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# Study on the Legal Aspects of Supplementary Protection Certificates in the EU

Annex II: International Reports

Max Planck Institute for Innovation and Competition

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# Study on the Legal Aspects of Supplementary Protection Certificates in the EU

Annex II: International Reports

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# INDEX

# 1 AUSTRALIA

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Australia does not have a system of Supplementary Protection Certificates for pharmaceutical (or other) products. Instead, in Australia, the owner of a patent claiming a pharmaceutical substance may obtain one extension of the term of the patent (**EoTerm**) if certain substantive and procedural requirements are met. The key requirements are that the patent claims a pharmaceutical substance, that the pharmaceutical substance is contained in a therapeutic good that has received regulatory approval, and that the EoTerm application is filed within six months of the later of the filing date of the patent and the date of first regulatory approval of a therapeutic good containing the pharmaceutical substance. The maximum EoTerm is five years, and the maximum "effective life" of the patent (i.e., the term following the first regulatory approval of a good containing the pharmaceutical substance claimed in the patent) is 15 years.

The EoTerm applies to the entire patent. However, the patentee's enforceable exclusive rights are significantly limited during the extended term to therapeutic uses of the pharmaceutical substance *per se*. A person owning multiple pharmaceutical patents relating to the same pharmaceutical substance may seek an EoTerm in respect of each of them, provided they timely file the EoTerm application (or obtain an extension of time within which to do so).

## 1.1 SOURCES OF LAW

In Australia, the owner of a patent claiming a pharmaceutical substance may obtain an extension of the term of the patent if certain substantive requirements[1] and procedural requirements[2] are met.

EoTerms for pharmaceutical patents are governed by Part 3 of Chapter 6 of the *Patents Act 1990* (Cth) (**Australian Patents Act**) (sections 70-79A). The source of the Australian Government's power to legislate in respect of patents is section 51(xviii) of the Australian Constitution. EoTerms are also subject to the regulations set out in Pt 2 of Ch 6 of the *Patents Regulations 1991* (Cth) (regs 6.7-6.11) (**Australian Patent Regulations**). Regulations are made by the Governor-General (acting on advice from Ministers) under section 228 of the Australian Patents Act. The Governor-General is the representative of The Queen in Australia.

The current EoTerm provisions in the Australian Patents Act were introduced in 1998 by way of amendments contained in the *Intellectual Property Laws Amendment Act 1998* (Cth) (**IP Amendment Act**).[3] They came into effect on 27 January 1999.[4] The EoTerm provisions apply to:

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1 Discussed in section 1.5. below.

2 Discussed in section 1.5.4 below.

3 *Intellectual Property Laws Amendment Act 1998* (Cth), s. 3 and Sch. 1.

4 *Intellectual Property Laws Amendment Act 1998* (Cth), s. 2. The Government Gazettes from 1998 and 1999 do not record any day being fixed for commencement by proclamation. Accordingly, the

a) all standard patents[5] granted on or after 27 January 1999; and
b) standard patents granted before 27 January 1999, other than a standard patent granted for a term of 16 years and whose term at the time of the grant was due to end before 1 July 1995.[6]

## 1.2 LEGAL NATURE

In Australia, where an EoTerm is sought and the EoTerm requirements are met, the term of the patent is extended. No separate or *sui generis* right comes into existence; rather, the duration of the patent is increased by a particular period of time.[7]

## 1.3 RATIONALE OF PATENT TERM EXTENSION

Regulatory approval for therapeutic goods (which includes pharmaceutical substances) must be obtained before they can be marketed in Australia. The regulatory approval takes the form of entry in the Australian Register of Therapeutic Goods (**ARTG**). The EoTerm provisions in the Australian patent legislation arose from the federal parliament's recognition that a pharmaceutical patentee is unable to commercially exploit a patent until regulatory approval has been received in respect of a product claimed by the patent.[8]

In the Explanatory Memorandum to the bill that became the IP Amendment Act, the government expressed the objectives of the EoTerm provisions as follows:

> The objective of this proposal 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. It is also intended to provide a patent system that is competitive with other developed nations.[9]

The Explanatory Memorandum makes clear that the EoTerm provisions were seen as important for attracting investment in research and development (**R&D**) in Australia's pharmaceutical industry.[10]

## 1.4 GRANTING AUTHORITY

An EoTerm application is made to the Commissioner of Patents.[11] The Commissioner of Patents is a public servant within Australia's intellectual property office, IP Australia. IP Australia is a federal government agency that falls under the Department of Industry, Innovation and Science.[12]

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extension of pharmaceutical patents provisions came into effect 6 months after the act received Royal Assent. The act received Royal Assent on 27 July 1998: Government Gazette No. GN 34, Wednesday, 26 August 1998, p. 2886.

5 Standard patents are explained further in section 1.5.1.2. below.

6 *IP Amendment Act*, Sch. 1, item 8.

7 The calculation of this period is explained in Section 1.5.

8 Ann Dufty and James Lahore, *Patents, Trade Marks & Related Rights*, Service 196 (April 2017), [5935]; Harris, T., Nicol, D., Gruen, N., 'Pharmaceutical Patents Review Report' (2013, Canberra) 61-62.

9 Explanatory Memorandum to the *Intellectual Property Laws Amendment Bill 1997* (Cth), p. 4.

10 *Ibid.* 3, 5, 6, 7, 9.

11 Australian Patents Act, s. 70(1).

12 See <https://www.ipaustralia.gov.au/about-us/agency-overview>.

The Commissioner must grant the EoTerm 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.[13]

In Australia, the authority responsible for granting regulatory approvals in respect of therapeutic goods is the Therapeutic Goods Administration (**TGA**). The TGA is part of the federal government Department of Health.[14] The TGA is not involved in decisions concerning EoTerms. However, in respect of an approved EoTerm, the patentee must lodge with the Secretary of the Department of Health:

a) the amount and source of Commonwealth funds spent on R&D for the pharmaceutical product;
b) the name of anybody with which the patentee has a contractual agreement and which has received Commonwealth funds; and
c) the total amount spent on each type of R&D (including pre-clinical research and clinical trials) in respect of the pharmaceutical product.[15]

These reporting provisions were introduced to assist the Australian Government to determine if the EoTerm provisions were achieving the objective of encouraging investment in R&D in Australia's pharmaceutical industry. A recent review of Australia's pharmaceutical patent system found that these reporting provisions are not meeting this objective. The information provided is inconsistent and of little value. Further, the Australian Government does not appear to be actively using it.[16]

## 1.5 SUBSTANTIVE ASPECTS

### 1.5.1 Subject matter eligible for patent term extension

#### *1.5.1.1 Technical fields where patent term extension is possible*

In Australia, only patents that in substance disclose and claim a "pharmaceutical substance"[17] are eligible for an EoTerm.[18] Patents claiming the invention of a plant product, a medical device, or an implantable device through which a medical product is administered are not eligible for an EoTerm, even though they may have a therapeutic effect.

#### *1.5.1.2 Category of patents eligible for patent term extension*

In Australia, there are two categories of patents, both of which are national: a standard patent and an innovation patent.[19] A standard patent is the stronger type of

13 Australian Patents Act, s. 76.
14 See TGA, *TGA basics* Therapeutic Goods Administration <https://www.tga.gov.au/tga-basics>.
15 Australian Patents Act, s. 76A.
16 Harris, T., Nicol, D., Gruen, N. 2013 *Pharmaceutical Patents Review Report*, Canberra, pp. 89-92.
17 See section 1.5.1.3. below.
18 Australian Patents Act, s. 70(2).
19 See Australian Patents Act, Sch. 1 (definition of "patent").

protection, with a usual term of 20 years from the filing date.[20] An innovation patent (Australia's equivalent of a utility model) is the weaker type of protection, with a usual term of eight years from the filing date.[21] An EoTerm is only available for standard patents. The term of an innovation patent, including an innovation patent claiming a pharmaceutical substance, cannot be extended.[22] The specific types of claimed inventions that may support an EoTerm are discussed in section 1.5.1.3. below.

An EoTerm is available for patents that disclose and claim a pharmaceutical substance so long as goods containing, or consisting of, that pharmaceutical substance, are listed on the ARTG.[23] The focus of the EoTerm inquiry is not on whether or not there is a new product with regulatory approval. The focus is on whether or not there is a patented pharmaceutical substance and a good or goods containing that substance have received regulatory approval. That there are multiple ARTG registrations of goods containing the claimed pharmaceutical substance has no bearing on the EoTerm for the patent. However, the patent may only be extended once. Further, provided that timing requirements are met, there is no barrier to the extension of multiple patents on the basis of a single ARTG registration.[24] This allows for patentees to "hedge their bets" by seeking EoTerms in respect of multiple patents as a quasi-insurance policy against a finding of patent invalidity.

#### *1.5.1.3 Pharmaceutical substance*

The "pharmaceutical substance" requirement of an EoTerm application is satisfied if either or both of the following conditions are met:

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; and/or
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.[25]

The term "pharmaceutical substance" is defined as:

> a substance (including a mixture or compound of substances) for therapeutic use ["therapeutic use" is defined further below] whose application (or one of whose applications) involves:
> a) 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.[26]

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20 Australian Patents Act, s. 67; Colin Bodkin, *Patent Law in Australia* (2008), Lawbook Co., Sydney, p. 14; Rodney M De Boos, "Patents", in Andrew F Christie (ed.), *The Laws of Australia – Intellectual Property*, [23.4.10].

21 Australian Patents Act, s. 68.

22 Ann Dufty and James Lahore, *Patents, Trade Marks & Related Rights*, Service 196 (April 2017), [5936]; Colin Bodkin, *Patent Law in Australia* (Thomson Reuters, 2nd ed., 2014), [15090].

23 See section 1.5.2.3. below.

24 Cf. Harris, T., Nicol, D., Gruen, N., 'Pharmaceutical Patents Review Report' (2013, Canberra) 103-104; Peter Maddigan, Damian Slizys and Paul Whenmann, *Patent Term Extensions in Australia* in Arne Markgraf (ed) *Ergänzende Schutzzertifikate - Patent Term Extensions* (2015), Nomos, Baden-Baden.

25 Australian Patents Act, s. 70(2).

26 Australian Patents Act, Sch. 1.

A "therapeutic use" means use for the purpose of:

a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons;
b) influencing, inhibiting or modifying a physiological process on persons; or
c) testing the susceptibility of persons to a disease or ailment.[27]

A "pharmaceutical substance" must itself be the subject of a claim. It is not enough that the substance appears in a claim in combination with other integers or as part of the description of a method (or process) that is the subject of a claim.[28] The policy adopted in section 70 was to confine extensions to patents that claim the invention of the substance itself.[29]

A "pharmaceutical substance" is not limited to a new chemical entity. It also covers a formulation. A solution in ready-to-use form comprising a physiologically acceptable salt of the anti-tumor anthracycline glycoside was held to be a "pharmaceutical substance *per se*",[30] as was a controlled release oxycodone formulation (oxycodone is a well-known drug used to provide pain relief and was first patented in Germany in 1916).[31] Thus, in principle, it is possible to obtain an EoTerm in respect of two patents, one claiming the non-salt form of a pharmaceutical substance, and the other claiming a salt form or new formulation. However, it is important to note that this possibility is subject to the EoTerm application timing requirement discussed in section 1.5.4. below. In general, the EoTerm application must be filed within the later of six months after: (i) patent grant and (ii) the date of first inclusion on the ARTG of goods containing or consisting of the pharmaceutical substance. The first inclusion on the ARTG of a good containing the pharmaceutical substance is the relevant date and not any subsequent date on which a salt form or a formulation of that substance is included on the ARTG. Note also that there is some inconsistency in Australian Patent Office decisions concerning the meaning of "pharmaceutical substance".[32]

The Australian Federal Court has cited with approval the following examples in the *Patent Manual of Practice & Procedure* of what does, and what does not, constitute a "substance" *per se*.[33]

Examples of claims that are directed to substances *per se* include:

- a substance of formula ----- ;
- substance X mixed with substance Y.

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27 Australian Patents Act, Sch. 1.
28 See section 1.5.2.2. below.
29 *Prejay Holdings Ltd v Commissioner of Patents* (2003) 57 IPR 424, [24].
30 *Pharmacia Italia SpA v Mayne Pharma* (2006) 69 IPR 1, [99].
31 *Spirit Pharmaceuticals Pty Ltd v Mundipharma Pty Ltd* (2013) 216 FCR 344, [1], [62]-[67], [71], [73]-[75].
32 Ann Dufty and James Lahore, *Patents, Trade Marks & Related Rights*, Service 196 (April 2017), [5935.10].
33 Patent Manual of Practice & Procedure, [3.12.1.1 Pharmaceutical Substance *per se*]; *Boehringer Ingelheim International v Commissioner of Patents* [2000] FCA 1918 (22 December 2000) [18]-[19] (decision affirmed in *Boehringer Ingelheim International GmbH v Commissioner of Patents* [2001] FCA 647).

Examples of claims that are not directed to substances *per se* include:

- substance X when used .... ;
- substance X when produced by method Y;
- a method of preparing substance X;
- a substance of formula ...., where component Y is produced by .... ;
- "Swiss" style claims referring to substance X;
- use of substance X in the treatment of Y;
- substance X for use .... ;
- (a specified quantum) of substance X.

Thus, claims to second medical uses for a known substance X and "Swiss" style claims may not be used to support an EoTerm application.[34] Even if substance X was never previously the subject of an MA and the MA on which applicant relies is the first MA, there can be no EoTerm for X because a claim to a second medical use of X, or a claim to the use of X in the manufacture of a medicament for the treatment of disease Y, is a claim to a use of pharmaceutical substance, not to a pharmaceutical substance *per se*. A Swiss-style claim or a method of use claim would not be directed to the invention of the pharmaceutical substance itself (see 1.5.1.3. above).

Australian Patent Office decisions indicate that the combination of two substances *may* constitute a pharmaceutical substance *per se* as "a mixture or compound of substances" (see the definition of "pharmaceutical substance above"), provided the two together form a substance.[35] However, the combination of a substance with what would reasonably be considered a separate physical device, layer or structure would not be a "pharmaceutical substance *per se*."[36] A patent claiming the use of two known active substances in combination, which combination does not involve any chemical interaction between the two to produce a new pharmaceutical substance, would likely not meet the "pharmaceutical substance" requirement. This is because such a patent would likely be construed as directed towards a method, and method patents are not eligible for EoTerms. If the "mixture or compound of substances" together formed a substance claimed in a patent claim, then it should be possible to obtain an EoTerm for that patent. This would be the case, irrespective of whether or not one or more of the ingredients comprising the "mixture" had previously been included on the ARTG. This is of course subject to the EoTerm application requirements being met, including that the patent has not previously been extended. An example, although an improbable one, may help illustrate the point: there are two patents filed on the same date; one for enantiomer A and one for a racemate containing enantiomer A and enantiomer B. Enantiomer A is included on the ARTG and marketed. Subsequently, the racemate is registered on the ARTG. It would be possible to obtain an EoTerm for the patent claiming the racemate and the relevant date of first inclusion on the ARTG would be the date on which the racemate was registered on the ARTG, not the date on which enantiomer A was registered on the ARTG.

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[34] The inability to obtain an EoTerm for a patent reciting a pharmaceutical substance in a "Swiss" style claim applies even where the recited pharmaceutical substance is produced by a process that involves recombinant DNA technology: *Commissioner of Patents v AbbVie Biotechnology Ltd* [2017] FCAFC 129. Thus, it is clear that the express requirement in s. 70(2)(a) of the Australian Patents Act that the patent's claim is directed to a pharmaceutical substance "per se" also applies to s. 70(2)(b).

[35] Patent Manual of Practice & Procedure, [3.12.1.4 Meaning of "mixture or compound of substances"].

[36] *Re NV Organan* [2009] APO 8, [22].

### 1.5.2 Conditions for granting a PTE

#### *1.5.2.1 Premise*

Section 70 sets out the substantive requirements for obtaining an EoTerm, which are:

a) the patent in substance discloses and claims: (i) one or more pharmaceutical substances *per se*, or (ii) one or more pharmaceutical substances when produced by a process that involves the use of recombinant DNA technology;[37]
b) goods "containing, or consisting of," the substance are included in the ARTG;[38]
c) the first regulatory approval for that pharmaceutical substance occurred more than 5 years after the date of the patent;[39]
d) the term of the patent has not have been previously extended.[40]

These requirements are discussed in turn.

#### *1.5.2.2 Patent in substance discloses and claims a pharmaceutical substance*

The requirement that the patent "in substance discloses" a pharmaceutical substance means that there must be a "real and reasonably clear disclosure" of the pharmaceutical substance in the body of the patent specification.[41]

The requirement that the patent "in substance claims" a pharmaceutical substance is not satisfied merely by virtue of the pharmaceutical substance being an integer (i.e. a component or an element) of a claim. What is required is that the pharmaceutical substance itself must be "included among the things claimed" in the patent – that is to say, it must be the "thing claimed in the patent sense".[42]

#### *1.5.2.3 ARTG entry requirement*

Goods "containing, or consisting of," the substance must be included in the ARTG.[43] Testing this requirement involves a simple comparison of the pharmaceutical substance with the "ingredients" of the corresponding good on the ARTG.[44] The word "contain" is a word of plain meaning, denoting a physical relationship that is something less than "consist of."[45]

The following goods would likely meet the ARTG entry requirement:

a) a combination of two active substances, provided one of the substances is disclosed and claimed in the patent;

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37 Australian Patents Act, s. 70(2).
38 Australian Patents Act, s. 70(3)(a).
39 Australian Patents Act, s. 70(3)(b).
40 Australian Patents Act, s. 70(4).
41 *Pfizer Inc v Commissioner of Patents* (2005) 141 FCR 413, [75].
42 *Boehringer Ingelheim International GmbH v Commissioner of Patents* [2001] FCA 647, [42].
43 Australian Patents Act, s. 70(3)(a).
44 *H Lundbeck A/S v Alphapharm Pty Ltd* (2009) 177 FCR 151, [239].
45 *H Lundbeck A/S v Alphapharm Pty Ltd* (2009) 177 FCR 151, [234]-[242].

b) a combination of two active substances where each: (i) is disclosed and claimed in the patent, (ii) constitutes a pharmaceutical substance *per se*, and (iii) is contained in a good on the ARTG;
c) a combination of an active ingredient with an adjuvant (or with a new adjuvant), provided the active ingredient, or the adjuvant, or the two together claimed as one invention, is disclosed and claimed in the patent;
d) an enantiomer, where either the enantiomer or the racemate is disclosed and claimed in the patent. Further, a patent claiming an enantiomer of a previously patented racemate may be eligible for an EoTerm. This could be the case even where the previously patented racemate was the subject of an ARTG registration, provided that the EoTerm application is timely filed or an extension of time within which to file is obtained (the application timing requirement is discussed in section 1.5.4.1 below);[46] and
e) a salt of a drug.[47]

(a) *"Timing of regulatory approval" requirement*

The first regulatory approval for the pharmaceutical substance must have occurred at least five years after the date of the patent.[48] The date of the patent is generally the date of filing of the relevant complete specification.[49] This provision limits EoTerms to cases where it took at least five years from the date of filing the patent to obtain regulatory approval for a good containing, or consisting of, a pharmaceutical substance claimed in the patent.

