Federal Court of Australia

Merck Sharp & Dohme Corp. v Sandoz Pty Ltd [2021] FCA 947

|  |  |
| --- | --- |
| File number(s): | VID 63 of 2021 |
|  |  |
| Judgment of: | **JAGOT J** |
|  |  |
| Date of judgment: | 12 August 2021  |
|  |  |
| Catchwords: | **PATENTS** – patent for treatment of diabetes – alleged threat of infringement – validity of extension of term of patent – pharmaceutical substance – construction of ss 71(2)(b) and 77 of the *Patents Act 1990* (Cth) – patent extension invalid – application dismissed – cross-claim allowed. |
|  |  |
| Legislation: | *Acts Interpretation Act 1901* (Cth)s 15AA *Patents Act 1990* (Cth) ss 3, 13, 70, 71, 74, 76, 77, 78, 192 |
|  |  |
|  | Explanatory Memorandum, Intellectual Property Laws Amendments Bill 1997 (Cth) |
|  |  |
| Cases cited: | *Director of Public Prosecutions v Leys* [2012] VSCA 304; (2012) 44 VR 1*Inco Europe Ltd v First Choice Distribution* [2000] UKHL 15; [2000] 1 WLR 586*Ono Pharmaceutical Co, Ltd v Commissioner of Patents* [2021] FCA 643*Pfizer Corp v Commissioner of Patents* [2006] FCAFC 190; (2006) 155 FCR 578 *R v A2* [2019] HCA 35; (2019) ALR 214*R v Young* [1999] NSWCA 166; (1999) 46 NSWLR 681*Taylor v Owners – Strata Plan No 11564* [2013] NSWCCA 55; (2013) 83 NSWLR 1*Taylor v The Owners – Strata Plan No* 11564 [2014] HCA 9; (2014) 253 CLR 531*Wentworth Securities Ltd v Jones* [1980] AC 74; [1917] 1 All ER 286 |
|  |  |
| Division:  | General Division |
|  |  |
| Registry:  | Victoria |
|  |  |
| National Practice Area:  | Intellectual Property |
|  |  |
| National Practice Sub Area: | Patents and Associated Statutes |
|  |  |
| Number of paragraphs: | 96 |
|  |  |
| Date of hearing: | 26 - 27 July 2021 |
|  |  |
| Counsel for the Applicants and Cross-Respondents:  | Mr D Shavin QC with Ms C Cunliffe |
|  |  |
| Solicitor for the Applicants and Cross-Respondents: | Jones Day |
|  |  |
| Counsel for the Respondent and Cross-Claimant:  | Mr C Dimitriadis SC with Ms M Evetts |
|  |  |
| Solicitor for the Respondent and Cross-Claimant: | Minter Ellison Lawyers |
|  |  |
| Counsel for the Commissioner of Patents: | Ms F Roughley |
|  |  |
| Solicitor for the Commissioner of Patents: | Australian Government Solicitor  |

ORDERS

|  |  |
| --- | --- |
|  | VID 63 of 2021 |
|  |
| BETWEEN: | MERCK SHARP & DOHME CORP.First ApplicantMERCK SHARP & DOHME (AUSTRALIA) PTY LTDSecond Applicant  |
| AND: | SANDOZ PTY LTDRespondent  |
|  |  |
| AND BETWEEN: | SANDOZ PTY LTDCross-Claimant |
| AND: | MERCK SHARP & DOHME CORP.First Cross-Respondent MERCK SHARP & DOHME (AUSTRALIA) PTY LTDSecond Cross-Respondent  |
| AND: | COMMISSIONER OF PATENTSIntervener |

|  |  |
| --- | --- |
| order made by: | JAGOT J |
| DATE OF ORDER: | 12 August 2021  |

THE COURT ORDERS THAT:

1. The originating application be dismissed.
2. The cross-claim be allowed.
3. Pursuant to s 192(2)(b) of the *Patents Act 1990* (Cth) the Register of Patents be amended so as to:
	1. remove all reference to the term of Australian patent 2002320303 (the **patent**) having being extended to 27 November 2023, or at all; and
	2. record that the term of the patent will expire on 5 July 2022.
4. The applicants pay the respondent’s costs of and in connection with the originating application and the cross-claim as agreed or taxed.

Note: Entry of orders is dealt with in Rule 39.32 of the *Federal Court Rules 2011*.

REASONS FOR JUDGMENT

JAGOT J:

##### Background

1. The principal issue in this matter is the validity of an extension of term of a patent granted by the **Commissioner** of Patents.
2. The **patent** is Australian patent 2002320303 relating to the treatment or prevention of diabetes. The date of the patent is **5 July 2002**: s 65 ***Patents Act*** *1990* (Cth). The term of the patent was for 20 years, that is until **5 July 2022**: s 67 Patents Act. The first applicant, referred to below as **MSD**, is the registered proprietor of the patent.
3. MSD applied for an extension of the term of the patent on 27 May 2009. The Commissioner granted the extension of term on 19 November 2009 and the term of the patent, as recorded in the **Register** of Patents, was extended until **27 November 2023**.
4. MSD contends that the respondent, referred to below as **Sandoz**, threatens to infringe the patent as Sandoz has undertaken not to exploit the invention claimed in the patent before 5 July 2022 but has refused to provide any undertaking preventing exploitation of the claimed invention beyond that date until 27 November 2023. This is because Sandoz contends that the extension of term is invalid as: (a) the application to extend the term did not comply with s 71(2)(b) of the Patents Act, and/or (b) if the application did comply with s 71(2)(b) of the Patents Act then, in accordance with s 77(1) of the Patents Act, the term of the extension was zero. Sandoz seeks rectification of the Register to reflect the fact that the patent expires on 5 July 2022. The Commissioner, who has intervened and filed written submissions, agrees with Sandoz’s second proposition about s 77(1) of the Patents Act operating in the present case to make the authorised term of the extension zero.
5. For the reasons which follow Sandoz and the Commissioner are correct about the operation of s 77(1) of the Patents Act. Pursuant to s 192 of the Patents Act, which enables rectification of the Register on application by a person aggrieved by an entry wrongly existing in the Register or an error or defect in an entry in the Register, an order should be made for rectification of the Registrar to the effect sought by Sandoz, that the term of the patent will expire on 5 July 2022 and not 27 November 2023.

##### Other facts

1. The other facts which need to be recorded, as identified in a statement of agreed facts between the parties, are as follows.
2. Sitagliptin is a “pharmaceutical substance” pursuant to Sch 1 of the Patents Act.
3. Sitagliptin/metformin is a “pharmaceutical substance” pursuant to Sch 1 of the Patents Act.
4. Sitagliptin/metformin is a different “pharmaceutical substance” (as defined in Sch 1 to the Patents Act) from sitagliptin.
5. The patent disclosed and claimed each of sitagliptin and a composition containing sitagliptin and metformin.
6. On or about **16 November 2006**, goods containing or consisting of sitagliptin were included in the Australian Register of Therapeutic Goods (**ARTG**) as an “export only listing”. The second applicant, a related company of MSD referred to below as **MSDA**, was the sponsor of the export only sitagliptin products.
7. The period beginning on the date of the patent (5 July 2002) and ending on the date of commencement of the first inclusion in the ARTG of goods that contain or consist of sitagliptin (16 November 2006) is **four years, four months and 11 days**.
8. On or about **27 November 2008**, goods containing or consisting of the composition of sitagliptin and metformin (**sitagliptin/metformin**) were first included in the ARTG as an “export only listing”. MSDA was the sponsor of the export only sitagliptin/metformin products.
9. The period beginning on the date of the patent (5 July 2002) and ending on the date of commencement of the first inclusion in the ARTG of goods that contain or consist of sitagliptin/metformin (27 November 2008) is **six years, four months and 22 days**.

