pty Ltd (“Alphapharm”) subsequently drew to the Commissioner’s attention that goods containing the (S)-enantiomer had, in fact, been included in the ARTG since 9 December 1997 by way of registration of citalopram bromide, which comprises both the (S)- and (R)- enantiomers.

In accordance with reg 10.7(7), the Commissioner notified Lundbeck that on the basis of the earlier registration date, the patent Register did not reflect the correct extension of term and that she intended to amend the Register to reflect the correct term. This revised term was some 18 months shorter than that originally recorded.

Lindgren J set out the legislation concerning pharmaceutical extensions and observed that provided ss 70 and 71 were satisfied, the Commissioner must grant an extension of term to the patent if there was no opposition to the grant. His Honour also noted that whilst the Commissioner must grant an extension, she is not required to specify the term of that extension and that the actual extension of term is not necessarily the period applied for, the period of the extension being defined in s 77. Finally it was observed that since sub-s 195(1) provides that the Register is *prima facie* evidence of any particulars registered in it, there is a general legislative intention



that the Register be correct and reliable.

Lundbeck referred to a number of authorities for the proposition that a power to make regulations is not to be construed as authority to make regulations which widen, vary or depart from positive provisions of the Act or extend the scope and general operation of the Act, and that reg 10.7(7) was therefore *ultra vires* with regard to s 228.

However, His Honour did not think that it was inconsistent with rights provided by the Act that a regulation should require the Commissioner to amend an entry in the Register which does not reflect the true extension of the term of a patent, where the Commissioner has become aware that the entry in the Register fails to do so. His Honour considered s 228 and noted that sub-s 228(2)(e) did allow the making of regulations that make provision for, and in relation to, amendment of an entry in the Register for any purpose. His Honour did not think that the expression “for any purpose” signified a regulation made for literally any purpose, for example, for a purpose which demonstrated bad faith or for a purpose totally foreign or antithetical to the concerns and objects of the Act, but could not think of a purposive limitation to be read into sub-s 228(2)(e) which would have the effect that reg 10.7(7) is *ultra vires*.

Lundbeck’s underlying submission, that by reason of entry in the Register the Patentee has the benefit of the extension entered, was firmly dismissed. His Honour noted that the term is set by s 77 and amendment of the Register to show a shorter period would do no more than remove a false entry and ensure the Register reflected the true extension fixed by s 77.

“The true extension is that brought about by the operation of s 77. The register does not give an indefeasible title and is only prima facie evidence of any particulars registered in it: s 195(1). A patentee has no right to insist that the Register continue to record an extension greater than it truly is.”

His Honour also dismissed the submission that to amend an entry in the Register to zero was inconsistent with s 76(1), pointing out that the notion that the extension might be zero is expressly contemplated by s 77.

The timing of an application for an extension is set by s 71(2) which, in this particular instance, required the application to be made within 6 months of the date of commencement of the first inclusion in the ARTG of goods that contain, or consist of, escitalopram. Whether the first regulatory approval date is 9 December 1997 (as contended by Alphapharm) or 16 September 2003 (as contended by Lundbeck) will be considered in a currently pending revocation action between Alphapharm and Lundbeck. If it is held that the date is in fact the earlier of the two, this raises the question of whether the extension was invalidly granted because the application for the extension was filed outside the 6 month period from the first inclusion date.

MORE INFORMATION

For further information or advice on patent term extensions or any other patent matters please contact:

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