

PTE Provisions Relating to Pharmaceutical Products in Australia in Comparison with European SPC and USA PTE

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Pharmaceutical products in Australia can win up to five years of Patent Term Extension (PTE). This article reviews Australian PTE Law and its relationship with regulatory pathway for approving medicinal products. The article describes recent PTE cases involving pharmaceutical products and analyses how effective these PTE provisions are in Australia. Finally, it compares PTE provisions in Australia with European SPC (Supplementary Protection Certificate) and USA PTE Provisions.

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Australian Patent Term Extension Provisions

The Australian Register for Therapeutic Goods (ARTG) maintains the list of therapeutic goods which are registered with the Therapeutic Goods Administration (TGA) of Australia. In Australia, for a patent to be eligible for Patent Term Extension (PTE), there should be a difference of more than five years between the dates of first ARTG registration, the first date on which any therapeutic drug is getting registered in ARTG and the basic patent filing date. The current provisions of the PTE for Pharmaceutical and Biotechnological products are governed by Sections 70 to 79A of the Australian Patents Act 1990. According to the PTE provisions, a maximum of five years of extension could be granted for a patent in Australia. The formula used to calculate the PTE term for any patent is as follows¹ –

$$\text{PTE} = [\text{First ARTG Registration Date} - \text{Basic Patent Filing Date}] - 5 \text{ years}$$

The first ARTG registration date appears to mean the date on which the drug product is registered in the ARTG for marketing or selling in Australia. However, there have been cases in the past where the Australian Patent Office (APO) and the Australian Court construed the meaning of the first ARTG registration date to cover products registered for export from Australia. An exemplary case is discussed below.

Under Section 70 of the Australian Patents Act, the patentee may apply to the Commissioner for PTE, if one or more pharmaceutical substances *per se* must be disclosed in the complete specification and in substance fall within the scope of the claims of patent or such substance (when produced by a process involving recombinant DNA technology) must be disclosed in the specification of patent. The products containing such substances must be included in ARTG in order to be eligible for the PTE. There must be at least five years of difference in the time period between the date of patent and the first ARTG date of the substance covered by such patent. The first ARTG approval date also includes registration of substance for export purposes, as impurities, as enantiomers or as racemates. The implication of such broad definition resulted in the case laws to develop in the Court which are discussed in detail in the article. Section 71 of the Act deals with the timing of filing the PTE application which is within six months time period of the letter of the date on which patent is granted or the date of first ARTG registration of the substance. Under Section 72 of the Act, it is necessary for Commissioner to publish the PTE application in the official journal for public inspection. The patentee can withdraw the PTE application under Section 73 by giving notice to the Commissioner. If all criterias of Sections 70 and 71 are satisfied then Commissioner accepts the PTE application or if not then refuses the same under Section 74.¹

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After grant of the PTE application, any person of the Minister can oppose the grant of the PTE on the grounds that one or more conditions of the Sections 70 and 71 are not satisfied under Section 75 of the Act. Finally, Section 76 relates to the grant of PTE application if no opposition is filed or in spite of opposition such extension should be granted based on the Commissioner's decision or the decision on appeal. Section 77 highlights the fact that maximum tenure of the PTE should be five years.

Once the PTE is granted, the exclusive rights of patentee are limited under Section 78. In case, where patentee filed for the PTE for any patent and such patent expires before the decision made on such PTE application, then Patentee has same rights as of patent, if such PTE is granted under Section 79. The Commissioner must not make any decision regarding any PTE application for the patent if proceedings are pending in the Court regarding that patent under Section 79A.¹

Goods Exported From Australia

Pfizer owns a patent, AU 598197, for injectable composition containing anthracycline glycosides. Pfizer applied for a PTE application on the basis of approval of *Idarubicin* which is covered in the scope of the claims of the '197' patent.²

In addition, Pfizer also informed the Patent Office that it markets a number of products (which were registered in the ARTG before *Idarubicin*) other than *Zavedos* that fall within the scope of the claims of the '197' patent (Fig. 1). These products had their "earliest first regulatory approval dates" as given below:

<i>Daunorubicin</i>	(20mg/10ml)	13 August 1991
<i>Adriamycin</i>	(10mg/5ml, 20mg/10ml, 50mg/25ml)	13 November 1989
<i>Pharmorubicin</i>	(10mg/5ml)	15 July 1992

For *Daunorubicin* and *Pharmorubicin*, this was said to be the date recorded in the ARTG and for *Adriamycin* the date of approval for importation by the Secretary of the Department of Health.