(b) *"No previous extension" requirement*

The term of the patent must not have been previously extended.[50]

### *1.5.2.4 Right to request and obtain an PTE*

In Australia, the holder of the ARTG registration (known as the "sponsor") may be a person other than the patentee. However, only the patentee may apply for an EoTerm.[51] Further, the patentee does not require the sponsor's agreement to apply for an EoTerm: the patentee may apply even if the sponsor does not agree to the EoTerm. However, it would be open to the sponsor (as it is open to any person) to file an opposition to the grant of the EoTerm.[52] The fact that the sponsor does not agree to the patentee seeking an EoTerm is not a ground on which an otherwise valid application for EoTerm can be refused.

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46 *Alphapharm P/L v H Lundbeck A/S* (2015) 234 FCR 306.
47 In the series of disputes between Lundbeck and Alphapharm concerning a patent claiming an enantiomer of the racemate citalopram, namely, escitalopram, the relevant first inclusion on the ARTG of a good "containing, or consisting of," that pharmaceutical substance was the inclusion of Cipramil as the salt citalopram hydrobromide (i.e., the salt of the racemate): *H Lundbeck A/S v Alphapharm Pty Ltd* (2009) 177 FCR 151, [106].
48 Australian Patents Act, s. 70(3)(b).
49 Australian Patents Act, s. 65.
50 Australian Patents Act, s. 70(4).
51 Australian Patents Act, s. 70(1).
52 Oppositions are explained further in section 1.5.4.3. below.

#### *1.5.2.5 Period of PTE (calculation of term)*

The length of the EoTerm is equal to the time between the date of the patent and the date of first regulatory approval (the **Approval Time**), minus five years.[53] Accordingly, no EoTerm is available where the Approval Time is five years or less.[54] The maximum length of the EoTerm is five years, irrespective of the length of regulatory delay.[55] This allows for a maximum "effective life" of 15 years. The duration of a standard patent in Australia is 20 years.[56] It follows that the maximum duration of a patent that is the subject to an EoTerm is 25 years.

To illustrate, take a patent with a date of 1 July 2017. If that patent is renewed for the maximum duration, it will expire on 1 July 2037 unless there is an EoTerm. If the date of first regulatory approval is 1 July 2020, no EoTerm will be available because the Approval Time is less than five years – meaning the maximum duration of the patent will be 20 years and the "effective life" will be 17 years. However, if the date of first regulatory approval is 1 July 2027, the EoTerm will be five years (Approval Time of 10 years minus five years) – meaning the maximum duration of the patent will be extended to 25 years (expiring 1 July 2042) and the "effective life" will be 15 years. Note that, if the date of first regulatory approval is 1 July 2028, the EoTerm will still be five years (because the maximum length of the EoTerm is 5 years) – meaning the maximum duration of the patent will be extended to 25 years (expiring 1 July 2042) and the "effective life" will be 14 years.

#### *1.5.2.6 Scope of protection*

Where an EoTerm has been granted, the effect is to extend the *duration* of the patent. It follows that the scope of protection afforded by a patent that is subject to an EoTerm is the same[57] as the scope of protection afforded by the patent prior to the EoTerm taking effect. While Australian patent law does not recognise a "doctrine of equivalents" as such, it does adopt "a purposive approach to patent construction and apply that construction in the context" of determining infringement.[58] That doctrine will apply, where appropriate, to the determination of the scope of protection afforded by a patent that is the subject of an EoTerm in the same manner, and to the same extent, as it applies to the determination of the scope of protection afforded by that patent prior to the EoTerm taking effect. Under a purposive construction, the skilled addressee "reads the specification on the assumption that its purpose is both to describe and to demarcate an invention – a practical idea which the patentee has had for a new product or process – and not to be a textbook in mathematics or chemistry or a shopping list of chemicals or hardware". [59]

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53 Australian Patents Act, s. 77.

54 As noted in Andrew F. Christie, Saba Elkman and Melanie J. Howlett, 'Review of Pharmaceutical Patent Extension and Springboarding Provisions in Various Jurisdictions' (Research Report, Intellectual Property Research Institute of Australia, 2002) 21, this is consistent with s. 70(3)(b), which requires a minimum period of 5 years between the date of the patent and the first regulatory approval date as a condition of applying for an EoTerm.

55 Australian Patents Act, s. 77(2).

56 Australian Patents Act, s. 67.

57 Subject to the limitation on the rights conferred, discussed in section 1.5.6.

58 *PhotoCure ASA v Queen's University at Kingston* [2005] FCA 344, [158]. See also: *Catnic Components Ltd v Hill & Smith Ltd* [1982] RPC 183, 242-3; *Populin v HB Nominees Pty Ltd* (1982) 59 FLR 37, 42-3.

59 *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd* [2005] 1 All ER 667, 680. Cited with approval in *Kimberly-Clark Australia Pty Limited v Multigate Medical Products Pty Limited* (2011) 92 IPR 21, 25.

### 1.5.3 Rights conferred by the extended patent

A patent for an invention gives the patentee the exclusive right to "exploit" the invention in Australia.[60] Where the invention is "a product" (which is what an invention being "a pharmaceutical substance" is considered to be), the right to "exploit" the invention includes the rights to make, use and sell the product.[61]

The exclusive rights of the patentee under a patent that is the subject of an EoTerm are significantly limited during the period of the extension compared with the rights of the patentee under that patent prior to the EoTerm commencing.[62] During the extended term, the patentee's rights are not infringed by a person who exploits (i.e. who makes, uses, sells, etc.):

a) the pharmaceutical substance for non-therapeutic uses; or
b) any form of the invention that is not the pharmaceutical substance.[63]

The patentee's exclusive rights during the extended term are thus limited to therapeutic uses of the pharmaceutical substance *per se*.[64] It is worth noting that the pharmaceutical substance claim will not be infringed by a person exploiting the pharmaceutical substance for the purposes of obtaining regulatory approval during either the original term or the extended term of the patent (see section 1.5.6).[65]

To illustrate, consider a patent containing: (i) a claim to the pharmaceutical substance *per se* and (ii) a dependent method claim involving use of that substance to treat a medical condition. Consider further that the pharmaceutical substance claim is revoked as invalid, but the method claim is upheld as valid. In principle, during the extended term, the patentee would have no enforceable exclusive rights under the patent. This is because, although the method claim is valid, it is a form of the invention that is not the pharmaceutical substance *per se*.[66]

### 1.5.4 Procedural aspects

The substantive benefits of an EoTerm may be lost to a patentee who does not comply with the procedural requirements.[67] The procedural requirements are explained below.

#### *1.5.4.1 Timing of application*

There are two timing requirements for an EoTerm application, both of which must be satisfied. The first of these (the **First Timing Requirement**) is that the application must be made during the term of the patent.[68] The second of these (the **Second**

60 Australian Patents Act, s. 13.
61 Australian Patents Act, schedule 1 (definition of "exploit").
62 Australian Patents Act, s. 78; Ann Dufty and James Lahore, *Patents, Trade Marks & Related Rights*, Service 196 (April 2017), [5935.70].
63 Australian Patents Act, s. 78.
64 *Spirit Pharmaceuticals Pty Ltd v Mundipharma Pty Ltd* (2013) 216 FCR 344, [50]-[53].
65 Australian Patents Act, s. 119A.
66 To our knowledge, this scenario has not been considered by an Australian court. However, the outcome is consistent with *Spirit Pharmaceuticals Pty Ltd v Mundipharma Pty Ltd* (2013) 216 FCR 344.
67 The procedural requirements (form and timing of the EoTerm application) are set out in s. 71 of the Australian Patents Act.
68 Australian Patents Act, s. 71(2).

**Timing Requirement**) is that the application must be made within 6 months after the latest of:

a) the date the patent was granted;
b) the date of first inclusion on the ARTG of goods containing or consisting of any of the pharmaceutical substances relied on to meet the pharmaceutical substance requirement; and
c) 27 July 1999 (the date of commencement of the EoTerm provisions.[69]

The First Timing Requirement may be considered a substantive condition of an EoTerm, because it is not extendable.[70] However, the Commissioner of Patents has the power to extend the Second Timing Requirement.[71]

If the EoTerm application is made before, but granted after, patent expiry, then the EoTerm is treated as having started on the original expiry date. Thus, the patentee may seek remedies for any infringement of its limited EoTerm rights that occur between patent expiry and grant of the EoTerm.[72]

Australian law does not provide for an interim EoTerm.

#### *1.5.4.2 Form of application*

An EoTerm application must be in the approved form, and must be accompanied by documents and information specified in the Australian Patent Regulations.[73]

The filing fee for an EoTerm application is currently A$2,000.[74] Annual renewal fees are also payable in respect of an extended patent.[75]

#### *1.5.4.3 Opposition to acceptance of application*

Any person may oppose the grant of an EoTerm, and only on the ground that the substantive requirements of section 70 and/or the procedural requirements of section 71 have not been met.[76] Any opposition must be filed within three months from the day notice of acceptance of the EoTerm application is published.[77] The EoTerm applicant and the opponent may appeal to the Federal Court against the decision of the Commissioner in the opposition proceeding.[78]

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69 Australian Patents Act, s. 71(2).
70 Australian Patents Act, s. 223 read together with Australian Patent Regulations, r. 22.11(4)(b); *Alphapharm Pty Ltd v H Lundbeck A/S* (2014) 254 CLR 247, [68], [73].
71 *Alphapharm Pty Ltd v H Lundbeck A/S* (2014) 254 CLR 247, [69]-[74].
72 Australian Patents Act, s. 79.
73 Australian Patents Act, s. 71(1). The approved form is currently available at: <https://www.ipaustralia.gov.au/tools-resources/forms/application-extension-term-no-pre-tga-marketing-approval>.
74 Australian Patents Regulations, Sch. 7, Part 2, item 238 of Table of fees—general fees.
75 Australian Patents Act, s. 143(a) read together with Australian Patent Regulations, Sch. 7, Part 2, item 211(q) of Table of fees—general fees.
76 Australian Patents Act, s. 75(1).
77 Australian Patents Act, s. 75(2) read together with Australian Patent Regulations, r. 5.4(2).
78 Australian Patents Act, s. 75(4).

### 1.5.5 The interplay with other forms of exclusivity

In Australia, an applicant for entry of a new chemical entity on the ARTG has the benefit of data exclusivity provisions under section 25A of the *Therapeutic Goods Act 1989* (Cth). The data exclusivity period is five years from the date of entry of that entity on the ARTG.[79] No provision is made in Australian legislation for the potential interplay between EoTerms and data exclusivity. However, it would only be in highly unusual circumstances that the data exclusivity period would extend beyond the expiry of an EoTerm.

### 1.5.6 Exemptions from infringement

#### *1.5.6.1 Bolar exemption*

Australia has a Bolar exemption.[80] Under Australia's Bolar exemption, acts undertaken solely for the purposes of obtaining regulatory approval of a pharmaceutical product are not an infringement of a patent. The exemption does not apply to the export of goods for the purposes of obtaining regulatory approval in a foreign country, unless the export takes place during the extended term of a patent that is the subject of an EoTerm.[81]

#### *1.5.6.2 Manufacturing waiver*

As of 25 August 2015, a person may make an application to the Federal Court for an order that a compulsory licence be granted to exploit a patented pharmaceutical invention to the extent necessary to enable the manufacture of a pharmaceutical product in Australia for export to an eligible importing country.[82] An "eligible importing country" includes a country in the list of least-developed countries maintained by the United Nations.[83]

#### *1.5.6.3 Other exemptions*

Australian patent law has exemptions from infringement, *inter alia*, for prior use[84] and for acts done for experimental purposes.[85] These exemptions apply to a patent that is the subject of an EoTerm in the same manner, and to the same extent, as they apply to that patent prior to the EoTerm taking effect.

The legislation provides that there is no infringement if the relevant act of exploitation (in this scenario, the manufacture of the pharmaceutical substance) is "for a purpose other than therapeutic use". The legislation defines a "therapeutic use" to mean, in essence, use for the purpose of treating disease, modifying a physiological process or testing susceptibility to disease. Although this question has not been addressed by an Australian court, we believe that the manufacture of the pharmaceutical substance for export for therapeutic use abroad would not be considered to be for a purpose other

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79 *Therapeutic Goods Act 1989* (Cth), s. 25A(2)(e).
80 Australian Patents Act, s. 119A.
81 Australian Patents Act, s. 119A(2).
82 Australian Patents Act, s. 136D; Ann Dufty and James Lahore, *Patents, Trade Marks & Related Rights*, Service 196 (April 2017), [20,305].
83 Australian Patents Act, Sch. 1 read together with Australian Patent Regulations, r. 1.4A, 1.3(1).
84 Australian Patents Act, s. 119.
85 Australian Patents Act, s. 119C.

than a therapeutic use. That is to say, we believe that the "other than therapeutic use" limitation only makes non-infringing a manufacture of the pharmaceutical substance where the substance will not be used in a therapeutic manner, whether that be in or outside Australia.

# 2 CANADA

*Prof. Giuseppina D'Agostino* Joseph F Turcotte Ph.D ***

## 2.1 SOURCES OF LAW

On 31 October 2016, an *Act to implement the Comprehensive Economic and Trade Agreement between Canada and the European Union and its Member States and to provide for certain other measures* **(Bill C-30)** [86] was introduced to Canada's House of Commons. Bill-30 received Royal Assent on May 16, 2017 and Certificate of Supplementary Protection Regulations were published in the Canada Gazetta on September 7, 2017[87] and Health Canada Guidelines were issued on September 21, 2017.[88]

Bill C-30 amends statute law in Canada, in general, and the *Patent Act* and other Acts of Parliament, in particular,[89] pursuant to Canada's obligations under the Canada-European Union Comprehensive Economic and Trade Agreement **(CETA)**.[90] The Government of Canada implements legislative changes that result from international trade agreements,[91] but as this practice is not constitutionally enshrined implementation can become complicated in matters of provincial jurisdiction.[92] Since the changes to the *Patent Act* contained in Bill C-30 related to pharmaceuticals could affect the delivery of health care services, a matter of provincial jurisdiction, these changes may garner scrutiny from provincial governments. However, as the provinces were consulted during the CETA negotiations, the likelihood of impending challenges is minimal. Furthermore, Bill C-30 is in line with the precedent of federal implementation of international trade obligations and changes to the *Patent Act* fall under the federal government's constitutional jurisdiction over 'Patents of Invention and Discovery'.[93]

A particular concern in this study is Bill C-30's introduction of the concept of a "certificate of supplementary protection", benefiting patent holders of inventions

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86 *Bill C-30, An Act to implement the Comprehensive Economic and Trade Agreement between Canada and the European Union and its Member States and to provide for certain other* measures, 1st Sess, 42nd Parl., 2017. http://www.parl.gc.ca/LegisInfo/BillDetails.aspx?Language=E&Mode=1&billId=8549249.

87 *Certificate of Supplementary Protection Regulations,* SOR/2017-165 September 1, 2017, Canada Gazette, EXTRA Vol. 151, No. 1, September 7, 2017. http://www.gazette.gc.ca/rp-pr/p2/2017/2017-09-07-x1/html/sor-dors165-eng.body.html.

88 *Guidance Document - Certificate of Supplementary Protection Regulations,* Health Canada, September 21, 2017. http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/csp/csp-guide-cps-ld-eng.php.

89 *Patent Act,* R.S.C. 1985, c. P-4. http://laws-lois.justice.gc.ca/PDF/P-4.pdf.

90 *Canada-European Union Comprehensive Economic and Trade Agreement* (signed 30 October 2016) (CETA). http://www.international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/ceta-aecg/text-texte/toc-tdm.aspx?lang=eng.

91 D. Steger, 'Canadian Implementation of the Agreement Establishing the World Trade Organization', in *Implementing the Uruguay Round*, eds. J.H. Jackson & A.O. Sykes (Oxford: Clarendon Press, 1997).

92 J. de Beer, 'Implementing International Trade Agreements in Federal Systems: A Look at the Canada-EU CETA's Intellectual Property Issues', *Legal Issues of Economic Integration* 38, no. 4 (2012): 51-71.

93 *Constitution Act*, 1867, 30 & 31 Victoria, c. 3 (U.K.), s. 92(22). http://laws-lois.justice.gc.ca/eng/Const//page-4.html#docCont. See also, J. de Beer & C. Brusnyk, 'Intellectual Property and Biomedical Innovation in the Context of Canadian Federalism', *Health Law Journal* 19 (2011): 45-82.

related to medicinal ingredients or combinations of medicinal ingredients, essentially pharmaceutical-related patents. While similar certificate frameworks exist in the European Union to provide additional patent protection for patented pharmaceutical[94] and plant protection products,[95] this CSP scheme is unprecedented in Canada. Certificates of supplementary protection **(CSPs)** will provide additional protection for existing patents based on the amount of time between the granting of a patent and the authorization to sell products based on that patent. The proposal to introduce CSPs generated criticism within Canada from groups worried about the repercussions on prescription medicine costs[96] and negative effects on the country's generic pharmaceutical industry.[97] Others found the potential drawbacks and associated costs to be relatively minimal and easily offset by other legislative measures.[98] Ultimately, it is too soon to tell which, if any, consequences will manifest as the legislation was only implemented recently.

## 2.2 SUI GENERIS PROTECTION

The amendments to the *Patent Act* outlined in Bill C-30 relate to Article 20.27 of the CETA. Article 20.27.2 states:

> "Each Party shall provide a period of *sui generis* protection in respect of a product that is protected by a basic patent in force at the request of the holder of the patent or his successor in title, provided the following conditions have been met:
>
> a) an authorisation[99] has been granted to place the product on the market of that Party as a pharmaceutical product (referred to as "marketing authorisation" in this Article)
> b) the product has not already been the subject of a period of *sui generis* protection; and
> c) the marketing authorisation referred to in subparagraph (a) is the first authorisation to place the product on the market of that Party as a pharmaceutical product."