##### Statutory provisions

1. There has been no material amendment to the statutory provisions since the making of the application for and the grant of the extension of term.
2. The relevant statutory provisions were as follows:

**3 (Sch 1 – Dictionary)**

***pharmaceutical substance*** means a substance (including a mixture or compound of substances) for therapeutic use whose application (or one of whose applications) involves:

(a) a chemical interaction, or physico-chemical interaction, with a human physiological system; or

(b) action on an infectious agent, or on a toxin or other poison, in a human body;

but does not include a substance that is solely for use in in vitro diagnosis or in vitro testing.

…

**70 Applications for extension of patent**

(1) The patentee of a standard patent may apply to the Commissioner for an extension of the term of the patent if the requirements set out in subsections (2), (3) and (4) are satisfied.

(2) Either or both of the following conditions must be satisfied:

(a) one or more pharmaceutical substances *per se* must in substance be disclosed in the complete specification of the patent and in substance fall within the scope of the claim or claims of that specification;

(b) one or more pharmaceutical substances when produced by a process that involves the use of recombinant DNA technology, must in substance be disclosed in the complete specification of the patent and in substance fall within the scope of the claim or claims of that specification.

(3) Both of the following conditions must be satisfied in relation to at least one of those pharmaceutical substances:

(a) goods containing, or consisting of, the substance must be included in the Australian Register of Therapeutic Goods;

(b) the period beginning on the date of the patent and ending on the first regulatory approval date for the substance must be at least 5 years.

Note: Section 65 sets out the date of a patent.

(4) The term of the patent must not have been previously extended under this Part.

(5) For the purposes of this section, the ***first regulatory approval date***, in relation to a pharmaceutical substance, is:

(a) if no pre-TGA marketing approval was given in relation to the substance—the date of commencement of the first inclusion in the Australian Register of Therapeutic Goods of goods that contain, or consist of, the substance; or

(b) if pre-TGA marketing approval was given in relation to the substance—the date of the first approval.

(6) For the purposes of this section, ***pre-TGA marketing approval***, in relation to a pharmaceutical substance, is an approval (however described) by a Minister, or a Secretary of a Department, to:

(a) market the substance, or a product containing the substance, in Australia; or

(b) import into Australia, for general marketing, the substance or a product containing the substance.

**71 Form and timing of an application**

*Form of application*

1. An application for an extension of the term of a standard patent must:

(a) be in the approved form; and

(b) be accompanied by such documents (if any) as are ascertained in accordance with the regulations; and

(c) be accompanied by such information (if any) as is ascertained in accordance with the regulations.

For this purpose, ***document*** includes a copy of a document.

*Timing of application*

1. An application for an extension of the term of a standard patent must be made during the term of the patent and within 6 months after the latest of the following dates:

(a) the date the patent was granted;

(b) the date of commencement of the first inclusion in the Australian Register of Therapeutic Goods of goods that contain, or consist of, any of the pharmaceutical substances referred to in subsection 70(3);

(c) the date of commencement of this section.

…

**74 Acceptance or refusal of application**

*Acceptance*

1. If a patentee of a standard patent makes an application for an extension of the term of the patent, the Commissioner must accept the application if the Commissioner is satisfied, on the balance of probabilities, that the requirements of sections 70 and 71 are satisfied in relation to the application.

…

*Refusal*

1. The Commissioner must refuse to accept the application if the Commissioner is not satisfied, on the balance of probabilities, that the requirements of sections 70 and 71 are satisfied in relation to the application.

…

**76 Grant of extension**

(1) The Commissioner must grant an extension of the term of a standard patent if:

(a) there is no opposition to the grant; or

(b) in spite of opposition, the Commissioner's decision, or the decision on appeal, is that the extension should be granted.

…

**77 Calculation of term of extension**

(1) If the Commissioner grants an extension of the term of a standard patent, the term of the extension is equal to:

(a) the period beginning on the date of the patent and ending on the earliest first regulatory approval date (as defined by section 70) in relation to any of the pharmaceutical substances referred to in subsection 70(2);

reduced (but not below zero) by:

(b) 5 years.

Note: Section 65 sets out the date of a patent.

(2) However, the term of the extension cannot be longer than 5 years.

**78 Exclusive rights of patentee are limited if extension granted**

If the Commissioner grants an extension of the term of a standard patent, the exclusive rights of the patentee during the term of the extension are not infringed:

(a) by a person exploiting:

(i) a pharmaceutical substance per se that is in substance disclosed in the complete specification of the patent and in substance falls within the scope of the claim or claims of that specification; or

(ii) a pharmaceutical substance when produced by a process that involves the use of recombinant DNA technology, that is in substance disclosed in the complete specification of the patent and in substance falls within the scope of the claim or claims of that specification;

for a purpose other than therapeutic use; or

(b) by a person exploiting any form of the invention other than:

(i) a pharmaceutical substance per se that is in substance disclosed in the complete specification of the patent and in substance falls within the scope of the claim or claims of that specification; or

(ii) a pharmaceutical substance when produced by a process that involves the use of recombinant DNA technology, that is in substance disclosed in the complete specification of the patent and in substance falls within the scope of the claim or claims of that specification.

##### Discussion

###### Section 70

1. The parties and the Commissioner had no dispute about the operation of s 70.
2. Specifically, s 70(2) was satisfied in respect of MSD’s application for an extension of term of the patent in that both sitagliptin and sitagliptin/metformin are pharmaceutical substances per se disclosed and are claimed in the patent as provided for in s 70(2).
3. One of those pharmaceutical substances also satisfied s 70(3) – sitagliptin/metformin. This is because goods containing or consisting of sitagliptin/metformin were included in the ARTG on 27 November 2008 so that the period between the date of the patent and the first regulatory approval date for that substance was at least five years (in fact, six years, four months and 22 days). Sitagliptin did not satisfy s 70(3) because goods containing or consisting of sitagliptin were included in the ARTG on 16 November 2006 so that the period between the date of the patent and the first regulatory approval date for the substance was not at least five years (in fact, four years, four months and 11 days).
4. The term of the patent had not been previously extended as provided for in s 70(4).
5. As to s 70(5), the parties agreed that the fact that the inclusion of the goods in the ARTG was for export purposes only was immaterial, consistent with the reasoning in *Pfizer Corp v Commissioner of Patents* [2006] FCAFC 190; (2006) 155 FCR 578.