However, on 12 January 2007, the PTE application was rejected by the APO on the grounds that *Adriamycin*, another anthracycline glycoside which falls within the scope of claims of '197' was registered prior to the approval of *Idarubicin* in the

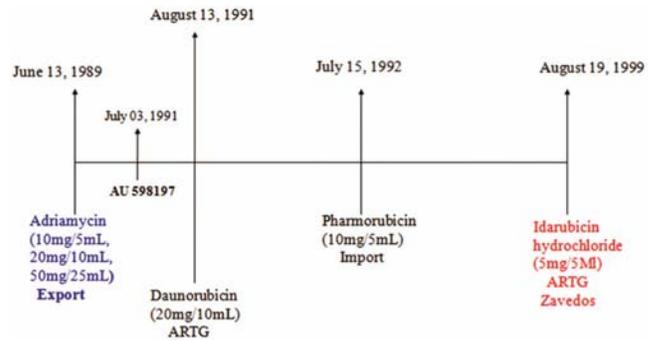


Fig. 1—Timelines in the Pfizer Case

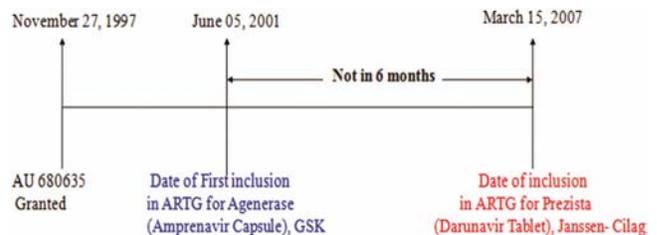


Fig. 2—Timelines in Gilead Case

ARTG for export purposes by Pfizer. Thus, it was clarified that "any" in Section 77(1)(a) means "all of" the pharmaceutical substances referred to in sub-Section 70(2) and it also includes those substances which are registered under export only purpose.²

First ARTG Approval

Another requirement for obtaining the PTE for pharmaceutical products in Australia is that an application for an extension should be made within six months of latest of three events - date of the first ARTG approval or date of grant of the basic patent or the date of commencement of this Section; as per Section 71(2) of the Australian Patent Act.¹

G.D. Searle had applied for the PTE application on the basis of approval of *Darunavir* with respect to the AU 680635 patent which generically claims two antiviral compounds, *Darunavir* and *Amprenavir*.³ However, on 5 December 2008, the PTE application was rejected by the APO on the basis that it was not made within six months of the first ARTG registration of therapeutic goods covered under '635' patent as per Section 71(2)(b). The APO located the registration of *Amprenavir* in the ARTG prior to the *Darunavir*. Further, *Amprenavir* was covered in the scope of claims of '635' patent (Fig. 2). The Commissioner said in conclusion, "If an application for extension of term could be made using the timing

of the inclusion in the ARTG of each relevant goods, the patentee would be able to sit on its hands until a later window opened. This is inconsistent with the existence of a limited window for making an application under Section 71(2).³

On 17 April 2002, in another case involving Merck, it was held that where an earlier ARTG registration contained the substance for which an extension was sought, even as a mere impurity, it was the earlier registration that was relevant for the first regulatory approval date.⁴

***Per Se* Pharmaceutical Substance, Method of Use and Process Patents**

Additional disputes arose in Australia about the meaning of term “*per se* pharmaceutical substance” in light of the PTE application. Schedule 1 of the Patents Act 1990 defines a “Pharmaceutical substance” as: A substance (including a mixture or compound of substances) for therapeutic use whose application (or one of whose applications) involves a chemical interaction, or physico-chemical interaction, with a human physiological system; or 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.¹

In Boehringer case⁵, on 6 June 2001, the Federal Court of Australia refused to grant the PTE application in case of *Ipratropium* product, where claim is directed to the container having Ipratropium bromide composition and nozzle adapted for nasal administration of composition.

Claim 1 of the AU Patent 531074 is directed to “a container comprising an aerosol or spray composition for nasal administration which composition comprises as active ingredient a quaternary tropane alkaloid derivative with atropine-like activity (here “the Substance” means Ipratropium bromide) and the container being provided with a nozzle adapted for nasal administration of the composition.”⁵

The PTE application was rejected on the basis that container and nozzle are required; otherwise the claim is not infringed. The composition of Ipratropium bromide “by itself” would not infringe the claim as it was not directed to a pharmaceutical substance *per se*. The correct interpretation of Section 70 (2)(a), means that the mere fact that a substance is mentioned in a claim does not mean that the substance is within the scope of the claim. In short, the nozzle and the container are physical integers which do not have any role on therapeutic activity of the composition.