Paragraph 50 of Bill C-30 sets out extensive changes to the *Patent Act* (by adding new sections at the end of the final section of the existing Act – §103), which outline the *sui generis* framework for CSPs in Canada, described in detail below. These changes will effectively provide for longer periods of patent protection for up to 2 years, consistent with the *sui generis* protection term period between two to five years prescribed in the CETA.[100]

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94 Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products. http://eur-lex.europa.eu/eli/reg/1992/1768/oj.

95 Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products. eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31996R1610.

96 J. Lexchin & M. Gagnon, 'CETA and Pharmaceuticals Impact of the trade agreement between Europe and Canadaon the costs of patented drugs', *Canadian Centre for Policy Alternatives Briefing Paper*, October 2013.

97 *Bill C-30: Canada-European Union Comprehensive Economic and Trade Agreement (CETA) Implementation Act,* Submission of the Canadian Generic Pharmaceutical Association to the Standing Committee on International Trade, 28 Nov. 2016. www.parl.gc.ca/Content/HOC/ Committee/421/CIIT/Brief/BR8680557/br-external/*CanadianGenericPharmaceuticalAssociation*-e.pdf.

98 D. Schwanen & A. Jacobs, 'Patents, Copyright and Competition: Assessing the Impact of Trade Deals on Canada', *CD Howe Institute Commentary*, No. 474. https://www.cdhowe.org/sites/default/files/attachments/research_papers/mixed/Commentary_474.pdf.

99 Note, Bill C-30 uses *authorization*.

100 *Supra note 86,* §E Art. 20.27.5.

## 2.3 REASONS FOR INTRODUCING CERTIFICATES OF SUPPLEMENTARY PROTECTION

As noted, Canada's *Patent Act* has not previously included a *sui generis* framework for CSPs and Bill C-30 is silent on the specific rationale for these amendments. However, the Summary of Bill C-30 clearly states the overarching goal of the Bill's provisions to be compliant with Canada's obligations under the CETA:

> "Part 2 amends certain Acts to bring them into conformity with Canada's obligations under the Agreement and to make other modifications. In addition to making the customary amendments that are made to certain Acts when implementing such agreements, Part 2 amends
>
> […]
>
> (b) the Patent Act to, among other things,
> (i) create a framework for the issuance and administration of certificates of supplementary protection, for which patentees with patents relating to pharmaceutical products will be eligible, […]".[101]

Paragraph 7(f) further states that a purpose of Bill C-30 is to "provide adequate and effective protection and enforcement of intellectual property rights in the territory where the Agreement applies." Health Canada's Guidance Document indicates:

> "The CSP regime implements Canada's commitment in CETA by providing for an additional period of protection for drugs containing a new medicinal ingredient, or a combination thereof, protected by an eligible patent. This new protection, which is intended to partly compensate for time spent in research and obtaining marketing authorization, provides patent-like rights in respect of drugs containing a medicinal ingredient or combination of medicinal ingredients."[102]

Amendments to introduce CSPs in Canada's *Patent Act* provide patent holders with the ability to secure supplementary protection for the duration of time it takes a patent holder to receive an authorization for sale – up to a maximum of two years. In effect, CSPs provide patent holders with the ability to receive protection for time necessary to acquire the authorization for sale necessary to sell their product(s) in the Canadian market. CSPs thus allow the patent term to be restored and account for the typical delay times that exist from the granting of the patent to the actual authorization to sell healthcare products based on that patent. Delays are commonly the result of the time required for clinical trials and testing and obtaining regulatory approvals, where the patent "clock" term would otherwise be running. These changes also bring Canada's patent system in line with other international jurisdictions and trading partners.[103]

## 2.4 GRANTING AUTHORITY

In line with existing practice relating to authorizations for sale and associated public health concerns, Canada's Minister of Health is responsible for issuing the patent holder a CSP for the patented invention (§113). Applications for a CSP are required to include: (1) the patent number (as recorded in the Patent Office), (2) the medicinal ingredients or combination of medicinal ingredients, (3) the number of the authorization for sale related to the CSP being sought as well as, (4) when necessary,

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101 *Supra note 86*, ii.
102 *Supra note 86,* 1.2.
103 *Patent Term Extensions and Adjustments*, The Law Library of Congress, March 2016. https://www.loc.gov/law/help/patent-terms/patent-term-extensions-adjustments.pdf

the day when an application for a marketing approval or equivalent to an authorization for sale was made in a country other than Canada. Other prescribed information may be required (§106[5]).

Applications for a CSP must meet all of the following conditions (Para. 59 §106[1]), which are equivalent to the conditions necessary for extending protection in Europe:

> "(a) the patent is not void and it meets any prescribed requirements;
> (b) the filing date for the application for the patent is 5 on or after October 1, 1989;
> (c) the patent pertains in the prescribed manner to a medicinal ingredient, or combination of medicinal ingredients, contained in a drug for which an authorization for sale of the prescribed kind was issued on or after the day on which this section comes into force;
> (d) the authorization for sale is the first authorization for sale that has been issued with respect to the medicinal ingredient or the combination of medicinal ingredients, as the case may be;
> (e) no other certificate of supplementary protection has been issued with respect to the medicinal ingredient or the combination of medicinal ingredients, as the case may be;
> (f) if an application for a marketing approval, equivalent to an authorization for sale, was submitted in a prescribed country with respect to the medicinal ingredient or combination of medicinal ingredients, as the case may be, before the application for the authorization for sale was filed with the Minister, the application for the authorization for sale was filed before the end of the prescribed period that begins on the day on which the first such application for a marketing approval was submitted."

The Minister shall issue a CSP to the patent holder if, on the day of issuance: (1) the Minister is satisfied that the above requirements are met, (2) the application has been filed prior to the end of the prescribed term of protection or authorization for sale, (3) there are no other applications pending relating to the same authorization for sale that has the same or higher priority than the application, and (4) any court proceedings relating to the application or another application relating to the same authorization for sale with the same or higher priority has been disposed of (§ 113). In other words, only one CSP is allowed per patent.

## 2.5 SUBSTANTIVE ASPECTS

### 2.5.1 *Subject matter and fields protected*

Bill C-30 amends Canada's *Patent Act* to provide supplementary *sui generis* protection for medicinal ingredient inventions[104] to a maximum of 2 years. Paragraph 46(2) defines medicine and rights holder accordingly:

> "*medicine* includes a *drug*[105] as identified in section 104 [of the revised *Patent Act*, as set out in Clause 59], and a medicinal ingredient; (*médicament)*
>
> *rights holder* means, in respect of an invention pertaining to a medicine, a patentee and the person for the time being entitled to the benefit of a certificate of supplementary protection for that invention, and includes, if any other person is entitled to exercise rights in relation to the certificate, that other person in respect of those rights; (*titulaire de droits*)".

[104] The *Patent Act* defines *invention* as "any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter; (*invention*).

[105] Para. 59 adds section 104 to the *Patent Act* and defines a *drug* as "a substance or a mixture of substances manufactured, sold or represented for use in (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals; or (b) restoring, correcting or modifying organic functions in human beings or animals. (*drogue*)".

Subsequently, in Para. 59, Bill C-30 adds subsections 105(1-6), which state that the *sui generis* protection is available for substances or mixtures of substances sold or represented for use in human beings as well as animals. In cases of medicinal ingredients contained in a drug authorized for use in human beings and animals, the medicinal ingredients or combination of medicinal ingredients are to be treated as different medicinal ingredients or combinations.

However, if medicinal ingredients contained in drugs authorized for use in *only* human beings *or* animals differ only in so far as being a prescribed variation, the medicinal ingredient(s) is to be treated as the same medicinal ingredient(s). Similarly, if the combination(s) of medicinal ingredient(s) differ only in so far as being a variation of the ratio between those ingredients, the combination of medicinal ingredients is to be treated as the same, where the drug is authorized for use in *only* human beings *or* animals.

#### *2.5.1.1 Category of patents*

As discussed above, the *Patent Act* defines *invention* as "any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter; (*invention*).[106] Bill C-30 does not amend the definition of invention. In order for an existing invention of medicinal ingredients to be eligible for a CSP, the product to which the marketing approval relates must have been previously granted a patent, which has not expired. As per §106(1)(c), CSPs will only be granted to patents related to drugs including medicinal ingredients or combinations of medicinal ingredients.

In order for a medical treatment or medical device to qualify for a CSP, the initial patent application must have been approved and relate to a pharmaceutical invention (drug). The *Food and Drugs Act* defines "device" as:

> "device means an instrument, apparatus, contrivance or other similar article, or an in vitro reagent, including a component, part or accessory of any of them, that is manufactured, sold or represented for use in
> (a) diagnosing, treating, mitigating or preventing a disease, disorder or abnormal physical state, or any of their symptoms, in human beings or animals,
> (b) restoring, modifying or correcting the body structure of human beings or animals or the functioning of any part of the bodies of human beings or animals,
> (c) diagnosing pregnancy in human beings or animals,
> (d) c aring for human beings or animals during pregnancy or at or after the birth of the offspring, including caring for the offspring, or
> (e) preventing conception in human beings or animals;
> however, it does not include such an instrument, apparatus, contrivance or article, or a component, part or accessory of any of them, that does any of the actions referred to in paragraphs (a) to (e) solely by pharmacological, immunological or metabolic means or solely by chemical means in or on the body of a human being or animal; (instrument)".[107]

In general, in order for medical treatments or medical devices to be patentable, method claims need to be presented as use claims; *The Manual of the Patent Office* indicates that such use claims "are scrutinized closely to ensure they do not equate to a medical or surgical method, for example by the inclusion of a medical or surgical

[106] *Supra note* 89.
[107] *Food and Drugs Act*, R.S.C. 1985, c. F-27. http://laws-lois.justice.gc.ca/PDF/F-27.pdf.

step."[108] The Canadian Intellectual Property Office does not allow patents for methods of medical treatment that provide a practical therapeutic benefit to a subject.[109] Section 17.02.03a of the *Patent Office: Manual of the Patent Office* clarifies that such medical treatments relate to the amelioration of an ailment or a pathological condition. Not all natural conditions are considered to be pathological; for example, methods to treat the effects of ageing are not proscribed. Furthermore, methods involving surgery – "the excision of tissue, organ, or tumour samples from the body" – on human beings or animals are also excluded.[110] A CSP will only apply to the patented drug itself.

### 2.5.2 *Requirements for CSPs*

As mentioned above, Bill C-30 proposes amendments similar to the European requirements for granting supplementary protection: (Para. 59 §106[1a]) a valid patent is in force, (Para. 59 §106[1c]) the patented medicinal ingredient(s) is a component of a drug that has been granted authorization for sale, and (Para. 59 §106[1e]) no other CSP has been previously issued for the medicinal ingredient(s). Bill C-30 further limits CSPs to the first authorization for sale issued with respect to the medicinal ingredient or combination of medicinal ingredients (Para. 59 §106[1d]) and each application for a CSP may only set out one patent (Para. 59 §106[6]).

As well, Bill C-30 includes an amendment to counter conflicts relating to competing claims over medicinal ingredients. Para. 59 proposes a new §106(1e) that states a CSP can only be granted if "no other certificate for supplementary protection has been issued with respect to the medicinal ingredient or combination of medicinal ingredients, as the case may be." §106(6) further states that "each application is permitted to set out only one patent." §108(2) and §108(3) clarify how CSP applications will be prioritized: applications for a CSP based on patents granted on or before the date the authorization for sale was issued will have priority over applications based on patents granted after the authorization for sale was issued; the priority between applications is deemed the same in cases where two or more applications are based on the same patent granted before the authorization for sale. If two or more pending applications set out the same authorization for sale and have the same priority, "the Minister shall provide each applicant with a written notice setting out the name and contact information of all the applications, as well as the number, as recorded in the Patent Office, of the patent set out in each application".[111]

Under Bill C-30, only the patent holder is eligible to obtain a CSP. Under the *Patent Act*, the patentee is defined as the person entitled to the benefit of a patent for the prescribed period of time. Authorizations for sale are generally issued to the manufacturer of a drug, however, the patent holder or their representative must apply for the CSP. At the time of filing, the applicant(s) for a CSP must attest that the patent holder is the recorded owner of the patent in the CIPO or that a manufacturer is authorized by the recorded patent holder to file a CSP application relating to the

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108 CIPO, *Patent Office: Manual of the Patent Office*, 1998 Ed. (updated January 2017), 17.02.03a & 11.10.02. https://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/vwapj/rpbb-mopop-eng.pdf/$file/rpbb-mopop-eng.pdf.

109 *Ibid.* at 12.05.02.

110 *Ibid.* at 17.02.03a.

111 *Supra note* 86 at, Para. 59 §109.

patent if the notice of compliance was issued to the manufacturer.[112] Conflicts between competing applications are dealt with through the allocation of priority for applications, described above, or through court proceedings for situations where the same priority is held by conflicting applicants.

## 2.6 CALCULATION OF TERM

The period of supplementary protection in Canada set out in Bill C-30 is for a maximum of 2 years. The term of the CSP is calculated by subtracting 5 years from the difference between the filing date of the patent application and the date on which the authorization for sale was issued.[113] In cases where this calculation results in a 0 or negative value, a CSP cannot be granted. This period may be reduced if both the holder of the authorization for sale and patent holder are the same person and if the Minister determines that it was the person's own actions that caused a delay in the process of obtaining the authorization for sale:

> §116(4) "Despite subsection (3), if the person to whom the authorization for sale set out in the certificate is issued is also the patentee, the Minister may, if he or she is of the opinion that that person's failure to act resulted in a period of unjustified delay in the process of obtaining the authorization for sale, reduce the term of the certificate when issuing it by the amount of that period".

## 2.7 SCOPE OF PROTECTION AND RIGHTS CONFERRED

The CSP grants the certificate's holder and their legal representatives the same rights and privileges granted by the patent named in the certificate. These rights and privileges only relate to the "making, constructing, using and selling of any drug that contains the medicinal ingredient, or combination of medicinal ingredients set out in the certificate, by itself or in addition to any other medicinal ingredient" (Para. 59 §115[1]). However, these rights do not apply to any person who performs such actions for the purpose of exporting the product from Canada (Para. 59 §115[2]).

## 2.8 EXAMINATION AND PROCEDURE

Upon the payment of a prescribed fee, the patent holder may apply to the Minister of Health for a CSP for a medicinal ingredient or combination of medicinal ingredients as set out in an authorization for sale. To be eligible: (1) a patent must not be void, (2) the filing date for the patent is on or after 1 October 1989, (3) the patented medicinal ingredient or combination of medicinal ingredients is contained in a drug for which an authorization for sale was issued on or after the day on which Bill C-30 comes into force, (4) the authorization for sale is the first authorization for sale issued for the medicinal ingredient or combination of medicinal ingredients, (5) no other CSP has been issued with respect to the medicinal ingredient or combination of medicinal ingredients, and, (6) if an application for a marketing approval equivalent to an

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112 *Supra note 86*, 6. Based on Bill C30, the Certificate of Supplementary Protection Regulations, and Health Canada's CSP Guidance Document, the applicant can be either the patent holder or the holder of the authorization for sale (with the permission of the patent holder).The application and documents do not require the patent holder to attest that the holder of the authorization for sale is involved in the application.

113 *Supra note 86,* § 116[3].

authorization for sale was submitted in another country with respect to the medicinal ingredient or combination of medicinal ingredients before the application for an authorization for sale was filed in Canada, the application for sale must have been filed prior to the end of the prescribed period that begins on the day in which the first such application was submitted (§ 106[1]). Notably, another CSP is deemed to have been issued even if that CSP has been deemed invalid, never takes effect or ceases to have effect:

> §106(2) "Another certificate of supplementary protection is considered to have been issued for the purposes of paragraph (1)(e) even if that other certificate is subsequently held to be invalid or void or it never takes effect or ceases to have effect."

The Minister of Health shall issue a CSP to the patent holder if, on the day of issuance: (1) the Minister of Health is satisfied that all requirements listed in § 106 have been met, (2) the applicable period referred to in § 106(3) has ended, (3) no other applications for the same authorization for sale with the same or higher priority are pending, and (4) any court proceedings brought forth with respect to applications with the same priority have not been disposed (§ 113).

A CSP or an application for a CSP is not transferrable unless the patent, or part of the patent set out in the certificate or application, has also been transferred. In such cases where the whole patent is transferred, the CSP or application for a CSP is transferred accordingly. In such cases where part of the patent is transferred, any part of the CSP or application for a CSP that corresponds to the transferred part of the patent is transferred accordingly. The transfer of part of an application for a CSP does not result in the division of the application into more than one application (§ 118).

## 2.9 CSPs AND DATA EXCLUSIVITY

In Canada, new drugs are provided with 8 years of data exclusivity.[114] The data exclusivity provides the manufacturer of an innovative drug 8 years of market exclusivity, which can be extended a further 6 months when pediatric use information is provided. For these purposes, an *innovative drug* is defined as "a drug that contains a medicinal ingredient not previously approved in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph (*drogue innovante*)."[115] Any drug that contains medicinal ingredients that have been previously approved in Canada will not receive protection.[116] As the term of a patent exceeds the period of data exclusivity, it is unlikely that a CSP will be affected by data exclusivity.

## 2.10 EXEMPTIONS

The *Patent Act* currently contains a research exemption (§ 55.2[1]), which states:

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114 *Food and Drug Regulations*, § C.08.004.1, C.R.C., c. 870. http://laws.justice.gc.ca/eng/regulations/c.r.c.,_c._870/page-135.html#docCont

115 *Ibid.*

116 *Guidance Document: Data Protection under C.08.004.1 of the Food and Drug Regulations*, Health Canada. http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/data_donnees_protection-eng.php.

> "It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product."[117]

Bill C-30 does not amend this section and, as mentioned above, explicitly provides a waiver for the manufacturing of protected drugs for export from Canada (Para. 59 §115[2]). This research exemption will allow Canadian generic pharmaceutical companies to continue to export generic medicines to developing countries, practices that were allowed via changes to the *Patent Act* in 2004.[118] The provisions are in line with the CETA's commitment to recognize the *Doha Declaration on the TRIPS Agreement and Public Health* and associated World Trade Organization decisions and protocols.