###### Section 71(2)(b)

1. The dispute about s 71(2)(b), as presented by the parties, was subsidiary. MSD contends that the reference to “any of the pharmaceutical substances referred to in subsection 70(3)” means the pharmaceutical substance that satisfies s 70(3). In this case, that substance is sitagliptin/metformin. The Commissioner agrees that only sitagliptin/metformin satisfies s 70(3). The application for an extension of term was within time as provided for in s 71(2)(b) as goods containing or consisting of that pharmaceutical substance were first included in the ARTG on 27 November 2008 and the application was made on 27 May 2009, within the prescribed period of six months.
2. Sandoz contends that s 71(2)(b) is ambiguous and that it is reasonably open to construe the reference to “any of the pharmaceutical substances referred to in subsection 70(3)” as meaning “those pharmaceutical substances” referred to in the preamble to s 70(3). Those pharmaceutical substances are those referred to in s 70(2). On that basis, the date of the first inclusion in the ARTG of goods containing or consisting of any of those pharmaceutical substances, in this case, was 16 November 2006 when sitagliptin was included in the ARTG. As the application for an extension of term was made on 27 May 2009, it was out of time as s 71(2)(b) required the application to be made within six months of 16 November 2006.
3. I agree that, on first consideration, s 71(2)(b) appears to be ambiguous as Sandoz contends. This is because s 70(3) refers to both “one of those pharmaceutical substances” meaning one of those pharmaceutical substances referred to in s 70(2) and “the substance” which is the one pharmaceutical substance that satisfies s 70(3)(a) and (b) which, if s 70(4) is also satisfied, enables the patentee to apply for an extension of term.
4. I do not agree that the dispute about s 71(2)(b) is subsidiary. This is because the statutory scheme must be construed as a whole. Meaning must be given to the scheme which makes sense of all of its provisions. As explained below, an important aspect of this scheme is that s 71(2)(b) refers to “the date of commencement of the first inclusion in the Australian Register of Therapeutic Goods of goods that contain, or consist of, any of the pharmaceutical substances referred to in subsection **70(3)**” whereas s 77(1) refers to “the period beginning on the date of the patent and ending on the earliest first regulatory approval date (as defined by section 70) in relation to any of the pharmaceutical substances referred to in subsection **70(2)**”. Another important aspect of the scheme is that ss 70(2) and (3) are related provisions but they relate in a particular way. Section 70(2) establishes the relevant class. Section 70(3) establishes a sub-set of that class. As a result, any reference to s 70(3), at one level, is necessarily also a reference to s 70(2). However, the converse does not follow. A reference to s 70(2) is not, on any level, a reference to s 70(3).
5. To resolve the proper construction of s 71(2)(b) it is necessary to turn first to s 77(1).

###### Section 77(1)

1. MSD contends that “the earliest first regulatory approval date (as defined by section 70) in relation to any of the pharmaceutical substances referred to in subsection 70(2)”, as those words appear in s 77(1), means either: (a) the earliest first regulatory approval date of *any* substance satisfying s 70(3) (**MSD’s primary construction**), or (b) the earliest first regulatory approval date of *all* substances satisfying s 70(3) (**MSD’s alternative construction**).
2. It would be fair to say that, during the oral argument, MSD focused greater attention on its alternative construction than its primary construction.
3. On MSD’s primary and alternative constructions, the earliest first regulatory approval date of any and all pharmaceutical substances in the patent satisfying s 70(3) was 27 November 2008 (the date of inclusion in the ARTG of sitagliptin/metformin). On this basis, the term of the extension must equal the period beginning on 5 July 2002 and ending on 27 November 2008 reduced by five years. This gives a term of the patent expiring on 27 November 2023 as granted by the Commissioner.
4. Sandoz and the Commissioner contend that “the earliest first regulatory approval date (as defined by section 70) in relation to any of the pharmaceutical substances referred to in subsection 70(2)” in s 77(1) means what it says. On this construction, the earliest first regulatory approval date of any pharmaceutical substances in the patent as referred to in s 70(2) is 16 November 2006 (the date of inclusion in the ARTG of sitagliptin). On this basis, the term of the extension must equal the period beginning on 5 July 2002 and ending on 16 November 2006 reduced by five years but not below zero. This gives a term of the patent expiring on 5 July 2022. In this regard, it is necessary to keep in mind that Sandoz’s approach to s 77(1) assumes that it, Sandoz, is incorrect about s 71(2)(b) and that MSD and the Commissioner are correct about the construction of that section.
5. Sections 70, 71 and 77 recognise that a patent may disclose and claim more than one pharmaceutical substance. The possible permutations are infinite but the basic pattern is as follows, if it is assumed: (a) no previous extension of the term of the patent has been granted, and (b) the relevant regulatory approvals were obtained by the patentee or its agent. The second qualification is necessary because in ***Ono*** *Pharmaceutical Co, Ltd v Commissioner of Patents* [2021] FCA 643 Beach J was confronted by a circumstance in which one company had obtained a regulatory approval for a substance and another unrelated company, subsequently, had sought an extension of term of a patent based on its own regulatory approval. Justice Beach held that the statutory scheme for the extension of the term of a patent operated by reference to the patentee’s regulatory approvals and not the regulatory approvals of unrelated parties. The Commissioner has filed an appeal against the orders of Beach J setting aside the Commissioner’s decision in that case and granting the extension of term of the patent. It will be necessary to return to *Ono* below. Because s 71(2)(b) is also potentially relevant, it is necessary to put that requirement to one side temporarily.
6. A patent may disclose one substance, **substance A**.
7. If the period between the date of the patent and the first regulatory approval date for goods containing substance A is less than five years the patentee may not apply for an extension of term given s 70(1).
8. If the period between the date of the patent and the first regulatory approval date for goods containing substance A is at least five years the patentee may apply for an extension of time given the terms of s 70(1). In that event, the term of the extension under s 77(1) will be the period from the date of the patent until the first regulatory approval date which will also be the earliest first regulatory approval date. That is, the competing constructions will make no difference to the term of the extension under s 77. Further, the competing constructions about s 71(2)(b) will make no difference because there is only one pharmaceutical substance under ss 70(2) and (3) and thus only one regulatory approval date for that date.
9. A patent may disclose two substances, **substances A and B**.
10. If the period between the date of the patent and the first regulatory approval date for goods containing substance A or substance B is less than five years the patentee may not apply for an extension of term given s 70(1).
11. If the period between the date of the patent and the first regulatory approval date for goods containing substance A is less than five years and substance B is at least five years or more the patentee may apply for an extension of time given the terms of s 70(1) relying on substance B. The term of the extension under s 77(1) will be the period from the date of the patent until: (a) on MSD’s primary and alternative constructions, the first regulatory approval date of substance B which is also the earliest first regulatory approval date of substance B, and (b) on Sandoz’s and the Commissioner’s construction, the first regulatory approval date of substance A or substance B whichever is the earlier, which is necessarily substance A. Because substance A had a first regulatory approval date of less than five years, the term of the extension in every such case will always be zero.
12. The competing constructions about s 71(2)(b), however, do make a difference to this example. On the constructions of MSD and the Commissioner s 71(2)(b) is satisfied if the application for extension is made within six months of the inclusion of substance B on the ARTG. If Sandoz is right about s 71(2)(b) the application for extension must be made within six months of the inclusion of substance A on the ARTG.
13. A patent may disclose three or more substances, **substances A**, **B** and **C**.
14. If the period between the date of the patent and the first regulatory approval date for goods containing substance A or substance B or substance C is less than five years the patentee may not apply for an extension of term given s 70(1).
15. If the period between the date of the patent and the first regulatory approval date for goods containing substance A is less than five years and substance B and substance C is at least five years or more the patentee may apply for an extension of term given the terms of s 70(1) relying on substance B or substance C. The term of the extension under s 77(1) will be the period from the date of the patent until: (a) on MSD’s primary construction, the first regulatory approval date of substance B or substance C as nominated by the patentee which is also the earliest first regulatory approval date of substance B or substance C, (b) on MSD’s alternative construction, the first regulatory approval date of substance B or substance C whichever is the earlier in fact, and (c) on Sandoz’s and the Commissioner’s construction, the first regulatory approval date of substance A or substance B or substance C whichever is the earlier, which is necessarily substance A. Because substance A had a first regulatory approval date of less than five years, the term of the extension in every such case will always be zero.
16. Again, the competing constructions about s 71(2)(b) make a difference to this example. On the constructions of MSD and the Commissioner, s 71(2)(b) is satisfied if the application for extension is made within six months of the inclusion of substance B or substance C on the ARTG (as nominated by the patentee on MSD’s primary construction or as in fact the earliest inclusion on the ARTG on MSD’s alternative construction). If Sandoz is right about s 71(2)(b) the application for extension must be made within six months of the inclusion of substance A on the ARTG.
17. Alternatively, with respect to **substances A**, **B** and **C**, if the period between the date of the patent and the first regulatory approval date for goods containing substance A, substance B and substance C is at least five years or more the patentee may apply for an extension of term given the terms of s 70(1) relying on substance A, substance B or substance C. The term of the extension under s 77(1) will be the period from the date of the patent until: (a) on MSD’s primary construction, the first regulatory approval date of substance A or substance B or substance C as nominated by the patentee which is also the earliest first regulatory approval date of substance A, substance B or substance C, (b) on MSD’s alternative construction, the first regulatory approval date of substance A, substance B or substance C whichever is the earlier in fact, and (c) on Sandoz’s and the Commissioner’s construction, the first regulatory approval date of substance A or substance B or substance C whichever is the earlier. Because that period will necessarily be more than five years the term of the patent will be extended by more than zero and will equal the period from five years after the date of the date of the patent until the grant of the earliest first regulatory approval for substance A, substance B or substance C.
18. Again, the competing constructions about s 71(2)(b) make a difference to this example. On the constructions of MSD and the Commissioner, s 71(2)(b) is satisfied if the application for extension is made within six months of the inclusion of substance A or substance B or substance C on the ARTG (as nominated by the patentee on MSD’s primary construction or as in fact the earliest inclusion on the ARTG on MSD’s alternative construction). If Sandoz is right about s 71(2)(b) the application for extension must be made within six months of the inclusion of substance A on the ARTG.
19. Every other example will be a variation on one of the above patterns.
20. MSD and Sandoz both called in aid the well-recognised principles of construction and the policy underlying the extension of term provisions in Pt 3 of Ch 6 of the Patents Act. The underlying policy is explained in the **Explanatory Memorandum**, Intellectual Property Laws Amendments Bill 1997 (Cth) as follows:

**P3**

Extensions of up to five years on the standard 20 year term are available for pharmaceutical patents in the United States, the European Union and Japan in recognition of the exceptionally long development time and regulatory requirements involved in developing and commercialising a new drug. The aim is to provide an ‘effective patent life’, or period after marketing approval is obtained during which companies are earning a return on their investment, more in line with that available to inventions in other fields of technology.

…

**20**

Section 77 sets out how the length of the extension of term is to be calculated. The maximum length of the extension will be 5 years. The length of the extension is equal to the period between the date of the patent and the date of the first regulatory approval less 5 years. For example, where the period between those two dates is 5 years or less, a patent will not be eligible for an extension of term, while a period of 10 years or more would allow a full 5 year extension.

1. MSD submitted that the Explanatory Memorandum does not speak to the current circumstances as it focuses on a single pharmaceutical substance disclosed and claimed in a patent whereas the present case involves two pharmaceutical substances disclosed and claimed in a patent, one within the period of five years referred to in s 70(3)(b) and one after that period.
2. The Explanatory Memorandum does not focus on any distinction between patents involving only one or more than one pharmaceutical substance. But it does explains one thing which is important. This is that the legislature considered that a period of time of less than five years between the date of the patent and the date of inclusion in the ARTG was not unacceptable and did not justify an extension of term of the patent.
3. MSD relies heavily on *Ono* at [118] and [144]. At [118] in *Ono* the Commissioner posited a circumstance in which one pharmaceutical substance was granted first regulatory approval within five years and another pharmaceutical substance was granted first regulatory approval after five years. As MSD said, that is the present case. However, the context in which Beach J was considering the provisions was different from the present case. His Honour was considering a case where the earliest first regulatory approval on which the Commissioner relied to refuse the grant of an extension of term was that of a third party competitor of the patentee.
4. Justice Beach said at [135] in *Ono* that:

The extension of term regime is beneficial and remedial. It is designed to compensate a patentee of a pharmaceutical substance for the loss in time before which it can exploit its invention. It is designed to remedy the mischief of a shortened period for an effective monopoly that has been caused by delays in obtaining regulatory approval. Accordingly, a liberal rather than a literal construction is to be preferred.

1. His Honour also made these points, which are unexceptionable:
2. s 70(3) is not free-standing in the sense that it is to be read with and in the context of s 70(2): [138]; and
3. s 71 is a timing provision. Understandably it refers back to s 70(3), which concerns timing requirements for a candidate pharmaceutical substance. Section 77 contains its own timing requirements expressly within s 77(1)(a). In any event, both ss 71 and 77 ultimately cross-refer back to the pharmaceutical substances referred to in s 70(2) in the light of the implicit cross-reference in s 70(3) back to s 70(2): [143].
4. His Honour then said:

[144] Further, the modified second scenario posited by the Commissioner, which I have set out at [118], demonstrates the inappropriateness of the construction for which the Commissioner contends. The Commissioner on the corollary of that construction identifies the circumstances in which different substances might be used for the purposes of s 71 and s 77, namely, where the substance with the earlier ARTG registration date did not satisfy the requirements of s 70(3)(b). But in the Commissioner’s modified second scenario, the term of the extension will always be reduced to zero by virtue of s 77, because goods comprising the earlier substance would have to have been included in the ARTG less than 5 years after the date of the patent, if they did not (by definition of this scenario) satisfy s 70(3)(b). The effect of the Commissioner’s construction is that the only circumstance in which a substance with a later-in-time ARTG registration might be used for the purposes of s 71 is one in which the extension application would not result in any extension of term. That construction leads to an absurd result.