The Australian regulation does not allow the PTE application for method of use patents. On 30 April 2003, the Full Federal Court of Australia (FCAFC) denied the PTE application for patent whose claims are directed to method of treating menopausal disorder using progestogen and estrogen in specified amounts.⁶ The APO and the Federal Court of Australia denied the PTE application on the grounds identical to *Boehringer case*. Even the Federal Court cited that “*In Boehringer the other integer was a particular physical device and in the present case the other integer is a particular method of use, which is a distinction without a difference.*”

On 30 April 2003, the Full Federal Court affirmed the lower court’s ruling. In its decision, the Full Court ruled that *Boehringer case* was not distinguishable because substance that is included in a claim only in combination with other products, as in *Boehringer*, is not a pharmaceutical substance *per se* that falls within the scope of the claim. Similarly, a substance that is mentioned only in the context of a claim for a method or process is not claimed *per se*.⁶

Based on the *Prejay Holding* case, patents that would not be eligible for the PTE in Australia includes: Substance A when used ...; Substance A for use ...; Substance A when produced by method Y; A method for preparing substance A; A specific amount of substance A; “Swiss style” claims referring to substance A; and Use of substance A in the treatment of B.⁶

However, in another case involving similar situation, the APO reached different conclusion, Sanofi applied for the PTE application for its patent covering *Zolpidem* tartrate controlled release product, which is bi-layered product having combination of immediate release portion and the delayed release portion which provides novel dissolution profile, the delegate of APO refused the PTE on the grounds that bi-layered goods listed in the ARTG are not pharmaceutical substances *per se*. The date of first inclusion of *Zolpidem* tartrate as a immediate release product appeared to be earlier than controlled release product, precluding the patent from an extension of term under Section 70.⁷

Sanofi appealed the decision to the Deputy Commissioner of Patent Office arguing that earlier product does not fall into scope of *Zolpidem* controlled release patent. In controlled release product, each layer is comprised of a mixture of *Zolpidem* tartrate and excipients which confer the

desired pharmacokinetic profile of the individual layer. The active agent involves a chemical interaction with a human physiological system. The composition of each layer involves a physico-chemical interaction with a human physiological system. In isolation, each layer is considered to be a pharmaceutical substance *per se*, as defined in the legislation. The controlled release product does indeed have a spatial arrangement but still does not qualify as a mixture in the Lohmann sense. On 2 October 2007, Commissioner reversed the decision and granted the PTE application.⁷

Similarly, Organon owns a product having vaginal drug delivery system comprising combination of Etonogestrel and Ethinyl Estradiol. Organon filed for the PTE application on the basis of the AU 726934 patent having claim relating to the drug delivery system comprising...a therapeutic polymer core and a thermoplastic polymer skin covering the core, said core comprising a mixture of [two known pharmaceutical compounds] in a ratio by weight that allows a direct release from the polymer of [both pharmaceuticals, the pharmaceuticals being dissolved in the polymer core in varying dosage]...said thermoplastic polymer skin being permeable for the [pharmaceutical].⁸

The issue was whether the product as disclosed and claimed in the patent was “pharmaceutical substance” within the meaning of the AU Patents Act 1990. In particular, the issue was whether substances (including a mixture or compound of substances) for therapeutic use was as provided in the definition given in Schedule 1. Whether the substance claimed was a combination of a substance having a therapeutic effect together with other components.

On 28 May 2009, the APO held that as the steroidal components are mixed with and necessarily diffuse through the thermoplastic materials in the core and skin regions and as the product as a whole exhibits a level of integration or interaction between the component parts that was considered more characteristic of a pharmaceutical substance in itself rather than a substance combined with another element or thing; the combination met the requirements of a pharmaceutical substance *per se*.

In this case, the APO observed that where it is difficult to determine whether a particular feature of a product can correctly be considered part of a “substance” rather than a separate physical integer, it is convenient to consider whether the characteristic of

what is claimed more predominantly lies with its being a substance, rather than a substance in combination with a separate integer.⁸

Sanofi and NV Organon decisions faced criticism by legal society for the reason that the past precedent of Boehringer and Prejay cases was not followed. In both the cases, there were physical integers present in the patent claims, and the product under ARTG registration clearly failed to qualify as pharmaceutical substance *per se*. Surprisingly, there were no appeals made to the court in both the cases.