## 2.11 CONCLUSIONS

The changes Bill C-30 makes to Canada's *Patent Act* are intended to comply with Canada's obligations under the CETA. Bill C-30 proposes substantial changes to Canada's *Patent Act*, most notably the proposals contained in the Supplementary Protection for Inventions — Medicinal Ingredients clause of the Bill (Cl. 59) by adding new sections 104 to 134 to the *Patent Act*.[119] As detailed above, these changes will implement a *sui generis* form of patent protection for pharmaceutical and healthcare-related products that offsets the amount of time between the granting of a patent and its approval for sale. The changes made via Bill C-30 attempt to strike a balance between the private rights of patent holders to commercialize and benefit from their inventions and domestic and international public health concerns relating to the availability and affordability of generic drugs and access to medicine. Further analysis will be necessary in due course and should also consider the implementation of the CSP framework and the directives to be issued by the Ministry of Health and Patent Office. For now, the changes proposed in Bill C-30 will bring Canada's pharmaceutical patent system in compliance with CETA and in line with the broad patent frameworks in the European Union and its member countries.

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117 *Supra note* 87, 54.

118 K. Douglas, 'Patent Protection for Pharmaceutical Products in Canada —Chronology of Significant Events', *Parliament of Canada-Law and Government Division*, PRB99-46E. http://www.lop.parl.gc.ca/ content/ lop/ResearchPublications/prb9946-e.htm

119 A. Gauthier, 'Legislative Summary of Bill C-30: An Act to implement the Comprehensive Economic and Trade Agreement between Canada and the European Union and its Member States and to provide for certain other measures', *Library of Parliament Research Publications* 42-1-C30-E, 22 Nov. 2016. http://www.lop.parl.gc.ca/About/Parliament/LegislativeSummaries/bills_ls.asp?ls=c30&Parl=42&Ses=1 &source=library_prb&Language=E#a17.

# 3 ISRAEL

*Tal Band* Yair Ziv***

## 3.1 SOURCES OF LAW

Patent term extensions for new medical products and medical devices were first incorporated into the Israeli Patents Law,[120] back in 1998. At the time, the Israeli PTE legislation was drafted uniquely, whereby calculation of the patent extension period was based on a formula linking the Israeli patent extension term and expiration, with that applicable to parallel patent extension terms in other jurisdictions, which already provided PTE. The Israeli linkage mechanism entailed that Israel PTE periods, in and of themselves, would not exceed the corresponding PTE periods and expiry dates granted in other countries. The applicable provisions of Israeli law relevant for PTE in Israel are sections 64A-P of the Patents Law. Issues dealing with PTE deadlines can be found in section 164 of the Patents Law.

## 3.2 LEGAL NATURE OF PTE

PTE in Israel is formally separated from the basic patent (see section 3.5.1.2 below), and only enters into force upon the expiry of the term of the basic patent. A PTE application may be opposed or grant of the PTE order revoked, regardless of the basic patent.

According to the Patents Law, where a PTE order, has been infringed, the holder of the PTE order shall be entitled to all the remedies provided under the Patents Law with respect to patent infringement, *mutatis mutandis*.

However, in terms of the scope of protection provided by means of PTE, it may not be considered an extension of the basic patent. The Patents Law provides that the holder of a PTE may prevent any person from marketing, or manufacturing for the purpose of marketing, the medical device or medical product containing the protected compound, for so long as the compound, its manufacturing process or its use or the medical product or its manufacturing process are claimed in the basic patent. Thus, there is no extension of the basic patent across its original scope, but rather an extended protection (providing similar remedies), limited to one specific product.

It is important to note that since the applicability of PTE depends on the validity of both the marketing authorization and the basic patent, PTE shall expire in Israel if the pertinent marketing authorization expires, as well as if the basic patent has either been revoked or amended so that it no longer protects the compound, its manufacturing process or its use or the medical product containing the compound or its manufacturing process, or the medical device.

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120 The Patents Law, 5727–1967 (**"the Patents Law"**).

## 3.3 RATIONALE OF PTE

Israel enacted PTE provisions into its legislation despite not being obligated to do so by any multilateral treaty. It was political pressure applied by the United States Government that ultimately convinced the Israeli legislator to provide for PTE in the Patents Law, at the same time as Israel enacted a "Bolar-type" exemption for the protection of patents.[121]

The main purpose of the Israeli PTE legislation was reviewed by both the Supreme Court[122] and the District Court in Jerusalem.[123] The Courts emphasized that the 1998 amendment to the Patents Law[124] introduced two new arrangements relating to the protection of patented drugs, in order to preserve a balance between the conflicting interests of the originator drug companies[125] and the generic companies. The first arrangement was a "Bolar-type" exemption, which abolished the *de facto* extension granted to products which require regulatory approval as a pre-condition for their marketing. This was the main purpose of the amendment. However, to "counterweight" the newly introduced "Bolar-type" exemption, a provision for PTE was also introduced into the Patents Law. The purpose for enacting the PTE legislation was to enable the patent owner to be compensated for the period of time taken to obtain marketing approval of a new drug by the Israeli Ministry of Health.

The District Court explained that the PTE legislation was designed to promote the interests of the generic pharmaceutical companies, and that benefiting the originator drug companies was merely incidental, and not an independent goal. This was because of the importance that the legislator attributes to the activity of the generic companies in the context of promoting the public interest (together with the public interest of encouraging research and development of new drugs by the originator drug companies). The public interest as promoted by the generic pharmaceutical companies incorporates their meaningful contribution to Israeli exports, the availability and provision of jobs for numerous employees (mostly academics), together with the benefit that the public derives from competition in the pharmaceutical market, and the accompanying reduction in the price of drugs. It was emphasized that this tendency of the legislator had remained constant over the years since enactment of the 1998 amendment. For example, in 2006, the Patents Law was again amended[126] to provide that the calculation of PTE in Israel (in terms of number of days) would be based on the shortest extension term granted in any of the reference countries (see section 3.7 below).[127]

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121 Explanatory notes of the bill to amend the Patents Law (Amendment No. 3) Bills 2651, p. 76 (27.10.1997); Tal Band, 'Pushing the limits of IP protection for pharmaceuticals via the Special 301 Report: The Israel experience' (2009) 6, 3 Journal of Generic Medicines 218.

122 LCA 8127/15 *The Manufacturers' Association of Israel v Merck Sharp & Dohme Corp*. (Published in Nevo.co.il, 15.6.2016), sections 8- 9.

123 MA (Jer) 223/09 *H. Lundbeck A/S v Unipharm Inc.* (Published in Nevo.co.il, 25.5.2009) [Patent no. IL90465] (**"Lundbeck"**), section 11.

124 The Patents Law (Amendment No. 3), 5758-1998.

125 Lundbeck (n 123), 11.

126 The Patents Law (Amendment No. 7), 5766-2006.

127 *Ibid.*

## 3.4 GRANTING AUTHORITY

The Registrar of Patents[128] is vested with sole authority for granting PTE orders in Israel and likewise bears sole responsibility for determining whether or not the conditions for granting PTE have been satisfied. It was held in Lundbeck[129] that the act of registering a medical product, although performed by the Ministry of Health, is merely one of the factual circumstances that is reviewed by the Registrar. The Court further emphasized that it is the Patents Law, and not the legislation to which the Ministry of Health is subject (such as the Pharmacists Ordinance[130]), that provides the considerations underlying the decision to grant PTE.

The Ministry of Health is, therefore, not deemed the competent authority for determining whether or not any of the conditions pertinent to the PTE application have been met. In this context, it was held that the Registrar has the exclusive authority to deal with the question as to whether a particular registration of a medical product, would be considered the first time such registration enabled use of the compound contained in the medical product for medicinal purposes in Israel. Therefore, no exchange of information between the Registrar and the Ministry of Health will be required in the context of satisfying the substantial conditions for granting PTE in Israel.

As for calculation of the period of PTE, according to the relevant principles (see section 3.7 below), in most (if not all) cases, such calculation is based on (1) the date first marketing authorization is obtained for the drug protected by PTE in a reference country; and (2) the extension period granted to, and expiry of, PTEs in the reference countries. Only in extremely rare cases, where registration of the medical product was applied for in Israel, and not in any reference country, would calculation of the period of PTE be based on the equivalent regulatory review period of the medical product at the Ministry of Health (provided that the applicant seeking PTE acted diligently in submitting and prosecuting the application for registration of the medical product). In these particular circumstances, the Registrar will need to obtain the pertinent information contained in the Ministry of Health records and provided by the applicant itself.

## 3.5 SUBSTANTIVE ASPECTS

### 3.5.1 Subject matter eligible for patent term extension

#### *3.5.1.1 Technical fields where patent term extension is possible*

PTEs are granted only for new medical products and medical devices that require registration, provided that such products/devices satisfy all the relevant requirements.

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128 The Registrar of Patents, Designs and Trademarks ("**the Registrar**") heads the Israel Patents, Designs and Trademarks Office (**"the ILPTO"**). The Registrar is conferred with both administrative and judicial powers. The Registrar is also responsible for examining and registering other intellectual property rights, namely trademarks and designs. Plant breeder's rights are registered in a separate registry.

129 Lundbeck (n 123).

130 The Pharmacists Ordinance (New Version), 5741-1981 (**"the Pharmacists Ordinance"**).

The distinction between medical products and medical devices is drawn in guidelines issued by the Ministry of Health on the subject.[131] Products are categorized as either medical products or medical devices according to their primary mode of action. Drug coated implantable devices are categorized as medical devices, since their primary mode of action is to function as medical device. However, if a certain medical product is intended to operate by means of a medical device, and its primary mode of action is to function as a medical product, such product will be considered a medical product. It is nonetheless noted in the guidelines that for categorisation proceses a relevant expert opinion may be required, including with respect to the quality of the medical product contained in the medical device.

#### *3.5.1.2 Category of patents eligible for patent term extension*

The Patents Law allows for PTE to be granted in respect of certain "basic patents". The term "the basic patent" is defined in the Patents Law as the patent that protects any compound, its manufacturing process or its use or a medical product containing the compound or its manufacturing process or a medical device that requires registration in Israel. As a consequence, both patents claiming a product or a process (including methods of use, provided that the claims covering such process are viewed as process claims) are, in principle, eligible for PTE.

#### *3.5.1.3 A medical product containing the active ingredient*

The concept of active ingredient was considered in Israel in the context of the requirement that registration of the medical product, subject matter of the PTE, is the first registration enabling use of the compound contained in the medical product for medicinal purposes in Israel.[132]

The term "compound" is defined in the Patents Law as the active ingredient in a medical product, or salts, esters, hydrates or polymorphs of said ingredient.[133] Since the said definition includes salts, esters, hydrates or polymorphs, it is clear that these derivatives would not be considered a new compound. In Lundbeck[134] it was held that the registration of a medical product containing an enantiomeric form, would not be considered the first registration enabling use of the compound contained in the medical product for medicinal purposes in Israel, where a medical product containing the racemate has already been registered, since the racemate contains the enantiomer. It was also explained in that case that any change in the purity of a compound will not affect its identity, and therefore will not constitute a new product.

In another case, it was held that a combination of two active substances, each of which having already been contained in a previously registered medical product, would not be considered a new compound.[135] A medical product will, therefore, satisfy the "first registration" requirement only where it contains at least one compound that was not contained in a previously registered medical product.

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131 Ministry of Health Circular No. 47 – Classification of medical products and devices, September 2002 (last amended in November 2005).
132 The Patents Law (n 120), section 64D(3).
133 The Patents Law (n 120), section 64A.
134 Lundbeck (n 123).
135 MA 1063/06 (Tel-Aviv Yafo) *Novartis AG v The Registrar of Patents, Designs and Trademarks* (published in Nevo.co.il, 26.2.2007) [Patent no. IL97219].

A fortiori, it is clear that changes such as the addition of an adjuvant to an active ingredient contained in a previously registered medical product will not constitute a new product for the purposes of obtaining PTE, for so long as the molecular structure of the active ingredient remains, and no new compound is formed.

## 3.5.2 Conditions for granting a PTE

### *3.5.2.1 Premise*

A basic patent may be eligible for PTE in Israel only where it complies with a number of substantial conditions as set out in the Patents Law.

A preliminary requirement for obtaining PTE in Israel is that the application for PTE was filed in good faith, and that the Registrar is convinced that the scope of protection sought under the PTE application will not exceed the protection afforded by the basic patent.[136] The remaining requirements are listed in section 64D of the Patents Law, which provides (in free translation) as follows:

a) The compound, its manufacturing process or its use or the medical product or its manufacturing process or the medical device, is claimed in the basic patent and the basic patent continues to remain in effect.
b) For a medical product - a medical product containing the compound is registered in the Registry of medical products according to section 47A of the Pharmacists Ordinance.
c) The registration according to paragraph (b) above is the first registration enabling use of the compound contained in the medical product for medicinal purposes in Israel.
d) No PTE was previously granted with respect to the basic patent or the compound.
e) If marketing authorization for the relevant medical product was granted in the US, PTE was similarly granted for such product in the US, and has yet to expire.
f) If marketing authorization for the relevant medical product was granted in a recognized EU member state (France, Germany, Italy, Spain and the United Kingdom), PTE was similarly granted for such product in the same state, and has yet to expire.
g) If marketing authorizations for the relevant medical product were granted in the US and in a recognized EU member state, PTEs were similarly granted for such product in the US and in such member state, and have yet to expire.

The conditions set out in paragraphs (e)–(g) above are known as the "two states" requirement, which provision was incorporated into the Patents Law in 2006, and was formulated in the context of the unique situation in Israel, where only in extremely rare cases, would registration of the medical product be applied for only in Israel, and not in any reference country. The legislator thus sought to clarify that PTEs in Israel are not granted for a theoretical period, but rather on the basis of grant of a reference PTE in the US and/or in Europe. The "two states" requirement also accords with the unique formula that applies in Israel for calculation of the period of PTE (see section

[136] The Patents Law (n 120), section 64B.

3.7 below). That requirement is meant to achieve generic competition in the Israeli market if it exists in any of the reference countries.

#### *3.5.2.2 First requirement: the product must be claimed by a patent in force*

The first requirement for granting PTE in Israel, as provided in section 64D(1) of the Patents Law, corresponds, in principle, to Art. 3(a) Reg. 469/2009: The compound, its manufacturing process or its use or the medical product or its manufacturing process or the medical device, must be claimed in the basic patent and the basic patent must continue to remain in effect. All the requirements for granting PTE must therefore be met prior to the expiry of the underlying basic patent.

The typical requirement that may lead to a situation in which the basic patent is about to expire, but not all of the conditions can be met, is the "two states" requirement. The Patents Law provides, in this context, that PTE applications will remain valid until such time as corresponding PTEs are granted in the US and in at least one other EU reference country, but no later than the expiration of the underlying basic patent in Israel. If, by that cut-off date, no PTE (or SPC) has been granted in both the US and one other EU reference country (where the medical product has been approved for marketing), or no notice is given of the grant of PTE (or SPC) orders within the specified timeframe, then no corresponding PTE (whether interim or final), may be granted in Israel.

It is important to note two specific situations in which PTE may be granted after the expiry of the underlying basic patent: (1) where the PTE application satisfies all the relevant requirements, save for the "two states" requirement, the applicant must notify the Registrar of Patents that the relevant PTE (or SPC) has been granted (or denied) within 90 days thereof. According to the Patents Law, notifying the Registrar of grant of the PTE (or SPC) within such 90 day period, may be considered valid even if the underlying basic patent expired during such 90 day time frame, provided that the relevant PTE (or SPC) was granted prior to the expiration of the underlying basic patent (section 64E(e) of the Patents Law); and (2) the Patents Law sets out strict timeframes for filing, examining and deciding PTE applications. However, the Patents Law also provides that the Registrar must complete examination of the application, and decide any opposition to a PTE application, if filed, "as much as possible" prior to expiration of the underlying basic patent (section 64O of the Patents Law).

The requirement regarding protection by the basic patent is specified in the Patents Law. First, the compound, its manufacturing process or its use or the medical product or its manufacturing process or the medical device, must be claimed in the basic patent (section 64D(1) of the Patents Law). Second, the scope of protection granted by virtue of PTE is limited to the compound, its manufacturing process, its use or the medical product or its manufacturing process or the medical device to the extent claimed in the basic patent (section 64H of the Patents Law). Third, a precondition for obtaining PTE is that the scope of protection sought pursuant to the PTE application will not exceed the protection afforded by the basic patent (section 64B of the Patents Law). For example, in one case[137] the Registrar granted PTE based on the medical

[137] PTE application no. 117459 *Merck Sharp & Dohme Corp.* (Published in Nevo.co.il, 11.1.2015) ("**the Gardasil® case**").

product Gardasil®, which contains four independent active ingredients, only one of which was claimed in the basic patent. The registration of Gardasil® was the first registration enabling the use of one of the active ingredients (HPV 18 L1) for medicinal purposes in Israel. With respect to the scope of protection, the Registrar emphasized that although the medical product contains several active ingredients, the protection afforded by means of PTE is limited to the protection afforded by the basic patent, in so far as it protects HPV 18 L1. It was therefore clarified that PTE, as granted, applied only with respect to HPV 18 L1, and did not extend to the other active ingredients.

#### *3.5.2.3 Second requirement: registration of the medical product containing the compound*

The second requirement for granting PTE is that the medical product containing the compound will be registered in Israel. As provided in section 64D(2) of the Patents Law: For a medical product, it is necessary that the medical product containing the compound is registered in the registry of medical products according to section 47A of the Pharmacists Ordinance.

In a number of cases, the Registrar allowed PTEs for patents claiming an active ingredient, based on a combination medical product containing several active ingredients.[138] In any event, the protection afforded by PTE covering patents of such nature is limited to the protection afforded by the basic patent, in so far as it protects the claimed active ingredient.

In one case, the Registrar held that where a patent is claiming a combination, but not a certain compound in and of itself, it may not be considered that the compound is claimed in the patent.[139]

#### *3.5.2.4 The product has not already been the subject of a PTE*

As aforesaid, the corresponding requirement in Israel is provided in section 64D(4) of the Patents Law, namely, no PTE was previously granted with respect to the basic patent or the compound. Therefore, the principle of one PTE, one product, one patent is entrenched in the Patents Law.[140] It is noteworthy that the Registrar held[141] that more than one PTE application can be filed with respect to the same product, based on different patents or patent applications. However, since only one PTE can be granted, where several PTE applications are filed, all such applications will be examined, but only the first one to complete the examination process can be accepted and published for oppositions (Israel applies a pre-grant opposition system, for patents as well as for PTEs, see section 3.10 below). In general, where two applications complete the examination process simultaneously, the application that was first to be filed will prevail.[142]

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138 The Gardasil® case; PTE application no. 178152 Glaxo Group Limited (Published in Nevo.co.il, 13.4.2016).

139 PTE application no. 142728 Biogen IDEC International GmbH (Published in the ILPTO website, 21.5. 2015, 27.5.2015).

140 The Patents Law (n 120), section 64D.

141 PTE application no. 159512 Immunex Corporation (published on Nevo.co.il, 2.4.2015).

142 *Ibid*.