[145] But there are also other scenarios. Say the competitor’s product was approved at year 6, so 1 year after the 5 years in s 70(3)(b). Say the patentee’s product is approved at year 9 and is the subject of a s 71(2)(b) application. Now come to s 77. On the applicants’ construction the patentee gets a 4 year extension. On the Commissioner’s construction the patentee gets a 1 year extension. Further, a different application by the patentee would have needed to have been made under s 71(2)(b) within a different timeframe. Possible scenarios of disadvantage to the patentee can be multiplied.

1. All of the above paragraphs from *Ono* are obiter dicta. The ratio of the case is confined to the answer Beach J gave to the issue of construction with which he was dealing, namely, as identified at [27]:

…whether an application for an extension must be filed within 6 months of the first inclusion in the ARTG of goods containing or consisting of any pharmaceutical substance falling with the claims of the patent:

(a) where the goods were those of the patentee (the applicants’ position); or

(b) irrespective of whether the goods were those of the patentee, that is, they could be the goods of a third party that had nothing to do with the patentee and, moreover, might be a competitor (the Commissioner’s position).

1. MSD submitted that all of the considerations which Beach J considered relevant in *Ono* are equally relevant to the present case. I disagree. In rejecting the Commissioner’s position in *Ono* Beach J observed that numerous questions would arise on the Commissioner’s construction which his Honour summarised at [28] as follows:

I should say now that apart from seeking to sell me a literal form of textualism, the Commissioner’s statutory construction has little to commend it. Indeed, the following questions would arise on the Commissioner’s construction. Is it suggested that a patentee would then need to strictly monitor the regulatory approvals for third party products? And how else could it ensure that its own or future extension application is not contaminated or stymied by the registration on the ARTG of a third party product earlier in time? And how could it tell if the third party product fell within the scope of the claim(s) of the patent or confidently work out whether it fell outside? That is not a simplistic desktop analysis based upon a superficial read of an ARTG public summary. And if the third party product fell within, what is the patentee to do? Is it compelled to file an extension based on the third party product? Indeed, should the patentee seek to amend the claims of the patent to define away the third party product thereby preserving its future right to extend based upon its own product?

1. None of these considerations arise in the present case in which both relevant regulatory approvals were obtained by MSDA, a company related to the patentee, MSD. To my mind the absurdity which Beach J was identifying in [144]-[145] of *Ono* is the fact that a patentee may be granted an extension of term of zero merely because the earliest first regulatory approval date would be that of an unrelated company relating to the same substance.
2. MSD made a point that it was difficult to identify any words in the statutory provisions which distinguished between the patentee and its agents and a third party. While this may be arguable (and it was the Commissioner’s case in *Ono*), it does not assist in resolving the present case. It is one thing to conclude that it is absurd for a patentee to be denied any term of an extension due to an earlier regulatory approval by another unrelated party of which the patentee may not have known and over which the patentee would have had no control. In such a case, the patentee, by definition, will still have been delayed in obtaining regulatory approval for a substance or the substance in its patent for at least five years. Such a patentee has been denied the capacity to exploit its patent for the full 20 year term. It is another to conclude that it would be absurd for a patentee to be denied any term of an extension due to an earlier regulatory approval by the patentee or its agent of which the patentee must have known and over which the patentee had control. In such a case, the patentee, by definition, will not have been delayed in obtaining regulatory approval for a substance or the substance in its patent for at least five years.
3. I accept that, at first glance, it may well seem odd that the statutory scheme would: (a) enable a patentee to apply for an extension of term as provided for in s 70, (b) enable a patentee to make an application within time as prescribed by s 71(2)(b), (c) require the Commissioner to accept the application under s 74(1), (d) require the Commissioner in fact to grant the extension of term under s 76, and (e) then provide a method for the calculation of the extension of term which results in an extension of term of zero. But oddness or even absurdity are not free-standing concepts. They are only able to be assessed in the light of the statutory text in issue and the context in which the statute operates. It cannot be concluded that the statutory scheme is odd or absurd in circumstances where, on its face, s 77(1) expressly contemplates not only that the extension of term may be zero, but also provides that the extension of term may not be “below zero”. Those words in s 77(1) “reduced (but not below zero)” expose the fact that a zero term of an extension is within the contemplation of the statutory scheme. It will be necessary to return to these words below because they also resolve the proper construction of s 71(2)(b).
4. MSD submitted that the only case in which there could be a zero term of an extension is when the earliest first regulatory approval, on its construction, was precisely five years after the date of the patent. But there is no reason to impose that limitation arising from the text or context of s 77(1). MSD submitted further that it would be absurd if “so many”, “most” or a “very large number” of extension of term applications resulted in a zero term of extension. The problem with this submission is that it is not apparent, one way or another, whether many or most or only some applications would result in a zero term of an extension if the construction of s 77(1) proposed by Sandoz and the Commissioner is accepted.
5. Assuming the construction of MSD and the Commissioner about s 71(2)(b) is correct (so that an application may be made within six months of the first inclusion on the ARTG of a substance satisfying s 70(3)), then the zero term results only if the one patent discloses and claims two or more pharmaceutical substances, one of which obtains first regulatory approval within the period of five years from the date of the patent.
6. Assuming the construction of Sandoz about s 71(2)(b) is correct (so that an application may be made within six months of the first inclusion on the ARTG of any substance as referred to in s 70(3) meaning any of “those pharmaceutical substances” identified in s 70(2)), then the zero term results only if: (a) the one patent discloses and claims two or more pharmaceutical substances, one of which obtains first regulatory approval within the period of five years from the date of the patent, and (b) the application for an extension of term is made within six months of the first inclusion of any pharmaceutical substance as identified in s 70(2) on the ARTG.
7. Nothing in the scheme suggests either alternative involves an absurd or unexpected result or would somehow conflict with the policy of the scheme. Specifically, in such a case:
8. the patentee will have been able to exploit the patent within a period of five years from the date of the patent, even if the exploitation is only of one pharmaceutical substance in a patent which discloses and claims more than one pharmaceutical substance; and
9. it is clear the legislature has accepted that anything under five years from the date of grant until the ability of the patentee to exploit the patent (by inclusion in the ARTG) is acceptable.
10. There is a further obvious answer to MSD’s proposition that the legislature could not have intended “so many”, “most” or a “very large number” of extension of term applications to result in a zero term of extension. The answer is that it may be inferred that the legislature inferred that a patentee would not make an application at all if, under s 77(1), the term of the extension would be zero.
11. It may be accepted that the legislature and the drafter could have achieved the same outcome in other ways. Presumably, the scheme could have been drafted so as not to permit an application for an extension of term where any pharmaceutical substance disclosed and claimed in the patent is the subject of a first regulatory approval date within the period of five years from the date of the patent. However, the issue is not how the scheme could have been drafted. It is the meaning of the scheme as drafted.
12. The concept of the patentee “nominating” or “selecting” the relevant pharmaceutical substance for the purpose of the application for an extension of term, in accordance with MSD’s primary construction and based on *Ono*, requires some care. Under s 70(1) a patentee applies for an extension of term of **the patent**, not a claim of the patent or the patent as it relates to a substance claimed and disclosed in the patent.
13. As recognised in *Ono*, for practical purposes, however, it is for the patentee to identify a pharmaceutical substance which satisfies s 70(2) and (3) and which is the subject of a first inclusion in the ARTG which enables satisfaction of s 71(2)(b). In this sense only, there is a nomination or selection of a pharmaceutical substance by a patentee. But the statutory scheme does not operate by reference to a nomination or selection of a pharmaceutical substance by a patentee. It operates by reference to the facts. There either is or is not a pharmaceutical substance per se disclosed and claimed in the patent for the purposes of s 70(2). There either is or is not goods containing or consisting of that substance included in the ARTG where the period beginning on the date of the patent and ending on the first regulatory approval date for the substance is at least five years for the purposes of s 70(3). The patent either has or has not been previously extended as referred to in s 70(4). The application for the extension of term either is or is not made within six months of the dates specified in s 71(2). The nomination or selection of a pharmaceutical substance by the patentee cannot affect these objective facts.
14. For these reasons, MSD’s primary construction has nothing to commend it. Without the concept of the patentee selecting or nominating the pharmaceutical substance (the “any” pharmaceutical substance satisfying s 70(3) approach), MSD’s primary construction collapses into its alternative construction (the “all” pharmaceutical substance satisfying s 70(3) approach). The issue with both approaches is that, on its face, s 77(1) refers to s 70(2), not s 70(3), whereas s 71(2)(b) refers to s 70(3) and not s 70(2).
15. It is time to confront these inescapable facts, that s 77(1) refers to s 70(2) and not s 70(3) and s 71(2)(b) refers to s 70(3) and not s 70(2). Could there be one or more drafting errors here capable of correction by a legitimate process of construction? Or is it possible to construe the reference in s 77(1) to s 70(2) as including satisfaction of the requirements in s 70(3) on the basis that as a beneficial provision s 77(1) should be construed liberally and not literally and, as MSD argues, that this gives best effect to the purpose of the statutory scheme and is the construction to be preferred by operation of s 15AA of the *Acts Interpretation Act 1901* (Cth)? Equally, is it possible, as Sandoz submits, to construe s 71(2)(b) as referring to any of “those pharmaceutical substances” in s 70(2) rather than any of the pharmaceutical substances referred to in s 70(3)?
16. MSD referred to the fact that s 77(1) refers to “the earliest first regulatory approval date (as defined by section 70)”, rather than as defined by s 70(5), as if that provided support to its constructions. I am unable to agree. “First regulatory approval date” is defined in s 70(5). It is apparent, however, that the reference in the preamble to s 70(5) to “a pharmaceutical substance” is a pharmaceutical substance that is “at least one of those substances” as referred to in s 70(3), which in turn is the one or more pharmaceutical substances referred to in s 70(2). In this sense, s 77(1) is accurate in cross-referring to s 70 generally as identifying the definition of “first regulatory approval date”.
17. In s 77(1), the addition of the word “earliest” is crucial. It recognises that there may be more than one pharmaceutical substance disclosed and claimed in a patent which satisfies ss 70(2) and (3) and s 71(2) (whatever the patentee may nominate in its application for an extension of term) and requires that the extension of term be calculated by reference to the first regulatory approval date of that substance. This also exposes why MSD’s primary construction cannot be correct. On MSD’s primary construction of s 77(1) “earliest” does not mean “earliest” at all. This is untenable.
18. What then of MSD’s alternative construction and the questions posed above? MSD referred to *Director of Public Prosecutions v* ***Leys*** [2012] VSCA 304; (2012) 44 VR 1, ***Taylor*** *v The Owners – Strata Plan No 11564* [2014] HCA 9; (2014) 253 CLR 531, and *R v* ***A2*** [2019] HCA 35; (2019) ALR 214 in support of its case.
19. *A2* involved an offence provision which gives rise to considerations not engaged in the present case. At [125] in *A2* Bell and Gageler JJ distinguished *Taylor* as a case in which “the words of the provision accommodate[d] a range of meanings” including the meaning for which the appellant had contended.
20. In *Taylor* French CJ, Crennan and Bell JJ referred to *Leys* (in which at [92] the Victorian Court of Appeal did not accept the qualification upon which Spigelman CJ insisted upon in *R v* ***Young*** [1999] NSWCA 166; (1999) 46 NSWLR 681 at [88] that the process of construction not extend beyond the “words actually used”). Their Honours continued:

[37] Consistently with this Court’s rejection of the adoption of rigid rules in statutory construction, it should not be accepted that purposive construction may never allow of reading a provision as if it contained additional words (or omitted words) with the effect of expanding its field of operation. As the review of the authorities in *Leys* demonstrates, it is possible to point to decisions in which courts have adopted a purposive construction having that effect. And as their Honours observed by reference to the legislation considered in *Carr v Western Australia* [[2007] HCA 47; (2007) 232 CLR 138], the question of whether a construction “reads up” a provision, giving it an extended operation, or “reads down” a provision, confining its operation, may be moot.

[38] The question whether the court is justified in reading a statutory provision as if it contained additional words or omitted words involves a judgment of matters of degree. That judgment is readily answered in favour of addition or omission in the case of simple, grammatical, drafting errors which if uncorrected would defeat the object of the provision. It is answered against a construction that fills “gaps disclosed in legislation” or makes an insertion which is “too big, or too much at variance with the language in fact used by the legislature”.

[39] …it is unnecessary to decide whether Lord Diplock’s three conditions are always, or even usually, necessary and sufficient. This is because the task remains the construction of the words the legislature has enacted. In this respect it may not be sufficient that “the modified construction is reasonably open having regard to the statutory scheme” because any modified meaning must be consistent with the language in fact used by the legislature. Lord Diplock never suggested otherwise. Sometimes, as McHugh J observed in *Newcastle City Council v GIO General Ltd* [[1997] HCA 53; (1997) 191 CLR 85 at 113], the language of a provision will not admit of a remedial construction. Relevant for present purposes was his Honour’s further observation, “[i]f the legislature uses language which covers only one state of affairs, a court cannot legitimately construe the words of the section in a tortured and unrealistic manner to cover another set of circumstances”.

[40]  Lord Diplock’s speech in *Wentworth Securities* [***Wentworth Securities*** *Ltd v Jones* [1980] AC 74 at 105-106; [1917] 1 All ER 286] laid emphasis on the task as construction and not judicial legislation. In *Inco Europe* [***Inco*** *Europe Ltd v First Choice Distribution* [2000] UKHL 15; [2000] 1 WLR 586 at 592] Lord Nicholls of Birkenhead observed that even when Lord Diplock’s conditions are met, the court may be inhibited from interpreting a provision in accordance with what it is satisfied was the underlying intention of Parliament: the alteration to the language of the provision in such a case may be “too far-reaching”. In Australian law the inhibition on the adoption of a purposive construction that departs too far from the statutory text has an added dimension because too great a departure may violate the separation of powers in the Constitution.

(Citations omitted).