But a later case found that the precedent of Boehringer and Prejay cases was governing and appropriately follows the interpretation of the Australian Patent law. The case involved a transdermal patch with Rotigotine as active substance. The transdermal patch also includes an acrylate or silicone based non-aqueous polymer adhesive compound into which Rotigotine free base is capable of being dissolved to enable transdermal application.⁹

The PTE application was filed on the basis of the AU 726934 patent claiming: “A pharmaceutical compound for the treatment of [X]...comprising an effective amount of free base...and an acrylate or silicone based non-aqueous polymer adhesive compound, wherein the solubility of the...base is greater than or equal to 5% (per weight), and a backing layer which is inert to the...base and the adhesive compound, having a protective layer, which is to be removed prior to administration of the pharmaceutical compound...to the patient”

According to the claim there was a three component system containing a polymer matrix containing Rotigotine, an inert backing layer and a protective layer responsible for therapeutic action.

On 21 August 2009, the APO found that the PTE could not be granted for the ‘934’ patent with respect to the transdermal patch with *Rotigotine* because claim is not directed to the *per se* pharmaceutical product as required by law. The backing layer and the adhesive component are separate integers that are not having any therapeutic activity of their own.⁹

Species Patent and Genus Patent

Dispute has also occurred in the species/genus relationship of two patents for reasonable disclosure required for the PTE application. Pfizer had applied for the PTE for *Voriconazole* product with respect to the AU patent 602638 which claims *Voriconazole* compound generically. The specification of the ‘638’

patent does not disclose *Voriconazole* compound specifically. On 4 June 2004, the PTE application was rejected by the APO for the reason that *Voriconazole* was not reasonably disclosed in '638' patent.¹⁰

The reason for the APO's rejection was Pfizer's argument made during prosecution of another patent, the AU 625188, claiming specific *Voriconazole* compound. During prosecution, Pfizer stated that the compounds of the AU patent '188' have surprisingly high level of antifungal activity, in particular against *Aspergillus* fungi, which is mainly attributable to their unexpectedly good pharmacokinetic properties resulting in longer half-lives. The prior AU patent '638' does not specifically describe or exemplify *Voriconazole* compound.

On that basis, the APO rejected the PTE application for the AU patent '638' patent arguing that if *Voriconazole* compound was in substance disclosed in the genus patent AU '638', then the selection patent AU '188', would have been Invalid under anticipation. Another point raised by the APO was "in substance disclosed" relates to the extent of the disclosure and it is the "real and reasonably clear disclosure" test that is fairly based.

Pfizer appealed the APO decision to the Federal Court of Australia (FCA) on the grounds that the prosecution of the selection patent AU '188' is irrelevant for the PTE application filed for genus patent AU '638'. Further, the "real and reasonably clear disclosure" test is incorrect for Section 70 (2)(a) of the Act. Pfizer argued that "in substance disclosed" should be given a different meaning to the words "fairly based on matter described" being the words in Section 40(3) of the Act and that these words import a different test. Pfizer emphasized that "in substance" impart a lesser requirement of disclosure than the test for fair basis. In addition, Pfizer's Expert Dr. Stamford clearly identified "*Voriconazole*" in the parent patent.

Pfizer questioned, "Is selection patent relevant to the question of the construction of the parent patent?" The answer was "No" because Section 70(2)(a) does not require examination of the validity of the patent sought to be extended.

Second question raised by Pfizer was, "Are the statements made by the patentee during prosecution of the selection patent relevant to the construction of the parent patent?" The answer from the Federal Court was "No". The claim disclosed a class of chemical compounds, including those in the proposed claims

which were sufficient to provide fair basis. The compound *per se* need not be disclosed. There is no requirement that each single compound be specifically claimed in order to be fair based. As a result, on 1 March 2005, the Federal Court of Australia reversed the decision of the APO and granted the PTE to '638' patent.¹⁰

Section 223 and *Escitalopram* Case

Recently, the High Court of Australia has agreed to hear an appeal made by generic applicants in *Escitalopram* case. The Court has taken up question as to whether or not it is possible to obtain an extension of time within which to apply for an extension of the term of a patent relating to pharmaceutical substance.