With respect to patents protecting second medical use, such patents may be considered basic patents which are eligible for PTE, as they relate to use of a compound. However, where the compound subject matter of such patents is included in an already registered medical product, the registration of the second medical indication will not be considered the first registration enabling use of the compound contained in the medical product for medicinal purposes in Israel.

## 3.6 RIGHT TO REQUEST AND OBTAIN A PATENT TERM EXTENSION

Although the Patents Law does not explicitly forbid a PTE application based on a marketing authorization obtained by a party other than the patentee, it is clear that the legislator intended to prevent such situations. The explanatory notes of the bill to enact PTE in Israel refer to PTE as compensation to patentees, who developed a new drug, but were precluded from marketing the new drug until completion of the authorization process.[143] In Lundbeck,[144] the court noted that compensation in the form of PTE correlates with the pre-condition to obtain marketing authorization for new drugs, in the sense that the purpose of PTE was to compensate the patentee for the period that had lapsed until issuance by the Ministry of Health of the relevant marketing authorization to the patentee.

## 3.7 PERIOD OF PATENT TERM EXTENSION (CALCULATION OF TERM)

As mentioned above, PTE in Israel is linked to that granted in other reference countries (currently the US, Italy, the United Kingdom, Germany, Spain and France) and comprises of the shortest possible term, based on the following principles:

a) *Shortest Period Principle*—calculation of PTE in Israel (in terms of number of days) shall be based on the shortest extension term granted in any of the reference countries;
b) *First to Expire Principle*—PTE in Israel will expire as soon as the first reference PTE order, or patent, in any other reference country, expires;
c) *Fourteen Years from first marketing authorization Cap*— the total combined protection afforded by the basic patent and PTE is limited to 14 years, commencing from the date first marketing authorization is obtained for the drug protected by PTE in a reference country;
d) *Five Years Maximum Cap*— In any event, the PTE period will not exceed five years beyond the elementary twenty-year period of protection granted by the basic patent.

## 3.8 SCOPE OF PROTECTION

The Patents Law provides that the holder of a PTE may prevent any person from marketing, or manufacturing for the purpose of marketing, the medical device or a medical product that contains the compound, in so far as the compound, its manufacturing process or its use or the medical product or its manufacturing process

[143] Explanatory notes of the bill to amend the Patents Law (Amendment No. 3) (n 124), 75.
[144] Lundbeck (n 123).

are claimed in the basic patent. The protection therefore extends only to the medical product (or medical device) as registered.

As aforesaid, the definition of the term "the basic patent" relates to the protection of any compound, its manufacturing process or its use or a medical product containing the compound or its manufacturing process or a medical device that requires registration in Israel. Therefore, since the term "protection" may include equivalents (according to the doctrine of equivalents which, in general, applies in Israel), the scope of protection may also include equivalents.

## 3.9 RIGHTS CONFERRED BY THE EXTENDED PATENT AND RIGHTS CONFERRED BY THE PTE

The Patents Law provides that infringement of a PTE confers on the owner (or exclusive licensee) of the basic patent the right to obtain all the remedies similarly available for a patent owner whose patent rights are infringed.

## 3.10 PROCEDURAL ASPECTS

The time to file a PTE application in Israel is 90 days from the date of registration of the medicinal product in accordance with the Pharmacists Ordinance. This timeframe is not extendable. An applicant for a basic patent is also required to file a PTE application in that identical timeframe (and prior to grant of the patent); however, in the event the basic patent has not yet been granted, its examination will commence within 30 days and completed as soon as possible. The PTE application will then be examined only once the basic patent is granted.

With respect to interim extension requests, it is noteworthy that in one case in the past, the Registrar granted an interim PTE where the basic patent was about to expire, but the corresponding PTE in the US had not yet been granted. This decision was opposed to by the Manufacturers' Association of Israel, and the Registrar ultimately decided to cancel the interim PTE, since 5 months has passed since the expiry of the basic patent, and the corresponding PTE in the US was not forthcoming. The applicant appealed to the District Court, which held that the Registrar is authorized to grant an interim PTE, if such remedy is required to satisfy the purpose of the legislation.[145] However, shortly after the said ruling, the patents law was amended and it now clearly provides that if, by the expiration of the underlying basic patent in Israel, no PTE (or SPC) has been granted in both the US and one other EU reference country (where the medical product has been approved for marketing), or no notice is given of the grant of PTE (or SPC) within 90 days of such grant, then no corresponding PTE (whether interim or final) may be granted in Israel.

The substantive examination of a PTE application shall begin within 60 days from its filing date. The applicant is required to respond to an office action and correct faults in the application within two months (extendable only once), and the Registrar shall complete the examination within 60 days from the filing date or correction of any

[145] LCA 33766-08-13 *BTG International Limited v The Manufacturers' Association of Israel.* (Published in Nevo.co.il, 10.11.2013) [Patent no. IL105078].

faults as aforesaid. Within 60 days from completion of the examination, the Registrar shall publish on the internet a notice of his intention to grant PTE and the period thereof, or a notice rejecting the PTE application.

If the Registrar is of the view that the conditions for the grant of PTE have been met save for the "two states" requirement (if marketing authorizations were granted in respect of the medicinal product in the US and in at least one reference EU country, then PTE orders must be granted and in force in the US and in such EU reference country, see section 3.5.2.1 above), the Registrar shall publish a notice of his intention to grant PTE, subject to the grant of reference PTE orders during the term of the underlying Basic Patent in Israel. The applicant is required to inform the Registrar of the grant of the reference PTE orders within 90 days (this timeframe is not extendable). If reference PTE orders are so granted, the Registrar shall publish a supplementary notice of his intention to grant PTE and the period thereof. If no reference PTE orders are granted, or no notice is given to the Registrar of the grant of such orders then, as aforesaid, no PTE (whether interim or final) shall be granted in Israel, and the Registrar shall publish a notice cancelling his said intention to grant PTE.

If a PTE application is rejected by the reviewing examiner, the applicant may apply to be heard by the Registrar in an ex parte procedure. If the Registrar rejects the application, the applicant may appeal to the District Court, and the Registrar will be a party to the proceedings as respondent. The District Court's judgment may be appealed to the Supreme Court only where leave to appeal is granted.

As mentioned above, Israel applies a pre-grant opposition system, for both patents and PTEs. Hence, where an opposition has been timely filed, PTE will be granted only if the opposition is finally rejected. In the event that a supplementary notice is published with regard to satisfaction of the "two states" requirement, an opposition may only be filed with respect to the existence of reference PTE orders. An opposition based on other grounds other grounds will only be heard if filed after publication of the first notice.

## 3.11 OTHER FORMS OF EXCLUSIVITY UNDER ISRAELI LAW FOR PHARMACEUTICAL INNOVATIONS

The Pharmacists Ordinance provides, under certain circumstances, protection to confidential data submitted as part of a marketing authorization application, provided that its origination entailed considerable effort. New chemical entities (**NCE**) registered in Israel are therefore entitled to a period of market exclusivity, during which the Ministry of Health will not issue a marketing authorization for a new medicinal product containing said NCE. The market exclusivity period will be capped by the earlier of the following:

a) six years from the registration date of the medicinal product that contains NCE in Israel; or

b) six years and six months from the registration date of the medicinal product that contains NCE in a recognised country.[146]

## 3.12 BOLAR EXEMPTION

The Patents Law provides a broad "Bolar-type" exemption that allows for experimental testing in order to obtain marketing authorization for a product following expiry of the patent. The "Bolar-type" exemption covers, *inter alia*, research for the purposes of obtaining marketing authorization in Israel as well as in any other country, in which an experimental act on a patent protected invention for the purpose of obtaining a licence is permitted before the patent expires. Commercial exploitation of a patented invention, where the "Bolar-type" exemption does not apply (on the premise that not all of the conditions were met), may constitute infringement of the patent, resulting in the infringer being liable to the sanctions provided under the Patents Law.

[146] A 'recognised country' is defined, for this purpose only, to mean Australia, Canada, members of the EU, Iceland, Japan, New Zealand, Norway, Switzerland and the USA.

# 4 JAPAN

*Prof. Yoshiyuki Tamura* Prof. Masahumi Suzuki** Prof. Ichiro Nakayama****

## 4.1 SOURCES OF LAW

In Japan, patent term extensions are regulated under Articles 67(2) to 68-2 of Patent Act No. 121 of April 13, 1959.

Article 67(2) Patent Act (Duration of patent rights)

Where there is a period during which the patented invention is unable to be worked because approvals prescribed by relevant Acts that are intended to ensure the safety, etc., or any other disposition designated by Cabinet Order as requiring considerable time for the proper execution of the disposition in light of the purpose, procedures, etc., of such a disposition is necessary to obtain for the working of the patented invention, the duration of the patent right may be extended, upon the filing of a request for the registration of extension of the duration, by a period not exceeding five years.

Article 67-3 Patent Act

(1) Where an application for the registration of extension of the duration of a patent right falls under any of the following items, the examiner shall render the examiner's decision to the effect that the application is to be refused:
   (i) where the disposition designated by Cabinet Order under Article 67(2) is not deemed to have been necessary to obtain for the working of the patented invention;
   (ii) where the patentee, or the exclusive licensee(s) or registered non-exclusive licensee(s) of the patent have not obtained the disposition designated by Cabinet Order under Article 67(2);
   (iii) where the period for which the extension is requested exceeds the period during which the patented invention was unable to be worked;
   (iv) where the person filing the application is not the patentee; and
   (v) where the request does not meet the requirements under Article 67-2(4).

Article 68-2 Patent Act (Effect of patent right in the case of duration extension)

Where the duration of a patent right is extended (including the case where the duration is deemed to have been extended under Article 67-2(5)), such patent right shall not be effective against any act other than the working of the patented invention for the product which was the subject of the disposition designated by Cabinet Order under Article 67(2) which constituted the reason for the registration of extension (where the specific usage of the product is prescribed by the disposition, the product used for that usage).

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## 4.2 LEGAL NATURE

In Japan, it is possible to extend the effective term of a patent by registration of extension under the patent term extension system. The registration of the extension does not give rise to any right independent of patent rights; therefore, if the patent is invalidated, it expires retroactively throughout its entire duration including the extended term. This is different from the system in Europe.

It is also possible to invalidate the registration of the extension if it was registered in absence of the prescribed requirements. The registration of extension may be invalidated by a request for an invalidation trial.[147] However, a trial decision to invalidate a registration of extension does not have the effect of invalidating the patent *per se*, but it is only deemed that the patent term was not extended.[148]

## 4.3 RATIONALE OF PATENT TERM EXTENSION

In cases where the patented inventions relate to pharmaceuticals or agricultural chemicals, as such products need to have government approval before being marketed, they may therefore require considerable time before actually being worked, and thus the duration of a patent may be shortened substantially. The patent term extension system has been established to make up for the period which may be lost in this way.[149] More specifically, the Patent Act was amended in 1987 to allow the term of a patent for an invention relating to pharmaceuticals or agricultural chemicals to be extended for up to five years if the patentee, who was unable to work said patented invention until obtaining the relevant marketing approval, filed an application for registration of extension.[150]

## 4.4 SUBSTANTIVE ASPECTS

### 4.4.1 Conditions for granting a patent term extension

In Japan, the conditions for granting a registration of extension are as follows:

- A regulatory approval designated by Cabinet Order under Article 67(2) was necessary to work the patented invention;
- It was the patentee, an exclusive or non-exclusive licensee who obtained the regulatory approval designated by Cabinet Order under Article 67(2);
- The period of extension sought does not exceed the period in which the patented invention could not be worked;
- It was the relevant patentee who filed an application for extension; and
- If the patent right is held jointly by more than one person, all the holders jointly filed the application for extension (Article 67-2(4)).[151]

147 Patent Act No. 121, Article 125-2(1).
148 Patent Act No. 121, Article 125-2(4).
149 Japan Institute for Promoting Invention and Innovation, *Kogyoshoyukenhou Chikujou Kaisetsu (Commentary on Industrial Property Right Law)* (19th edn, 2012) p. 222.
150 Patent Act No. 121, Article 67(2); Order of Enforcement of the Patent Act, Article 2.
151 Patent Act No. 121, Article 67-3(1).

### 4.4.2 Major differences between Japan and the EU: category of patents eligible for patent term extension

In Japan, registration of extension is allowed in cases where regulatory approval designated by Cabinet Order needs to be obtained to work a patented invention.[152] Such approval is necessary for agricultural chemicals, as required by the Agricultural Chemicals Regulation Act; and for pharmaceuticals and regenerative medicine products, as required by the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics (hereinafter, the "Pharmaceuticals and Medical Devices Act").[153] Medical devices, quasi-drugs and cosmetics are regulated by the Pharmaceuticals and Medical Devices Act like pharmaceuticals but are not eligible for patent term extension.

In Europe, only medicinal products and plant products are eligible for SPC protection. In contrast, as mentioned above, the eligibility for extension is determined in Japan not by what is the subject matter of the patented invention, but only by the test of whether pharmaceuticals or regenerative medicine products are subject to regulatory approval which is the ground for registration of extension.[154] Therefore, a patented invention relating to a medical device may be eligible for registration of extension even if marketing approval is obtained only for the pharmaceutical product that works the patented invention. For instance, if an invention relating to a spray-type nebulizer is patented and marketing approval is obtained for a pharmaceutical product for rhinitis which works the patented invention and it is in the form of a spray-type nebulizer,[155] it is possible to seek an extension of the patent relating to a spray-type nebulizer based on the marketing approval for the pharmaceutical product.

Additionally, in Europe the titles of protection that qualify as basic patents within the meaning of Article 3(a) of the SPC Regulations are national or European patents that include a claim to the product (composition claim), a claim to a process to obtain the product or a claim for a new use of the product. In contrast, in Japan the eligibility for registration of extension is determined not by the subject matter claimed, but by the test of whether marketing approval has been obtained for agricultural chemicals, pharmaceuticals or regenerative medicine products. For example, if marketing approval obtained for a pharmaceutical product has made it possible to work a patented invention, the relevant patent is eligible for registration of extension, regardless of whether the patented invention is a product, process or use invention. It is also possible to register two or more patent term extensions on the basis of a single regulatory approval.

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152 Patent Act No. 121, Article 67(2).

153 Order of Enforcement of the Patent Act, Article 2.

154 Regenerative medicine products are defined in Article 2(9) of the Pharmaceuticals and Medical Devices Act as items obtained after culturing or otherwise processing human or animal cells, intended either for reconstruction, repairing, augmentation or formation of the structure or function of the bodies of humans or animals, or for treatment or prevention of diseases, or items introduced to human cells through gene therapy.

155 This is a hypothetical case developed by the author based on the decision of the Intellectual Property High Court, 30 March 2014, 2012 (Gyo-Ke) 10399 – *Multi-dose Powdered Medicine Administering Device*. Although the registration of extension was not granted in this case for other reasons, the court assumed, and the parties did not dispute, that such a patented invention was eligible for registration of extension.

### 4.4.3 Requirement that regulatory approval was necessary to work the patented intention

#### *4.4.3.1 Introduction*

In Japan, one of the requirements for granting an extension is that an approval designated by Cabinet Order was necessary to work the patented intention.[156] This requirement consists of two conditions:

The first condition is that the regulatory approval which allegedly is the ground for applying for extension enables the working[157] of the patented invention.[158]

The second condition is that the patented invention could not be worked before obtaining the regulatory approval which allegedly is the ground for applying for extension.

If no regulatory approval has been obtained before filing a request for the regulatory approval which allegedly constitutes the ground for registration of extension, registration of extension is to be granted because the relevant approval is normally deemed to have made it possible to work the patented invention for the first time. However, if regulatory approval was already obtained (hereinafter, the "first approval") before obtaining regulatory approval which allegedly constitutes a ground for registration of extension (hereinafter, the "second approval"), the issue will be the degree of difference between embodiments enabled by the first approval and those by the second approval – whether they are different enough to prove that the second approval was necessary to work the patented invention. Over this issue, there were great changes in court decisions.

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156 Patent Act No. 121, Article 67-3(3).

157 As the term extension applies only to Japanese patents, it is implicitly premised that the working of the patented invention enabled by regulatory approval needs to be the one executed in Japan. Regulatory approvals designated by Cabinet Order are at present operated by the Japanese ministries. However, it does not matter whether the clinical trials necessary to obtain the regulatory approval were performed in Japan or abroad and thus it does not affect the calculation of the duration of the extension.

158 In this connection, one of the requirements in Europe is that "*a valid authorisation to place the product on the market as a medicinal product has been granted*", which has caused discussion as to how to deal with the following cases:

*Patent protects A*
*MA covers a medicinal product including A-B*
*SPC for A?*

*Patent protects A-B*
*MA covers only A*
*SPC for A-B?*

Since the subject matter of an application for extension is not a topic of discussion in Japan, whether an SPC is for A or A-B in the above cases does not matter in Japan (however, depending on the subject matter of a regulatory approval stated as the ground for extension, the scope of protection of an extended patent right pursuant to Article 68-2 of the Patent Act may be determined differently in an infringement case which may be filed subsequently to allege an infringement of the extended patent right).
Whether MA covers a product working a patented invention or not will be an issue in Japan because it is required that a Cabinet Order approval was necessary to work a patented invention. In the first of the above cases where a medicinal product covered by MA works the patented invention, the patent may be extended based on the MA. However, in the second case where a medicinal product covered by the MA does not work the patented invention, it is not allowed to extend the patent based on the MA.

#### *4.4.3.2 Former practice*

Previously, the Japan Patent Office (**JPO**) and Japanese courts used to focus on Article 6 8-2 of the Patent Act, which stipulates that an extended patent right is enforceable only against the act of working the patented invention for the approved "*product*" and "*use*". For the reason that it is unfair to allow a patent right to be extended two or more times when different pharmaceuticals to which the effect of the patent right extends are approved, the JPO and the courts used to take the view that in such cases where each of the different pharmaceuticals that fall within the scope of a patented invention is approved, registration of extension should be granted only once in response to the first approval, even though it was not required by statutory provisions. Further, interpreting that "*product*" and "*use*" under Article 68-2 meant "active ingredient" and "effect/efficacy" respectively, they used to grant an extension only if different pharmaceuticals sharing the same "active ingredient" and "effect/efficacy" were approved. According to this practice, extension was rejected in cases where, for example, a pharmaceutical product was first approved as an encapsulated formulation and later another approval was obtained as a nasal solution,[159] and where a pharmaceutical product was first approved as a pharmaceutical applicable to adults only and later another approval was obtained by expanding its applicability to children.[160]

However, the first problem in such former practice to determine the eligibility for extension based on "active ingredient" and "effect/efficacy" is that, if a product whose active ingredient and effect/efficacy falls within the technical scope of a patented invention was first approved but it was not allowed to work the patented invention (i.e. if the first approval did not allow the patented invention to be worked), even the second approval which made it possible to work the patented invention for the first time cannot serve as a ground for extension.[161] Yet, such handling is against the provision of Article 67-3(1)(i) of the Patent Act, which assumes that an application for registration of a patent term extension is not to be rejected where the disposition designated by Cabinet Order is deemed to have been necessary to be obtained for the working of the patented invention.