1. Lord Diplock’s three conditions from *Wentworth Securities* at 105-106 as re-formulated in *Inco* at 592 are: (a) identification of the precise purpose of the provision, (b) satisfaction that the drafter and the Parliament inadvertently overlooked an eventuality that must be dealt with if the provision is to achieve its purpose, and (c) the court must be abundantly sure of the substance, although not necessarily the precise words, the legislature would have enacted. The fourth additional condition adopted by McColl JA in *Taylor v Owners – Strata Plan No 11564* [2013] NSWCCA 55; (2013) 83 NSWLR 1 at [40] is that the modification “must be consistent with the wording otherwise adopted by the draftsman”.
2. In *Leys*, in departing from the observations of Spigelman CJ in *Young*, the Victorian Court of Appeal said at [93]:

The proposition that, before a non-literal and purposive construction can be adopted, the words that actually appear in the statute “must be reasonably open to such a construction” had been stated in varying ways […] Lord Diplock had said in *Wentworth Securities Ltd v Jones* [at 105] that the task “remains one of construction … even where this involves reading into the Act words which are not expressly included in it”. But none of these observations are to the effect that a literal meaning of the words used, even standing in context, must be capable of reflecting the discerned legislative purpose.

(Citations omitted).

1. The Victorian Court of Appeal in *Leys* continued at [96]:

Where an alternative construction may be required, there will ordinarily be some level of disconformity between the literal meaning of the words actually used and the statutory scheme. The literal meaning of the words used will either be too narrow to cover an intended purpose or too broad, thereby effecting an unintended purpose. In either case, the reading in of additional words may be justified if the modification brings the language into conformity with the intended purpose and the modification can be accommodated with the additional words used. This process should not, in our respectful opinion, be described as construing “the words actually used”. It is precisely the deficiency of the words actually used that renders necessary, if the purpose of the Act is to be achieved, the process of identifying “the additional words that would have been inserted by the draftsman and approved by Parliament had their attention been drawn to the omission before the Bill passed into law”. It is rather, as Gibbs CJ said in *Cooper Brookes (Wollongong) Pty Ltd v Federal Commissioner of Taxation* [[1981] HCA 26; (1981) 147 CLR 297 at 306], that regard must be had to “a full view of the Act, considering its scheme and its machinery and the manifest purpose of it”, together with its legislative history, to “explain … how the mistake occurred”. The task must always remain one of interpretation, but it is interpretation that derives meaning from the statutory scheme. In this respect, the process of construction is not construction “of the words used”, but rather the process of determining whether the modified construction is reasonably open having regard to the statutory scheme, set against the background that Lord Diplock’s three conditions have been met.

(Citations omitted).