Earlier, Lundbeck was granted an extension of its Australian Patent, AU 623144, till 13 June 2014 based upon the listing of *Escitalopram* in the ARTG. However, the extension was later found invalid because *Escitalopram* was not the first product to be listed in the ARTG which is covered under claims of the AU 623144 patent.

Lundbeck was earlier granted approval of *Citalopram* which was registered in ARTG on 9 December 1997, for mixture of escitalopram and other enantiomers. As a result, in order to obtain the PTE for AU patent 623144 for *Citalopram* product, Lundbeck filed application for the PTE, just one day before natural expiry of patent, along with request for the extension of the deadline by ten years to make valid PTE application.

Under Section 71(2), an application for extension of patent term must be filed within latest of:

- (a) six months of the date of first inclusion of a product containing the patented compound on the ARTG; or
- (b) six months of the date of grant of the patent; or
- (c) 26 July 1999 (six months after commencement of the extension of term provisions).

In addition, under Section 223 of the Patent Act, an extension for deadline can be sought under appropriate circumstances, like error or omission on the part of an applicant, patentee or his/her agent. In Lundbeck's case, the relevant error was a misunderstanding as to the correct application of the law regarding extensions of the patent term, and the resulting misidentification of the appropriate ARTG product registration, *Escitalopram*, upon which its extension of term

application should be based. Under Section 223 of the Patent Act, the third deadline of Section 71(2) seemed to be relevant in Lundbeck's case.

Under Regulation 22.11(4)(b), some deadline described in the Patent Act are exempted from extension under Section 223. One of them is filing, during the term of a standard patent under sub-Section 71(2) of the Act, an application under sub-Section 70(1) of the Act for an extension of the term of the patent.

Generic companies in Australia read this regulation as saying that the time for filing an application for an extension of term is not extendible under Section 223. However, if that is so, then it would appear that the words "during the term of a standard patent as required by sub-Section 71(2) of the Act" are completely unnecessary.

On 1 June 2011, the APO allowed the extension which was affirmed by the Administrative Appeals Tribunal (AAT) on 4 December 2012. The Full bench of Federal Court of Australia¹¹ also allowed the extension of time despite objections raised by several generic manufacturers on 18 November 2013.

The Federal Court noted in its decision affirming the AAT and the APO's decision to grant extension that, there are two time limits to make an application under Section 70(1) of the Act: the application must be made "during the term of the patent" and "within six months of the applicable date in Section 71(2) (a) to (c)".

The Court further noted that Regulation 22.11(4)(b) does not simply prescribe the filing of an application under Section 70(1) of the Act. The phrase "during the term of a standard patent under sub-Section 71(2) of the Act" specifically identifies the action that is prescribed. Hence Regulation 22.11(4)(b) distinguishes between separate actions and prescribes one, not the other.

The result is that the action of filing the application under Section 70(1) during the term of the patent is prescribed and cannot be a relevant act to which Section 223(2) refers. On the other hand, the action of filing the application within six months of the applicable date is not prescribed and is taken to be a relevant act to which Section 223(2) can respond. The intention appears to have been to prevent the expired patent from being revived by posthumous applications for an extension of term accompanied by a request for an extension of time.

Despite the decision by the Full Federal Court, generic companies including Alphapharm appealed

the decision to the High Court because of the prospective damages to be paid by generic companies who have already been selling their generic product in competition with Escitalopram.

On 11 April 2014, the High Court has only taken up single question that is "Whether an extension of time to apply for an extension of term is available at all under the provisions of the Australian Patents Act 1990 and Patents Regulations 1991"? As a result, this appeal and the decision of High Court clarified ambiguity with respect to Regulation 22.11(4)(b). The High Court decision is final one and cannot be appealed further.

On 5 November 2014, the High Court of Australia handed down its decision confirming (by a three-to-two majority) that it is possible to obtain an extension of time within which to apply for an extension of the term of a patent relating to a pharmaceutical substance, so long as the extension application is filed prior to expiry of the patent.¹²

The majority in the High Court took what might be regarded as a 'common sense' approach, in order to interpret the regulation according to its 'plain English' meaning. Specifically, the Court focussed on the time requirements, rather than the nature of the act itself, stating:

"Time is critical to Section 223(2)(a) and 71(2) and reg 22.11(4)(b). The critical expression in the regulation is 'during the term of a standard patent', which must be construed in its immediate context in accordance with the principles expressed by this Court The part only of the parenthesis upon which Alphapharm relies so heavily merely identifies the statutory source of the critical time requirement. The text, syntax and immediate context of reg 22.11(4)(b) show that the natural and ordinary meaning of the 'prescribed action' identified is the 'filing (or making) of a s 70(1) application during the term of the standard patent' (that is, before the term of the patent has expired)." Alphapharm now has option to seek leave to appeal that decision to the full bench of the court.