The second problem is that the former practice might have fitted the innovative development of new drugs with new active ingredients and effects/efficacies, which was common at the time when the Patent Act was amended in 1987. However, it does not fit the innovative development of Drug Delivery Systems (DDSs), which are unique in formulation, dosage, dose regimen or other features and have become increasingly more important since the 1990s. The former practice could not afford sufficient protection to patented inventions with such unique features.

#### *4.4.3.3 Pacif Capsules 30mg case*

The former practice underwent a drastic change by virtue of the decisions of the Intellectual Property High Court and the Supreme Court in the *Pacif Capsules 30mg* case, which addressed the first problem mentioned above.

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159 Tokyo High Court, 5 March 1998, Hanrei Jiho 1650, p. 137 – *Ketotifen Fumarate Novel Manufacturing Method.*

160 Tokyo High Court, 10 February 2000, Hanrei Jiho 1719, p. 133 – *Ondansetron Hydrochloride.*

161 Intellectual Property High Court, 11 October 2005, 2005 (Gyo-Ke) 10345 – *Buserelin Acetate.*

In this case, the plaintiff holding the patent at issue (related to the formulation art to enable substantial drug release in the small and large intestines) filed an application for patent term extension based on the second approval, obtained for an extended-release capsule formulation which worked the invention. The JPO rejected the application on the ground that there was already a first approval for a pharmaceutical product which had the same active ingredient and effect/efficacy. However, the pharmaceutical product for which the first approval was obtained did not work the invention.

With regard to the interpretation of Article 67-3(1)(i) of the Patent Act, the Intellectual Property High Court[162] and the Supreme Court[163] clearly stated that, if the act of marketing a pharmaceutical product having obtained the first approval did not fall within the technical scope of the patented invention, the existence of such first approval should not serve as a reason for rejecting an extension based on a second approval. The Intellectual Property High Court and the Supreme Court denied the former practice in Japan in relation to the first problem.

However, regarding the second problem (i.e. in cases where, unlike this case, the first approval already made it possible to work a patented invention) of how much the second approval needs to be different from the first one to warrant an extension, the Intellectual Property High Court stated in the dictum that Article 67-3(1)(i) should not be interpreted with reference to Article 68-2 and extension should be granted for smaller elements of an invention, but the Supreme Court was silent on this issue.

#### *4.4.3.4 Avastin case*

The second problem was addressed more generally in the *Avastin* case before a Grand Panel[164] of the Intellectual Property High Court[165] and in the appeal case.[166]

The patented invention at issue in this case obtained the first regulatory approval for a product with the following dosage and administration: "*adults are ordinarily intravenously infused with bevacizumab at a dose of 5 mg/kg (weight) or 10 mg/kg (weight) at intervals of at least two weeks*". Based on this first approval, the plaintiff, holder of the patent, registered an extension of the patent for 4 years, 2 months and 3 days. Subsequently, the plaintiff obtained the second regulatory approval for another product which had the same effect/efficacy but with the following new dosage and administration: "*in combination with other anticancer drugs, adults are ordinarily intravenously infused with bevacizumab at a dose of 7.5 mg/kg (weight) at intervals of at least three weeks*" (partial amendment to marketing approval). Based on the second approval, the plaintiff filed an application to extend the patent term for five years; which, however, was rejected by the JPO.

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162 Intellectual Property High Court, 29 May 2009, 65 Minshû 3, p. 1685 – *Release Control Composition.*

163 Supreme Court, 28 April 2011, 65 Minshû 3, p. 1654 – *Release Control Composition.*

164 While normal cases are assigned to one of the four normal divisions in the Intellectual Property High Court and judged by a panel of three judges, Grand Panel cases are judged by a panel of five judges. The four divisions each elect at least one of the five judges. Legally, decisions by Grand Panels have the same binding effect as by normal divisions, but in fact have a lot of influence on subsequent decisions of the Intellectual Property High Court and district courts.

165 Intellectual Property High Court, 30 May 2014, Hanrei Jiho 2232, p. 3 – *Vascular Endothelial Growth Factor Antagonist.*

166 Supreme Court, 17 November 2015, 69 Minshû 7, p. 1912 – *Vascular Endothelial Growth Factor Antagonist.*

Under these circumstances, the Intellectual Property High Court and the Supreme Court rescinded the JPO's decision of rejection, stating that registration of extension should be granted. The courts clarified that registration of extension might be granted even if a pharmaceutical product approved by the first regulatory approval and a pharmaceutical product approved by the second regulatory approval had the same "active ingredient" and "effect/efficacy".

The Supreme Court ruled that whether or not to grant an extension based on the second approval should be determined depending on whether a pharmaceutical product approved by the second approval fell within the scope of the pharmaceutical product approved by the first approval. In other words, if the pharmaceutical product subject to the first approval is substantially identical to the pharmaceutical product subject to the second approval, an extension based on the second approval should not be granted. The Supreme Court further held that such substantial identity as pharmaceutical drugs should be assessed by comparing the approved "*ingredients, quantity, dosage, administration, effect and efficacy*", in the case of "*an invention of a product for which the subject matter is the ingredient of a pharmaceutical product*". While the Intellectual Property High Court had already explained this view, except for minor differences, in the dictum in the aforementioned *Pacif Capsules 30mg* case,[167] it is important that the Supreme Court upheld the view, this time in the *ratio decidendi*.

#### *4.4.3.5 Scope of applicability of the Supreme Court decision in Avastin*

In the Avastin case, the Supreme Court ruled that whether or not to grant an extension should be determined depending on whether "the scope of the manufacturing and sale of the pharmaceutical product subject to the prior regulatory approval is deemed to include the manufacturing and sale of the pharmaceutical product subject to the regulatory approval stated as the ground for the application". However, the Supreme Court did not mean to readily grant an extension if there was little difference between the first and the second approvals. This is because, in concluding that the pharmaceutical product subject to the first approval and that subject to the second approval were different, the Supreme Court took into account a substantial difference between them – although the first approval adopting administration intervals of two weeks did not enable a combination treatment with XELOX at administration intervals of three weeks, the combination treatment was possible in the second approval which also adopted administration intervals of three weeks.

In fact, before this decision of the Supreme Court, and on the same date as the Grand Panel's decision in the lower instance, the Intellectual Property High Court handed down a decision in a separate case.[168] In that case, the court compared the technical idea of the patented invention at issue with the structure of equipping a nozzle with a counter, whose structure was enabled by the second regulatory approval for the first time. Thereby the court found that the counter was irrelevant to the function achieved by the structure of the patented invention and that the function "*display of the number of times of spraying*" achieved by the counter was "*an additional function*"

[167] Intellectual Property High Court, 29 May 2009, 65 Minshû 3, p. 1685 – *Release Control Composition.*
[168] Intellectual Property High Court, 30 March 2014, 2012 (Gyo-Ke) 10399 – *Multi-dose Powdered Medicine Administering Device.*

irrelevant to the technical idea of the patented invention. The court then concluded that the patent term should not be extended, since the second approval having made such an insignificant difference should not have served to lift any additional prohibition and enable "working of the patented invention".

According to this approach, to focus on whether there is a substantial difference between the scope of the first approval and that of the second approval, a product subject to the second approval which has the same active ingredient and is different only in the excipient or other additives, or in the racemate or enantiomer, is likely to be deemed not to make a substantial difference; which, however, needs to be judged on a case-by-case basis. Since there is no case law that directly deals with this issue, we must wait for future court decisions.

#### *4.4.3.6 Example*

The logical conclusion extracted from the Supreme Court's decision in the *Avastin* case is explained below by using some specific examples:

> Patent discloses and claims compound Y
> First MA covers only a medicinal product including Y
> Second MA covers a medicinal product including Y-Z (two active ingredients)

In this case, there is no doubt that an extension based on the first MA would be granted.

An extension based on the second MA may also be granted for the two following reasons. Firstly, a medicinal product approved by the second MA works the patented invention which claims compound Y. Secondly, while the first MA has already been granted to approve the marketing of a medicinal product comprising compound Y as an active ingredient, the first and second MAs do not share the same active ingredient. Consequently, they are not to be found substantially identical according to the aforementioned Supreme Court's decision in the *Avastin* case. The existence of the first MA could then have no effect on the conclusion that an extension based on the second MA is to be granted under the case law in Japan.

In short, a single patent may enjoy two or more extensions in Japan insofar as the first and the second regulatory approvals are not regarded as substantially identical.[169]

In Europe, the principle of "only one SPC, one product, one patent" has been adopted (although this has been corrected in part by the CJEU), which opens the way to abuse when several patent or divisional applications are filed and some of them are transferred to other entities so that several patents are owned by several patentees for a single pharmaceutical product. In Japan, however, it is allowed to file two or more applications for extensions of a single patent right, and an extension may be granted to quite small elements of an invention according to the Supreme Court's decision in the

[169] In the case of multiple extensions on a single patent, the extended terms are calculated separately and independently for each extension from the expiry of 20 years from the date on which the application for the patent was filed. For example, if a patentee obtains for the same patent three extensions in durations of 1.5 years (1st extension), 2.5 years (2nd extension) and 4.5 years (3rd extension), the 2nd extension will start from the expiry of 20 years and not 21.5 years which would include the 1st extension. Accordingly, the patent after the second extension will expire in 22.5 years. The same way of calculation applies to the 3rd extension and therefore the patent after the 3rd extension will expire in 24.5 years from the date on which the application for the patent was filed.

*Avastin* case. This means that, for those who would like to obtain multiple extension registrations in Japan, there is no need to have multiple patents granted.[170]

For example, in cases where an invention relating to a novel use of a known compound is patented and this patent (hereinafter "New Use Patent B") is owned by a person who also owns a prior patent relating to the compound (hereinafter "Compound Patent A"), the New Use Patent B as well as the Compound Patent A can be extended in Japan if regulatory approval to enable the working of the patented invention is obtained. Even if the patentee already has an extension on Compound Patent A based on another previous marketing authorisation for a certain use of such compound, he can nevertheless enjoy extensions again both on Compound Patent A and New Use Patent B respectively, based on a new marketing authorisation for a certain use of such compound, provided that those two authorised items are not "substantially identical" within the meaning of the Supreme Court's decision in the *Avastin* case.

The same rule applies to the issue of whether to grant an extension for a combination product if one of the products included in that combination has already been the subject of an extension.

The answer depends on whether the combination product approved by the second authorisation is substantially similar to the combined product approved by the first authorisation. For example, a new extension will be acknowledged if the difference between those two products consists in a difference of active ingredients, because they are not "substantially identical" within the meaning of the Supreme Court decision. Furthermore, in the case where both the combination product and the combined product are patented, both patents can enjoy an extension respectively, based on the second authorisation.

Incidentally, in Europe, the requirement that "*the product is protected by a basic patent in force*" (Article 3(a) SPC Regulations) has caused controversy as to whether an SPC may be granted in cases such as the following:

> Patent discloses and claims compound Y
> First SPC requested for Y
> Second SPC requested for Y-Z (two active ingredients)

In Japan, there is no concept of specifying or identifying the scope of extension by active ingredients or other factors at the time of applying for the extension. An application for extension is filed for each patent and an extension is registered for each patent. Further, according to the decision of the Supreme Court in the *Avastin* case, a single patent may enjoy two or more extensions if there is a substantial difference between the first and the second regulatory approval.

Having said that, the scope of protection of an extended patent right does not extend to the entire scope of the patent right before the patent term expiration, but only extends to the scope stipulated in Article 68-2 of the Patent Act, as will be discussed below. However, the scope limited under Article 68-2 is not identified at the time of

[170] Since even a single patent is allowed to enjoy two or more extensions, there is no foundation to deem it as abusive to grant extensions of separated patents.

registering the extension, but is to be determined by the court before which an infringement action against the extended patent right is filed, as the case may be.

## 4.5 PROCEDURAL ASPECTS

### 4.5.1 Applicant

In order to obtain a patent extension, the patentee is required to apply for an extension of the patent.[171] The relevant regulatory approval must be obtained by the patentee, the exclusive licensee or the non-exclusive licensee.[172] Therefore, it is possible for a patentee to get an extension by referring to a third-party authorisation, on condition that a licence relationship exists between them.

### 4.5.2 Application period

The application requesting the registration of the extension should normally be filed within three months[173] after the regulatory approval, and no application for registration of extension may be filed after the patent term expires.[174] Thus, if a patentee fails to obtain the regulatory approval before the patent expires, he can no longer file for the extension registration.

In the past, the patent term extension system did not allow applications for extension to be filed within six months prior to the expiration of the patent term, but the Patent Act was amended in 1999 to relax this requirement and came to allow filing for the period from six months prior to the expiration of the patent term on condition that prescribed steps are taken.[175] However, the drafters of the 1999 amendment did not express any intention to alter the above-mentioned requirement that regulatory approval must be obtained before the expiration of the patent and the JPO set a standard implicitly premised on this requirement.[176] The wording of Article 67-2(3) and Article 67-2-2 of the Patent Act is admittedly ambiguous about the relationship between both articles; it is generally thought that regulatory approval must be obtained before the patent right expires.

Even under this generally accepted interpretation after the 1999 amendment, if a patentee succeeds in obtaining regulatory approval before the patent term expires, it is sufficient to file an application for extension before the patent's expiration, and an extension can be registered even if the examination on whether or not to grant the extension takes place after the patent term expires. Thus, once an application for extension is filed, the patent term is deemed to have been extended.[177] If a decision to reject the application becomes final and binding afterwards, the deemed extension becomes invalid.[178] This means that, if a decision to reject the application becomes final and binding after expiration of the original patent term, the patent is deemed not

171 Patent Act No. 121, Article 67-3(1)(iv).
172 Patent Act No. 121, Article 67-3(1)(ii).
173 Order of Enforcement of the Patent Act, Article 3.
174 Patent Act No. 121, Article 67-2(3).
175 Patent Act No. 121, Article 67-2-2.
176 Examination Guidelines for Patent and Utility Models in Japan, Part IX Extension of Patent Term 3.1.3(1) and (3).
177 Patent Act No. 121, Article 67-2(5), first sentence.
178 Patent Act No. 121, Article 67-2(5), second sentence.

to have been extended with retroactive effect from the time of the patent term expiration.

### 4.5.3 Examination

A filed application is subject to substantive examination. If a patentee files an application for registration of extension, the JPO examines whether to register the extension by examiners.[179] Neither the Ministry of Health, Labour and Welfare (**MHLW**) nor the Ministry of Agriculture, Forestry and Fisheries (**MAFF**) is involved in the examination process. By means of a written application for registration of extension, which the patentee is required to submit along with copies of the necessary documents, the fact that he obtained regulatory approval which is the ground for registration of extension and details of the approval are notified to examiners at the JPO.[180] In the examination process, examiners are not expected to exchange information with the MHLW or MAFF.

### 4.5.4 Trial and revocation procedure

After an extension is registered, persons concerned may request a trial for invalidation of the registration of extension.[181]

If an application for extension is rejected, the applicant, having received the decision of rejection,[182] may request a trial against the decision of rejection.[183] If a trial decision to deny the request is rendered, the applicant may then file a lawsuit to revoke the trial decision before the Intellectual Property High Court.[184]

## 4.6 PERIOD OF PATENT TERM EXTENSION (CALCULATION OF TERM)

An extension may be registered only for the period in which the patented invention could not be worked,[185] which cannot exceed five years.[186]

The period in which the patented invention could not be worked means a period in which a patented invention could not generate revenue because various tests or examinations were being performed in order to obtain regulatory approval and the approval was not yet obtained. It is interpreted that the period starts on "*the date of beginning the test which is required for the approval, or the date of patent registration, whichever is later*" and ends not on the date of the approval but on "*the date immediately before the date on which the approval took effect by reaching the applicant*".[187]

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179 Patent Act No. 121, Article 67-3(1).
180 Examination Guidelines for Patent and Utility Models in Japan, IX-2.5(4).
181 Patent Act No. 121, Article 125-2.
182 Patent Act No. 121, Article 67-3(i).
183 Patent Act No. 121, Article 121(1).
184 Patent Act No. 121, Article 178(1); Act for Establishment of the Intellectual Property High Court, Article 2(ii).
185 Patent Act No. 121, Article 67-3(1)(iii).
186 Patent Act No. 121, Article 67(2).
187 Supreme Court, 22 October 1999, 53 Minshû 7, p. 1270 – *New Group of Polypeptides.*

The benchmarks are (i) the date of beginning the test which is required for obtaining an approval, (ii) the patent registration date, and (iii) the date immediately before the date on which the approval took effect by reaching the applicant.

If they occur in the order of (i), (ii) and (iii), the period of extension is a period of up to five years from (ii) to (iii).

If they occur in the order of (ii), (i) and (iii), then the period of extension is a period of up to five years from (i) to (iii).

## 4.7 SCOPE OF PROTECTION

Unlike in Europe, the patent term extension system in Japan is not independent of patent rights and is a system to merely extend the effective term of a patent. Therefore, rights conferred by registration of extension are patent rights *per se*, but subject to the aforementioned limitation on the scope of protection under Article 68-2 of the Patent Act.

Article 68-2 of the Patent Act stipulates that an extended patent right is effective with regard to the subject of the regulatory approval (or if the specific use of the product is prescribed by the approval, the product used for that usage).

As mentioned above, the former practice of the JPO and the Japanese courts was to assume that the terms "*product*" and "*use*" in Article 68-2 of the Patent Act mean "active ingredient" and "effect/efficacy" respectively, and determine the grant/rejection of an extension with reference to the effect of the extended patent right. Contrary to this practice, the Intellectual Property High Court stated in the *Pacif Capsules 30mg* case, and a Grand Panel of the same court stated in the dictum in the *Avastin* case, that the grant/rejection of an invention should not be determined with reference to the scope of protection, which the extended patent right may enjoy under Article 68-2 of the Patent Act. However, since the Supreme Court did not refer to Article 68-2 of the Patent Act in the *Avastin* case, a guiding principle needs to be established by the courts in the future.