1. Once these principles are recognised it is apparent that MSD’s constructions of s 77(1), primary and alternative, require judicial legislation, not judicial construction. It also becomes apparent that Sandoz’s subsidiary argument about the proper construction of s 71(2)(b) cannot be correct if that provision is construed in the context set by s 77(1), specifically the words “(but not below zero)”.
2. First, and as noted, s 70(2) establishes the class of relevant pharmaceutical substances. Section 70(3) establishes a smaller subset of that class, confined to pharmaceutical substances as referred to in s 70(2) which also satisfy s 70(3). In this sense, as noted, any reference to s 70(3) is also a potential reference to s 70(2) but the converse does not apply. Every reference to s 70(2) is not also a reference to s 70(3). Section 77(1) inescapably refers to s 70(2) not s 70(3). This is important because it indicates that MSD’s attempt to transform the reference in s 77(1) to s 70(2) into a reference to s 70(3) by a process of construction is illegitimate if the reference is not an obvious error (which, as will be explained, it clearly is not).
3. Second, it is apparent that the statutory provisions specifically identify either s 70(2) or s 70(3). Thus, s 71(2)(b) refers to s 70(3) whereas s 77(1) refers to s 70(2). Leaving aside the possibility of a typographical error in either or both of those provisions, the effect of the references to these different provisions may be examined.
4. The different constructions of s 71(2)(b) and s 77(1) give rise to three primary possibilities.
5. If MSD and the Commissioner are right about s 71(2)(b) and MSD is right about s 77(1), then a patentee with a patent disclosing and claiming more than one pharmaceutical substance can: (a) obtain an inclusion for one pharmaceutical substance in the ARTG within five years, (b) wait to see if another pharmaceutical substance disclosed and claimed in the patent is included in the ARTG five or more years after the date of the patent, (c) then apply within six months of that second inclusion date for an extension of term of the patent, and (d) thereby obtain an extension equal to the period between the date of the patent and the latter inclusion date reduced by five years.
6. If MSD and the Commissioner are right about s 71(2)(b) and the Commissioner and Sandoz are right about s 77(1), then a patentee with a patent disclosing and claiming more than one pharmaceutical substance can obtain an inclusion for one pharmaceutical substance in the ARTG within five years. While in theory a patentee could then wait to see if another pharmaceutical substance disclosed and claimed in the patent is included in the ARTG five or more years after the date of the patent and, if this occurs, apply within six months of that second inclusion date for an extension of term, there would be no pint in doing so as any extension will always be equal to zero in every such case.
7. If Sandoz is right about s 71(2)(b) and the Commissioner and Sandoz are right about s 77(1), then a patentee with a patent disclosing and claiming more than one pharmaceutical substance can obtain an inclusion for one pharmaceutical substance in the ARTG within five years and then cannot apply for an extension of term at all unless, by a quirk of timing, a pharmaceutical substance disclosed and claimed in the patent is included on the ARTG any time from four years, six months and one day until four years and 364 days after the date of the patent and another pharmaceutical substance disclosed and claimed in the patent is included on the ARTG between five years and five years and six months after the date of the patent. In the event of that quirk of timing alone the patentee would be able to make an application for an extension of term within six months of the inclusion of the latter pharmaceutical substance in the ARTG and would be granted an extension of term of zero.
8. Untethered from the statutory text and context, it might appear reasonably arguable that the scheme operates more sensibly on Sandoz’s construction of s 72(1)(b) and Sandoz’s and the Commissioner’s construction of s 77(1). This is a result of the simple fact that the scheme would not then involve a capacity to make an application for an extension of term which result in a term of extension of zero except in one class of case, the quirk of timing as described above. As to that possibility, it would not be inferred that the legislature and drafter tested the operation of the statutory provisions against every possible permutation.
9. Tethered to the statutory text and context, however, the reasons supporting Sandoz’s and the Commissioner’s construction of s 77(1) and against Sandoz’s construction of s 72(1)(b) are compelling. Once text and context are both considered, there is also no ambiguity about the provisions. There is conceptual complexity, but not ambiguity.
10. MSD’s approach to s 77(1) does not involve either the “reading down” or the “reading up” of the section. It involves replacing the reference to s 70(2) with a reference to s 70(3) as if the reference to s 70(2) were a drafting error.
11. However, it is by no means clear that refusing to read the reference to s 70(2) as if were a reference to s 70(3) would defeat the object of the provision. To the contrary, it is strongly arguable that reading the reference to s 70(2) as if were a reference to s 70(3) would result in something the legislature never intended. This is because, as I have said, it is clear that the legislature considered a delay of less than five years in the capacity to exploit a patent disclosing and claiming a pharmaceutical substance was acceptable and did not require a capacity for an extension of term of the patent. There is no reason to infer that the legislature intended that a patentee with a patent disclosing and claiming more than one pharmaceutical substance intended that there could be an extension of term if the patentee obtained inclusion of one or more pharmaceutical substances in the ARTG within five years of the date of the patent but then also obtained inclusion of one or more pharmaceutical substances in the ARTG five years or more after the date of the patent. Provided one pharmaceutical substance has been included in the ARTG within five years of the date of the patent, the patentee has had the benefit of the monopoly afforded by s 13 of the Patents Act within the period of delay the legislature considered acceptable.
12. While the proposition in the last sentence of the paragraph above is sufficient to make it strongly arguable that reading the reference to s 70(2) as if were a reference to s 70(3) would result in something the legislature never intended, Sandoz emphasised the facts of this case as an example of the overreach involved in MSD’s construction of s 77(1). In this case, substance A is sitagliptin. MSD has been able to exploit its monopoly in respect of sitagliptin since 16 November 2006 when that substance was included in the ARTG. The period from the date of the patent (5 July 2002) until the date of inclusion of that substance in the ARTG (16 November 2006) was less than five years. If matters had remained thus MSD would never have been able to satisfy s 70(3). MSD then obtained inclusion in the ARTG of the composition sitagliptin/metformin more than five years after the date of the patent (on 27 November 2008). On MSD’s construction of s 77(1) MSD could obtain an extension of term of the patent for the period of time from 5 July 2002 until 27 November 2008 reduced by five years. The result is MSD obtains a monopoly over sitagliptin for more than 20 years in circumstances where it never suffered any unacceptable delay in its capacity to exploit sitagliptin.
13. Further, the modified meaning that MSD seeks in respect of s 77(1) is not “consistent with the language in fact used by the legislature”: *Taylor* at [39]. It is not possible to read the reference in s 77(1) to s 70(2) as a reference to a pharmaceutical substance referred to in s 70(2) which also satisfies s 70(3). This is because the s 70(2) substances include the s 70(3) substances but the s 70(3) substances do not include the s 70(2) substances. Thus, s 77(1) does not “accommodate a range of meanings” including the meaning for which MSD contends: *A2* at [125].
14. It is also not possible to identify the precise purpose of s 77(1) as a purpose of ensuring that an application validly made can never result in a zero term of an extension except in the event that the only or earliest pharmaceutical substance satisfying s 70(3) was included in the ARTG five years exactly after the date of the patent. This is because the words “(but not below zero)” in s 77(1) disclose the legislature’s express contemplation of the prospect of a zero term of an extension. Nor can I be satisfied that the legislature and drafter overlooked an eventuality that must be dealt with. To the contrary, the legislature has expressly contemplated that the extension of term may be zero (or, indeed, but for the words “(but not below zero)”, less than zero). I cannot be “abundantly sure” (*Inco* at [592]) of the substance of what the legislature would have enacted. To the contrary, I consider that the legislature has enacted what it intended.
15. MSD asserted that it was better that a few extensions of term were granted in cases such as the present than “so many” extensions of term being zero. As I have said, however, an extension of term will only be zero if the patentee has had the benefit of inclusion of a pharmaceutical substance in the ARTG within five years of the date of the patent and then obtains inclusion of another pharmaceutical substance in the ARTG five years or more after the date of the patent. This, of course, brings me back to the capacity to make an application in accordance with the time requirement in s 71(2)(b).
16. Section 77(1), in specifying that the term of an extension is the period as specified (between the date of the patent and the date the pharmaceutical substance disclosed and claimed in the patent is included in the ARTG) reduced (but not below zero) by five years, necessarily contemplates that, but for the words “(but not below zero)”, a reduction below zero would be possible. There is only one way in which an application for an extension of term could result in a term of extension of below zero, namely, if a pharmaceutical substance disclosed and claimed in a patent is included in the ARTG within five years of the date of the patent. In other words, s 77(1) necessarily contemplates that there may be an application for an extension of term which can be made as required by s 70, can be made within time as required by s 71(2)(b), must be accepted as required by s 74, and must be granted as required by s 76, but which would result in a reduced term of the patent (that is, less than 20 years) but for the words “(but not below zero)” in s 77(1). It is those words that ensure that in any such case the term of the extension is zero and not a negative number.
17. What this means is that Sandoz’s construction of s 72(1)(b) must be wrong. Section 72(1)(b), in referring to s 70(3), means what it says. It must mean what it says because s 77(1) expressly contemplates an application for an extension being made but resulting in an extended term of zero where one pharmaceutical substance disclosed and claimed in the patent is included in the ARTG within five years and another pharmaceutical substance disclosed and claimed in the patent is included in the ARTG five or more years after the date of the patent. There can only be such an application if MSD and the Commissioner are right about the construction of s 71(2)(b). This analysis reinforces the fact that Sandoz and the Commissioner must be right that s 77(1), in referring to s 70(2), s 77(1) also means what it says.
18. MSD submits that it is hardly a liberal construction of the statutory scheme to involve patentees in making fruitless applications for extensions of term which result in no extension at all. This argument is readily answered. It may be inferred that the legislature did not expect that a patentee who had received the benefit of the monopoly given by s 13 of the Patents Act for a pharmaceutical substance disclosed and claimed in a patent within five years of the date of the patent would apply for an extension of term on another pharmaceutical substance being included in the ARTG five years or more after the date of the patent because the patentee would know that the extended term would be zero.

###### Section 78

1. Sandoz submitted that s 78 also supported the construction of s 77(1) proposed by it and the Commissioner. I agree. Section 78 reinforces the fact that it is the patent which is the subject of the extension of term under s 76, not the claims of the patent. By s 78 the exclusive rights of the patentee under s 13 are narrowed to some extent. By s 78(a) there will be no infringement of a patent for a pharmaceutical substance if a person exploits the substance for other than a therapeutic use. By s 78(b) there will be no infringement of a patent for a pharmaceutical substance if a person exploits a form of the invention other than that disclosed and claimed within the patent.
2. Sandoz also raised the prospect that if MSD was right about the construction of s 77(1) (that is, it means “pharmaceutical substances referred to in subsection 70(2) and which satisfy subsection 70(3)”), then “a pharmaceutical substance” in s 78(b) should similarly be construed as “a pharmaceutical substance referred to in s 70(2) and which satisfies s 70(3)”. As Sandoz had not pleaded this as an alternative defence to MSD’s claim for infringement, I indicated that I would not deal with s 78(b) other than in respect of the issue of construction. Sandoz’s capacity to apply for leave to amend its defence, if necessary, would be preserved. The conclusions I have reached above make it unnecessary for any such application for leave to be contemplated.

##### Conclusions

1. For these reasons, by operation of s 77(1) of the Patents Act, the term of extension of the patent is zero. The entry in the Register identifying the term of the patent as expiring on 27 November 2023 is wrong and contains an error, as the patent expires on 22 July 2022. Under s 192(2)(b) I should order that the Register be rectified as sought in Sandoz’s cross-claim. It also follows that MSD’s originating application claiming threatened infringement of the patent by Sandoz must be dismissed. Costs should follow in Sandoz’s favour.

|  |
| --- |
| I certify that the preceding ninety six (96) numbered paragraphs are a true copy of the Reasons for Judgment of the Honourable Justice Jagot. |

Associate:

Dated: 12 August 2021