Comparison of PTE Provisions of Australia with PTE Provisions in USA and SPC Provisions in Europe

In USA and Europe, PTE or SPC (in Europe PTE is known as SPC) is available in pharmaceutical field for the method of use patents or the method of treatment patents in addition to other patents. On the other hand, Australian regulation does not provide the

Table 1–Comparison of the PTE Provisions

Parameters	United States	Europe	Australia
Length of extension	5 years	5 years	5 years
Pediatric extension	6 months	6 months	Not available
PTE for method of use patents	Available	Available	PTE not available
PTE for enantiomers	Available	Available	Not available
Multiple PTEs per patent	Not available	Available	Available
Multiple PTEs per product	Not available	Available	Available
Patent Term Adjustment for delay from Patent Office (PTA)	Yes	No	No

PTE for method of use patents or the method of treatment patents. But, there is lack of consistency in the rulings by the APO and courts. It can be seen from NV Organon and Sanofi cases where the PTE was granted (in both the cases the product according to authors failed to satisfy “*per se* substance” definition as required by law) despite the Boehringer and Prejay Court rulings (where meaning of “*per se* pharmaceutical substance” was interpreted correctly) in the past. However, in case of LTS Lohmann, the Court followed the Boehringer and Prejay Holding decisions.

There is a need in Australia to follow uniform approach about the definition of pharmaceutical substance *per se*. Many times incremental inventions of new method of use of already known substance or novel treatment therapies or new processes are of great importance to the society. Australian regulations discourage such inventions by not allowing the PTE to such patents. In contrast, USA and Europe allows the PTE for such method of use patents.

Section 70(3) of the Australian Patents Act is ambiguous with respect to the meaning of the date of first ARTG approval that is the date on which goods “containing or consisting of, the substance” get first listed on the ARTG. The word “containing” could include products like enantiomers or impurities.

In Lundbeck’s case, PTE for *Escitalopram* was initially rejected based on the fact that it was not the first ARTG approval. The *Citalopram* product was the first ARTG approval which contains *Citalopram* which is a mixture of enantiomers containing *Escitalopram*. The Court considered the *Citalopram* as first ARTG registration to cover *Escitalopram*. Similarly in Merck case, the active ingredient *Lovastatin* was present as an impurity in prior ARTG registration for other product. In both of these cases, substances whose registration in the ARTG was considered as first were not falling into the scope of the patent.

Australia does not provide the pediatric extension to already granted PTE in reward of performing pediatric studies. In contrast, USA awards six months extension to the PTE, if successful studies have been carried out in the pediatric patients. European authority moves one step ahead; they not only grant six months extension in return of performing pediatric studies but also provides negative PTE, like in *Sitagliptin* case in UK. In that case, the PTE calculation based on European PTE formula was giving “negative value” meaning the difference between the First Drug Approval and the Basic patent filing date was less than five years. As a result the PTE was not possible but Merck applied for six months of pediatric extension for *Sitagliptin* and got it. Eventually, when the six months were added to the “negative value” it came out to be positive value, finally Merck was successful in getting few months of the extension for *Sitagliptin*.¹³

Pediatric studies are important for taking care of infants and new born. If Australia allows extension in reward of performing pediatric studies, then innovator companies will be encouraged to perform the clinical studies in pediatric patient population. Both Australia and Europe grant multiple PTEs to single product registration for different patents. However, US allow only one extension per product and only one extension per patent. In Australia, multiple PTEs are allowed to same product or patents resulting into extension of the monopoly and results in excessive pricing by innovators.

The requirements of disclosure as pharmaceutical substance *per se* are quite flexible in Australia as seen in *Sanofi* ruling. However, in Europe, recent rulings demand the product to be identified and specifically disclosed in the basic patent. Under the Australian regulation, the PTE can be granted to novel compositions having modified therapeutic profiles whereas in Europe in similar case examples the Court rejected the PTE application stating that composition

cannot be qualified as active ingredient when it is present in the mixture with other agents like excipients which do not have any activity.

The conclusion of the comparison of PTE provisions of Australia with PTE provisions in USA and SPC provisions in Europe is summarized in Table 1.

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