Amid these situations, a Grand Panel of the Intellectual Property Court handed down a decision over this issue.[188] The court stated that an extended patent right should be effective not only against the "*product*" (medicine) specified by the "*ingredients, quantity, dosage, administration, effect and efficacy*" prescribed by a regulatory approval designated by Cabinet Order (hereinafter "Cabinet Order approval"), but also against a product which is "*substantially identical*" to said product as a medicine. It further stated that the substantial identity should be assessed in light of the common general technical knowledge of persons ordinarily skilled in the art and based on the nature of the patented invention by comparing and examining the technical features, function and effect of the "*product*" subject to the Cabinet Order approval and those of the accused product. It then stated that substantial identity could be found in the following types of cases:

[188] Intellectual Property High Court, 20 January 2017, Case No. 2016 (Ne) 10046 – *Pharmaceutically Stable Preparation of Oxaliplatinum (Elplat).*

"(i) Where the accused product represents a pharmaceutical product of a patented invention which is characterised only by its active ingredient and whose duration was extended, and in which a different ingredient (not active ingredient) is added, converted, etc., based on well-known or common art as of the time of the filing of an application for the Cabinet Order approval;
(ii) Where the accused product represents a pharmaceutical product of a patented invention relating to the stability or dosage form, etc., of a pharmaceutical product comprising a publicly known active ingredient, in which a different ingredient is added, converted, etc. based on well-known or common art as of the time of the filing of an application for the Cabinet Order approval, and the accused product and the product subject to the Cabinet Order approval are regarded as being identical in the technical features, function and effect in light of the nature of the patented invention;
(iii) Where the accused product and the product subject to the Cabinet Order approval have only a quantitatively insignificant difference in the 'quantity' or 'dosage and administration' prescribed by the Cabinet Order approval; and
(iv) Where the accused product and the product subject to the Cabinet Order approval differ in the 'quantity' prescribed by the Cabinet Order approval but are regarded as being identical in consideration of 'dosage and administration' as well."

However, how to deal with cases that do not fall under these types is not clear from the above-mentioned decision. In this case, the court found that the accused product did not even fall within the technical scope of the patented invention before the extension. Therefore, the specific scope to which an extended patent right may apply according to the logic provided by this decision of the Intellectual Property High Court needs to be carved out by future court decisions.

In the above-mentioned case, the Intellectual Property High Court also stated in the dictum that a patent right, even if it was extended, should undergo the test of whether the accused product fell within the technical scope of the patented invention as usual, irrespective of the limitation by Article 68-2 of the Patent Act, and the applicability of an infringement test under the doctrine of equivalents should also be examined. This means that, in infringement cases concerning an extended patent, courts examine whether the accused product falls within the technical scope of the patented invention, both literally and under the doctrine of equivalents, and then go further to examine the issue of whether the accused product still encroaches upon the scope of protection even after the scope is narrowed under Article 68-2 of the Patent Act (as a matter of course, the order of examining the two issues is not binding).

## 4.8 EXEMPTIONS

### 4.8.1 Interplay with other forms of exclusivity

Separately from the patent term extension system, new drugs are protected in Japan under the pharmaceutical administration and regulations by the following two systems:

The first is a patent linkage system, which generally prohibits the approval of generic drugs while substance patents or use patents for new drugs are effective. This is not a statutory rule under the Pharmaceuticals and Medical Devices Act, but has been introduced by Notification[189] under the pharmaceutical administration and regulations.

[189] Director of the Economic Affairs Division, Health Policy Bureau, MHLW (Notification No. 0605001) and Director of the Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, MHLW (Notification No. 0605014), *Review of generic products for pharmaceutical use for approval under the*

The second is a system to ensure the efficacy and safety of new drugs. The Pharmaceuticals and Medical Devices Act obliges a person who has received marketing approval for a pharmaceutical product to investigate the results of using the product and report on those results to the Minister of Health, Labour and Welfare within a prescribed period (re-examination period of up to 10 years). In addition, it is not allowed to file an application for approval of a generic drug during this period.[190] Although this system is intended to ensure the efficacy and safety of new drugs, it eventually works to protect new drugs, whether patented or not, from competition with generic drugs on the market for a certain period (data protection of new drugs).

### 4.8.2 Bolar exemption

Article 69(1) of the Patent Act states that a patent right is not effective against the working of a patented invention for experimental or research purposes. It is generally understood that this Article exempts experimental use or use for research purposes of the patented invention itself, i.e. the exemption cannot be applied to the use of patented inventions made for experimental or research purposes of inventions or technologies other than the relevant patented invention. For instance, in one judgment, Article 69(1) was found not to apply to the working of a patented invention in a test for filing an application registration of a pesticide.[191]

Having said this, there is an exception – the Supreme Court has found that the experiments conducted to file an application for approval under the Pharmaceutical Act for the purpose of manufacturing and selling pharmaceutical products after the expiration of the patent right fell under "*working of the patented invention for experimental or research purposes*" as stipulated in Article 69(1) and therefore held that it did not constitute an infringement of the patent right.[192] Following this decision of the Supreme Court, it is now interpreted that the working of a patented invention for experiments conducted in order to obtain marketing approval after the patent expires does not infringe the patent.

Nonetheless, no court has ever decided on the issues of whether the act of a third party to manufacture instruments necessary for experiments and transfer them to a person who is to conduct the experiments does not constitute an indirect infringement pursuant to Article 69(1), and whether the act of a third party to manufacture compounds necessary for experiments and transfer them to a person who is to conduct the experiments also does not constitute a direct infringement pursuant to Article 69(1). The first issue on indirect infringement has been discussed by scholars and the prevailing theory is that indirect infringement should be denied by Article 69(1).[193] The second issue on direct infringement was addressed by the Supreme Court, which ruled that a person who, having received an order from a person holding a right of prior use, manufactured and sold a product working the relevant patented invention solely for the benefit of the prior-use right holder should be found to have acted as an agent for the prior-use right holder and should therefore be allowed to refer to the right of prior use.[194] Accordingly, direct infringement may be denied

*Pharmaceutical Affairs Act, and handling of pharmaceutical patents relating to National Health Insurance price listing*.

190 Enforcement Regulations of the Pharmaceuticals and Medical Devices Act, Article 40(2).
191 Tokyo District Court, 10 July 1987, 19 Mutaishû 231 = 20 IIC 91 – *Herbicide.*
192 Supreme Court, 16 April 1999, 53 Minshû 627 – *Foipan Tablets.*
193 Yoshiyuki Tamura "*Chitekizaisanhou* (Intellectual Property Law)" (5th edn, Yuhikaku, 2010), p. 260.
194 Supreme Court, 17 October 1971, 23 Minshû 10, p. 1777 – *Globe-shaped Radio*.

pursuant to Article 69(1) in future cases where a third party who, having received an order from a person who is to conduct experiments, similarly manufactures and sells a product working a patented invention solely for the benefit of the ordering person.

# 5 KOREA

*Prof. Jun-seok Park* *

## 5.1 SOURCES OF LAW

In Korea, the patent term extension system is mainly prescribed in the current Korean Patent Act (**KPA**)[195], Article 89 to Article 92 and Article 95. Also, the invalidation trial system of the PTE is prescribed in Article 134(1). Moreover, the trial against final rejection to PTE application is managed by Article 132-17.

Based on the delegation of the above Article 89, Article 7 in the presidential decree of the KPA clearly stipulates that it is possible to extend the patent term of "the medicinal products and agrochemical or raw materials of agrochemicals". Within the scope stipulated by the above laws, the Korean Intellectual Property Office (**KIPO**) establishes the regulation on the Operation of PTE System corresponding Authorization and Etc.[196] (hereinafter referred to as "**the KIPO Regulation**").

The PTE system of KPA was introduced for the first time through the amendment[197] of KPA in December 1986 which was inevitably made mainly due to the strong political pressure combined with potential economic sanctions of US government and came into effect in July 1987. The PTE system is different with the Patent Term Adjustment system which was introduced in the article 92[bis] of KPA on 2011. The latter is to compensate unjustifiable delays of patent examination and to adopt the similar system in the US.

By the way, even after the first appearance of PTE application case in 1999, the number of cases had been relatively small for more than 10 years and especially the PTE invalidation trial case or court case had been hard to find. [198] However, since the PTE invalidation trial cases before KIPO exploded under the influence of the newly launched patent-linkage system in March 2015, more than five hundred cases of PTE invalidation trial were filed until the end of 2016 and also related court cases rapidly increased.[199] Moreover, PTE became the very issue on which the Special Panel[200] of Korean Patent Court (KPC) rendered the first decision[201] on March 2017 since it's installment in early 2015. In short, even though PTE system in Korea had been out of focus for a long time, it has become one of the hottest issues in recent years.

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195 Amended by Act No. 14371, Dec. 2, 2016.

196 The latest revised version of this regulation is the KIPO Notification No. 2015-19, August 21, 2015.

197 By this amendment, KPA changed heavily. Such change included the adoption of not only PTE system but also chemical substance patent system.

198 Min-zung Lee, 'Policy direction on Korean patent term extension system', briefing paper of 19 April 2017, 6-8; KIPO, 'The patent trial system related to the patent-linkage for medicinal products is stabilized', press release of 6 April 2017, 3.

199 *Ibid.*

200 In perspective of being a specially intensified panel to deal with some highly important cases, this panel is similar with the Grand Panel of the Japanese Intellectual Property High Court and even with the Enlarged Board of the EPO.

201 KPC, 2016Huh21 decided on March 16, 2017 (Special Panel). At same day, the Special Panel rendered 2016Huh4498 decision for another case, with similar ruling on PTE.

## 5.2 LEGAL NATURE

Unlike the European SPC system which has independent, *sui generis* IP rights character, the PTE system in Korea has the basic patent right itself extended. So, the extended patent can be invalidated on the grounds which have already existed in the basic patent.[202] In such a perspective, the PTE system of Korea has basically the same appearance as those of the United States and Japan. Although such a common character could arguably be the result caused by the fact that the wide amendment of KPA in 1986 by which Korea adopted the PTE system was mainly caused by the pressure of US as mentioned above or the fact that the legislation in Korea including KPA has heavily affected by that of Japan even after independence from Japan several decades ago, the clear investigation about this point is a difficult job due to lack of explicit data or reference.

## 5.3 GRANTING AUTHORITY

KIPO exclusively determines whether to register the extension of the patent term. Meanwhile, the Ministry of Food and Drug Safety (**MFDS**, formerly known as the Korea Food & Drug Administration or **KFDA**) is in charge of marketing authorization for medicinal products. However, KFDA has no authority to intervene in the PTE procedure.

There is no official cooperation channel such as mutual exchanging of related information between KIPO and KFDA when the procedure of PTE reviewing and its registration. The absence of such cooperation could be one of the reasons why the invalidation trial had been rare. It is difficult for an opponent party requesting an invalidation trial to acquire the information submitted by the patent owner in the MA procedure before MFDS and consequently it is hard for the party to find any flaw existing in PTE registration before the patent office.

## 5.4 SUBSTANTIVE ASPECTS

### 5.4.1 Subject matter eligible for patent term extension

#### *5.4.1.1 Technical fields where PTE is possible*

Based on the explicit provision[203], only medicinal products and agrochemical or raw materials of agrochemicals are recognized as subjects of PTE. In Korea, unlike in the European Union and US, it is not clear whether medical devices including implantable devices are excluded from that subject or not. In this perspective, there are no cases and almost no scholastic arguments in Korea.[204]

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202 See Article 95 KPA.

203 Article 7 Presidential Decree of KPA.

204 One exception is a comment by Ahn Kim, saying that "medical device combined with a drug" could arguably be eligible for PTE in Korea. See Arne Markgraf, *Ergänzende Schutzzertifikate - Patent Term Extensions* (Nomos Baden-Baden, 2015), p. 393. However, such a comment is seemingly not plausible because the above author missed even the most important legal change introduced by the Presidential Decree of KPA 2013. For more details, see Chapter 5.4.1.3 in this article.

#### *5.4.1.2 Category of patents (rectius: patent claims) eligible for PTE*

In the past, the KIPO Regulation stated that the patents which are eligible for PTE application are limited to substances, manufacturing methods, uses and composition patents.[205] In the current provision, such limited wording was deleted from the regulation. However, as in the past, the PTE is authorized only for substances, manufacturing methods, uses and composition patents in the practice of KIPO.[206]

#### *5.4.1.3 In the field of medicinal products: concept of active ingredient*

In the case of Korea, there had been fundamental confusion for a long time in practice because no definition for medicinal products in Article 7 Presidential Decree of KPA had been provided. Particularly not for cases of new drugs but for cases of so-called data submission drugs,[207] some precedents treated them as the "medicinal products" and allowed them to get a PTE while other precedents regarded them as not falling under "medicinal products" and rejected PTE application.[208]

However, since 2012, the practice of excluding data submission drugs from "medicinal products" has been established, and in accordance therewith, the Presidential Decree of KPA has been amended in 2013 to clearly define that "medicinal products" only means the medicinal products produced with new substances as active ingredient and authorized for the first time".[209] Also here, the new substances are defined as the substances whose chemical structure of the active part is new.[210] This part is one of the most important differences between the PTE systems of Korea and Japan though those systems are similar in many aspects.

Therefore, not only in the case that a new use (indication) of existing drugs is found, but also in the case of a combination drug in which two or more already known active ingredients are mixed, and in the case of adding an additive to an existing active ingredient, those things will not be further treated as the "medicinal product" above even though there is little possibility of opposition. In this regard, in case of new formulations of existing drugs, it has been relatively clearly treated as not eligible for PTE even before the 2013 Presidential Decree amendment.[211]

Meanwhile, in Korea, whether or not the PTE can be given if some of the two or more active ingredients contained in a combination are new substances is unclear because it is difficult to find cases or discussions. However, one opinion[212] by the prominent

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205 Article 2(1) in the past KIPO Regulation (Notification No. 2005-13, June 17, 2005).

206 This is the official position taken by KIPO in its current website. <http://www.kipo.go.kr/kpo/user.tdf?a=user.html.HtmlApp&c=8044&catmenu=m06_02_06> [last accessed 30 April 2017].

207 Compare with new drugs which are having new active ingredient, data submission drugs are having new salt of existing active ingredient or new indication of it, or new formulation of it etc. and also need to get MA from MFDS. See Article 2, Subparagraph 8 and Art. 25(1) in the Regulation of Authorization, Notification, Examination of Medicinal Product (MFDS Notification No. 2017-44, May 23, 2017).

208 This explanation is from the decision of KPC (2015Huh1256 decided on Jan. 29, 2016). After such explanation, the decision seemingly took a position that only new active ingredient would be eligible for PTE after the Presidential Decree of KPA amendment in 2013.

209 Article 7, Subparagraph 1 in Presidential Decree of KPA (No. 24491, April 3, 2013).

210 *Ibid.*

211 Chun-won Kang, 'Whether or not the PTE is granted in case of new formulation patent including already authorized active ingredient' [2011] 8 IP Policy 76, 81.

212 Chun-won Kang, 'Ⅴ. Improvement plan of patent term extension in Korea (as of April 2011)' < http://blog.naver.com/PostView.nhn?blogId=kpatent9&logNo=40126654107> [last accessed 30 April 2017].

administrative judge in KIPO that is favoring to PTE is seemingly plausible. Moreover, which is the exact relation between PTE and the racemate or the enantiomer is remaining for any first cases or discussions in Korea.

### 5.4.2 Conditions for granting a patent term extension

#### *5.4.2.1 Premise*

In the case of South Korea, as a condition for PTE is described on Article 89 of KPA. "When an authorization or registration under other Acts…. shall be obtained to use a patented invention and the authorization or registration takes a long time due to the test for effectiveness or safety and etc., the term of the patented invention which is prescribed in the presidential decree of the KPA may be extended…. up to five years during which the patented invention cannot be used." And the presidential decree is the Article 7 Presidential Decree of KPA mentioned above.

#### *5.4.2.2 First requirement "the product is protected by a basic patent in force"*

Because KPA[213] explicitly restricts that PTE application shall be filed within three months from the date of authorization, etc. and no later than six months before the expiration of the basic patent term, it is not possible to file PTE after the expiration.

The term is deemed to be extended temporarily only by the fact that there is a PTE application unless the final rejection to the application becomes non-reversible, to avoid any circumstances where the term of basic patent expires while the PTE application is still pending.[214]

Because the EU and Korea have different statutory phrases, the debates in the European Union over the requirements of Article 3(a) of the SPC provision[215] that "the product is protected by a basic patent in force" is matching with the discussions in Korea over the requirements of Article 89 paragraph 1 of KPA that "an authorization or registration under other Acts…. shall be obtained to use a patented invention", in other words, the necessity to obtain authorization for use of a patent.

However, unlike the European Union, there has been no severe conflict of complicated opinions and no so much detailed criteria. In Korea, the KIPO Regulation recognizes the above necessity if the specific active ingredient that received an MA is stated in the claims of the patent.[216] However, in order to be recognized as to being so stated, it is required that the patented substance and the authorized substance are the same,[217] or, if not, the patented substance is a super-ordinate concept.[218] In light of this, in my opinion though there is some vagueness, it is more close to the position of

213 Article 7 Presidential Decree of KPA.
214 Article 90(4) KPA.
215 Council Regulation (EEC) No 1768/92/EC.
216 See Article 7(1) KIPO Regulation.
217 'Guidelines for examination on patent and utility patent' (the KIPO Established Rules No. 97, March 1, 2017), p. 7114.
218 Article 7(1), Subparagraph 1 in the KIPO Regulation.

CJEU[219] that an authorized product should be clearly specified into the claims of patent than to the other opinion just requiring that the product infringes the patent claims.

#### *5.4.2.3 A valid authorization to place the product on the market as a medicinal product has been granted*

Similarly to the above explanation related to Article 3(a) of the SPC regulation, the discussion in the European Union over the requirement of Article 3(b) that there shall be a valid authorization for the product is corresponding with the discussions in Korea over the same requirements of Article 89 paragraph 1 of KPA, the necessity to obtain authorization for use of a patent.

In connection with the combination drug, no noteworthy case or meaningful discussion in Korea is found about whether a patent can be eligible for PTE if the patent claim is a mixture of A + B while the authorization relates only to ingredient A. A short comment[220] favoring not to give PTE for the case is found. However, in my opinion, PTE should be given for the case because the statutory requirement in Art. 89(1) KPA is different from that of the EU and it would be difficult to deny the necessity to obtain authorization for use of a patent.[221]

#### *5.4.2.4 The product has not already been the subject of a PTE*

The principle, only one PTE for one patent, is firm in Korea.[222]

If more than one authorization is given to the same active ingredient included in one patent right, PTE can be granted only for the first authorization.[223] This is the same as in the EU, the US and Japan. In contrast, if one patent contains multiple active ingredients and the respective authorization is given for each active ingredient, only one of such multiple authorizations shall be selected by patentee for PTE.[224] In this respect, Korea is in the same position as the United States, opposite to Japan.

On the other hand, if multiple patents are related to one authorization, it is possible to get multiple PTEs by obtaining one respective PTE for each patent.[225]

## 5.5 RIGHT TO REQUEST PTE AND OBTAINING A PTE

Only patentee can be an applicant for PTE.[226] Also, in Korea, in order to obtain PTE, the patentee himself/herself, the exclusive licensee or non-exclusive licensee who registered his/her right must be the grantee of authorization, etc. It is required to attach documents certifying the above fact to the PTE application form.[227] In case of

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219 Case C-322/10 *Medeva v Comptroller-General of Patents, Designs and Trade Marks* [2011] ECR I-12051.
220 Yoon-suk Shin, 'Patent Term Extension in Korea', briefing paper of 22 October 2012, 16.
221 In Korea, unlike in the EU, it is more likely than not that PTE can be given if some of the two or more active ingredients contained in a combination are new substances. See supra note 212.
222 Article 3(1) KIPO Regulation.
223 Article 3(3) KIPO Regulation.
224 KIPO, *The examination Manual for Patent Term Extension* (KIPO Drug/chemistry Examination Team, June 2006), 9.
225 Article 3(2) KIPO Regulation.
226 See Article 91(4) KPA.
227 Article 6(1), Subparagraph 8 in the KIPO Regulation.

violation, it becomes the cause for final rejection against PTE application or PTE invalidation trial after term extension registration is carried out.[228]

## 5.6 PERIOD OF PATENT TERM EXTENSION (CALCULATION OF TERM)

It is the same as the SPC system of the EU in that the added period by the PTE in Korea is up to a maximum of 5 years.[229] However, there are the following differences from the SPC system.

In Korea, there is no automatic deduction of the 5 years in the added period calculation. Meanwhile, the KPA stipulates that the period used for responsible reasons to those who obtained authorization, etc. will be excluded from the calculation of the additional protection period.[230] In the recent important judgment[231] of the KPC Special Panel[232], the period shall not be excluded from the calculation when different documents are examined in parallel in each respective department of MFDS and at least one department conducts a proper examination without delay even if it takes more time for the other departments to review their documents due to reason which the applicant should be responsible for (i.e. a delay caused by allowing time for the applicant to fulfil the request for supplementation of the already submitted documents). Compared to the fact that the PTE system in Korea had been managed in more stringent or even adverse way to a patentee in general, the decision means a lot because it made a more favorable interpretation to the patent owner.

And, in Korea, any period of the time required for clinical test and the MFDS' document review can be included on the condition that the time was consumed after the patent registration.[233] In other words, any time taken for clinical test or the MFDS' document review will be excluded until the patent itself is registered.

In the calculation for clinical test period, the time consumed for clinical test in foreign countries, will be basically excluded.[234]

## 5.7 SCOPE OF PROTECTION

The notable precedent of KIPT[235] clarified that any patent right to which the PTE was granted could not rely on the doctrine of equivalents. The reasons for such position are as follows. First, considering that the PTE is granted as a special benefit to very limited type of patents such as medicinal product, very restrictive interpretation of the patent's scope would be appropriate. Second, the article 95 of KPA prescribing that the scope of the extended patent shall cover "only the product which was the subject of

228 See Infra note 242.
229 Article 89(1) KPA.
230 Article 89(2) KPA.
231 KPC, 2016Huh21 decided on March 16, 2017 and 2016Huh4498 decided on same day.
232 About the KPC Special Panel, See supra note 200.
233 Article 4 KIPO Regulation.
234 Min-zung Lee, supra note 200. 198.
235 Korean Intellectual Property Tribunal (**KIPT**), 2015Dang3931 decided Sep. 13, 2016. KIPT is a branch under KIPO.

authorization and etc." is a special exception rule triumphing over the article 97 used as the statutory basis of the doctrine of equivalents.[236]

However, in cases where the application of the equivalent doctrine for extended patents is officially abandoned due to the above circumstances, the extended patents is likely to be very vulnerable to unjustifiable competition because it is impossible to prevent any cunning act of manufacturing chemicals of the same active ingredient by substituting other salt. In order to avoid such risks, some strong and very plausible opinions[237] argue that the scope of the extended patent should be interpreted to include all substitutable salts of the active ingredient beyond the specific form of the active ingredient authorized by MFDS. According to this opinion, substantially same result as applying the doctrine of equivalence could be drawn. However, the opinion still does not explicitly mention the actual relationship to equivalent doctrine.

## 5.8 RIGHTS CONFERRED BY THE EXTENDED PATENT

In general, the extended patent confers the same right that was granted before extension. However, the actual scope of it would be limited if the above KIPT decision[238] is followed.

## 5.9 PROCEDURAL ASPECTS

As mentioned above, an application for PTE shall be filed within three months from the authorization and no later than six months before the expiration.[239] Unlike US, where the interim extension request is required,[240] the term is deemed to be automatically extended by the fact that there is a PTE application.[241]

Because the amendment of KPA in 1990 changed the PTE process from the pure application procedure to semi-prosecution procedure similar to patent prosecution, the review of the PTE requirement becomes relatively severe.

Due to the change in 1990, the invalidation trial for PTE registration before KIPT was established. Only interested party or examiner can file the trial against the Patentee.[242] The enumerated grounds for such invalidation include no necessity for authorization prior to use patent, a PTE application by other than patentee, acquisition of authorization by other than patentee, exclusive licensee or registered non-exclusive licensee, etc.[243] On the other hand, as for the final rejection to PTE application, the applicant may file the trial against final rejection to PTE application.[244]

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236 *Ibid.*
237 Chun-won Kang, 'Article 95 (Scope of extended patent by authorization, etc)' in Sang-jo Jung & Sung-su Park (eds), *The Commentary on the Korean Patent Act* (Park-young-sa, 2010) p. 1072; Hye-Eun Shin, 'Effects of patent right with its term extended by permit' [2016] 51 Industrial Property Rights 108, 152.
238 See supra note 235.
239 See 1.4.2.2.
240 See 35 U.S.C. 156(e)(2).
241 See 1.4.2.2.
242 Article 134(1) KPA.
243 *Ibid.*
244 Article 132-17 KPA.

## 5.10 THE INTERPLAY WITH OTHER FORMS OF EXCLUSIVITY

So far, there has been no substantial discussion or case about the interplay with other forms of exclusivity (data exclusivity, etc.) in Korea.

## 5.11 BOLAR EXEMPTION

In the KPA as in the EU directive and US patent law, the scope of patent is restricted from a use of patented invention for the purpose of conducting a clinical test to obtain authorization for a generic drug.[245] It is functioning to hit the balance with the other side of coin where the status of patent holder for the original drug has been strengthened through the adoption of PTE system. Whether or not third suppliers invoke the above Bolar exemption style immunity has not been explicitly discussed or dealt with in a specific case. However, there is no doubt that third suppliers could rely on the protection of Bolar exemption.

[245] Article 96(1), subparagraph 1 in KPA.

# 6 NEW ZEALAND

*Prof. Susy Frankel* Dr. Jessica C Lai***

## 6.1 SOURCES OF LAW

| Source | Role |
|---|---|
| Patents Act 2013 | Primary patent legislation |
| Patent Regulations 2014 | Secondary patent legislation |
| Trans-Pacific Partnership (**TPP**) Agreement Amendment Act 2016 (not yet in force) | Implements the TPP Agreement (does not enter into force unless and until the TPP Agreement enters into force) |
| Medicines Act 1981 | Regulates regulatory approval of any substance or article to be administered to human beings for a therapeutic purpose, whether manufactured, imported, sold, or supplied (s 3) |
| Agricultural Compounds and Veterinary Medicines (**ACVM**) Act 1997 | Regulates regulatory approval of any substance, mixture of substances, or biological compound, used or intended for use in the direct management of plants and animals, or to be applied to the land, place, or water on or in which the plants and animals are managed for a listed set of purposes (s 2) |

Table 6.1:

## 6.2 LEGAL NATURE

New Zealand does not currently have patent-term extension under the Patents Act 2013 or any kind of *sui generis* IP rights specifically to extend patent rights. New Zealand has, however, passed the TPP Agreement Amendment Act 2016, to implement the Trans-Pacific Partnership Agreement (hereinafter - **TPP Agreement**),[246] which would introduce two kinds of patent-term extension.[247] Though enacted, the TPP Agreement Amendment Act does not come into force until the TPP Agreement comes into force. At this writing, the TPP Agreement is unlikely to come into force because the United States has withdrawn from the signed agreement before it was ratified. Similar language to the TPP Agreement has been introduced into other trade negotiations, including the Regional Cooperation Economic Partnership

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246 Trans-Pacific Partnership Agreement (signed 4 February 2016), Articles 18.46 and 18.48.
247 Patent-term extension in New Zealand is discussed in depth in Susy Frankel and Jessica Lai, *Patent Law and Policy* (LexisNexis, 2016) pts 7.5 and 10.3; Susy Frankel et al, *The Web of Trade Agreements and Alliances and Impacts on Regulatory Autonomy* in Susy Frankel and Deborah Ryder (eds) RECALIBRATING BEHAVIOUR: SMARTER REGULATION IN A GLOBAL WORLD (LexisNexis, 2013); Susy Frankel and Meredith Kolsky Lewis, *Trade Agreements and Regulatory Autonomy: The Effect on National Interests* in Susy Frankel (ed) LEARNING FROM THE PAST, ADAPTING FOR THE FUTURE: REGULATORY REFORM IN NEW ZEALAND (Lexis Nexis, 2011) p. 411.

(**RCEP**).[248] The provisions in the TPP Agreement, relating to patent-term extension, were largely included because of the offensive interests of the United States. It may, therefore, be that New Zealand will not enact patent-term extension until it is obliged to do so via an agreement with the United States (perhaps involving other parties) or with the EU.

The two kinds of patent-term extension that might be introduced are:

a) General patent-term extension for unreasonable delays in granting a patent.[249] The delay must be caused by the Intellectual Property Office of New Zealand (**IPONZ**). This can implicate patents covering medicines or agricultural chemicals or veterinary medicines, which require regulatory approval in New Zealand, per the Medicines Act 1981 and the ACVM Act 1997, respectively.
b) Patent-term extension for pharmaceuticals for humans with respect to the unreasonable curtailment of the effective patent term as a result of the marketing approval process per the Medicines Act 1981.[250]

The following addresses the latter. That is, term extensions for the unreasonable curtailment of the effective patent term resulting from the marketing approval process of medicines for humans.

## 6.3 RATIONALE OF PATENT TERM EXTENSION

Patent term extension is not a wholly new for New Zealand. Prior to entering the TRIPS Agreement, New Zealand allowed patent-term extension on the basis of "inadequate remuneration" under the Patents Act 1953. This provided:[251]

> if upon application made by a patentee in accordance with this section the Court or Commissioner is satisfied that the patentee has not been adequately remunerated by the patent, the Court or Commissioner may by order extend the term of the patent, subject to such restrictions, conditions, and provisions, if any, as may be specified in the order, for such period (not exceeding 5 years or, in an exceptional case, 10 years) as may be so specified; and any such order may be made notwithstanding that the term of the patent has previously expired.

Under the above provision, almost all applications for extension of pharmaceutical patents, made between 1976 and 1996, were granted on the basis of inadequate remuneration. The average extension was for 7.91 years, which was over 50% of the then patent term of 16 years. The only applications that were not granted were those abandoned prior to a decision being made. In total, 30 applications were made (20 relating to pharmaceuticals),[252] 22 (20 relating to pharmaceuticals) were granted, one declined and seven withdrawn. Although this is not a large number many were for significantly expensive pharmaceutical products.[253]

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248 Leaked RCEP intellectual property chapter (15 October 2015 version), Article 5.13 (opposed by New Zealand).
249 TPP Agreement Amendment Act 2016, s 75 introducing ss 111A and 111B.
250 TPP Agreement Amendment Act 2016, s 75, introducing ss 111C-111I.
251 Patents Act 1953, s 31(1) (repealed). Patent term extension was also available on grounds of loss resulting from war: Patents Act 1953, s 32 (repealed).
252 This includes three applications for an extension of two patents, so 32 discrete applications are on record.
253 For more information, see Frankel and Lai (n 247) pp. 241-43; Frankel et al (n 247) p. 17; Frankel and Lewis (n 247) pp. 439-42.

The TRIPS Agreement requires all WTO members to provide a minimum patent term of 20 years. The 20-year term was in part justified, in the TRIPS negotiations, as necessary because it took into account regulatory delays.[254] Therefore, when New Zealand extended the term from 16 years to 20 years, in order to comply with the TRIPS Agreement, the government did not consider that any further term extension over and above the 20 years was necessary and it repealed its previous patent term provisions. Since the coming into force of the TRIPS Agreement, New Zealand has looked at extending pharmaceutical patent term, but has chosen not to do so largely because of the obvious cost to healthcare.[255] In 2003, the estimated cost of patent term extension for pharmaceutical patents was $85 million to $135 million per annum, depending on the ability of Pharmac (the New Zealand government agency that decides which pharmaceuticals to publicly fund in New Zealand) to renegotiate supply agreements.[256]

Although the grounds for extension under the TPP are not, like New Zealand's pre-TRIPS legislation, based on a showing of inadequate remuneration, but rather are based on unreasonable delay of the patent office or regulatory safety regime, the government has done an about face on the previous policy. Presumably, the New Zealand Government believed that the TPP as a whole would be of overall benefit, outweighing the costs of patent-term extension.[257] In its Regulatory Impact Statement (**RIS**) for the Bill implementing the TPP, the Ministry of Business, Innovation and Employment (**MBIE**) acknowledged that patent term extension could lead to very large net costs in New Zealand.[258] Specifically with respect to patent-term extension for pharmaceuticals, MBIE stated:[259]

> There is unlikely to be any benefit to New Zealand in providing for an extension of the patent term for pharmaceuticals. All, or nearly all, of the patented pharmaceuticals available in New Zealand have been developed outside New Zealand. Given the small size of the New Zealand market for pharmaceuticals, the length of the patent term in New Zealand is unlikely to have any effect on the decisions of overseas pharmaceutical companies to invest in the development of new pharmaceuticals. This will be the case even for New Zealand researchers, as the costs involved in developing a new pharmaceutical are so large that they could not be recouped from the New Zealand market alone.
>
> If a patent covers a pharmaceutical, any extension of the patent term will have the effect of delaying entry into the market of generic versions of the patented pharmaceutical. Typically, when a generic version of a patented pharmaceutical enters the market after the patent expires, the price can drop by as much as 80 – 90%. In the New Zealand context, a delay in generic entry can impose significant costs on the public health system to compensate for the lost savings, or reduce health outcomes. It is estimated that this cost to the government will be on average no more than $1 million per year because New Zealand practices are already very efficient. This is based on one product being extended by six months each year, but the actual costs, if any, will be lumpy and will vary over time. Costs will also be imposed on consumers (in the case of over-the-counter pharmaceuticals).
>
> On this basis, extending the patent term for pharmaceuticals has the potential to impose a significant net cost on the economy. The actual costs to the economy of any extension would depend on the nature of the pharmaceutical concerned, and the length of the extension. If the

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254 Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis* (4th edn, Sweet & Maxwell 2012) pp. 510-11.

255 Ministry of Economic Development, *Review of the Patents Act 1953: The Pharmaceutical Patent Term in New Zealand, Discussion Paper* (June 2003).

256 *Ibid*. paras 46-47.

257 On trade-offs in international trade agreements, see See also Frankel and others (n 247) especially pp. 42-43.

258 MBIE, *Regulatory Impact Statement: Analysis of Options Relating to Implementation of Certain Intellectual Property Obligations under the Trans-Pacific Partnership Agreement* (8 April 2016) paras 13 and 16.

259 *Ibid.* paras 49-51 (emphasis added).

> extension applies to a high cost pharmaceutical, or one that is dispensed in high volumes, the costs could be very high.

The TPP Agreement Amendment Act 2016 was, thus, designed to "minimise the impacts of changes to IP settings to maintain an appropriate balance between right holders and users" and "provide certainty and minimise compliance costs".[260]

## 6.4 GRANTING AUTHORITY

Under the TPP Agreement Amendment Act, it would be the Commissioner of Patents who grants patent-term extensions.[261] Medsafe (the New Zealand Medicines and Medical Devices Safety Authority) would provide the Commissioner of Patents with a "certificate" regarding the marketing approval process, including the date marketing approval was applied for, the date that marketing approval was granted and the portion of the time interval between these two dates that is attributable to Medsafe's actions.[262] The Commissioner of Patents "must rely on, and must not inquire into the accuracy of, the statements contained in the certificate".[263]

## 6.5 SUBSTANTIVE ASPECTS

### 6.5.1 Subject matter eligible for patent term extension

#### *6.5.1.1 Technical fields where PTE is possible*

Patent-term extension with respect to the unreasonable curtailment of the effective patent term as a result of the marketing approval process per the Medicines Act 1981, would only apply to pharmaceutical substances and biologics.

According to the TPP Agreement Amendment Act 2016:[264]

> **biologic** means a pharmaceutical substance that is produced by a process that involves the use of recombinant DNA technology
>
> **pharmaceutical substance** means 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
>
> **therapeutic use** means use for the purpose of—
> a) preventing, diagnosing, curing, or alleviating a disease, ailment, defect, or injury in persons; or
> b) influencing, inhibiting, or modifying a physiological process in persons; or
> c) testing the susceptibility of persons to a disease or ailment

From the definition of "medical device" in the Medicines Act (compared to the definitions of pharmaceutical substance and biologic), it does not appear that medical

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260 *Ibid.* para. 2.
261 This was also the case when term extension was dealt with under the former law.
262 TPP Agreement Amendment Act 2016, s 75, introducing s 111F(2); MBIE (n 258) para 129.
263 TPP Agreement Amendment Act 2016, s 75, introducing s 111F(3).
264 TPP Agreement Amendment Act 2016, s 75, introducing s 111C.

devices would qualify for term extension.[265] The situation with medical products that are administered through an implantable device is unclear.

#### *6.5.1.2 Category of patents eligible for patent term extension*

The TPP Agreement Amendment Act requires that one or more pharmaceutical *substances* (not products) *per se* or biologics have to be disclosed in the complete specification and be wholly within the scope of the claim or claims.[266] Furthermore, the application for patent-tem extension must refer to the first marketing approval of the pharmaceutical substance or biologic.[267]

#### *6.5.1.3 In the field of medicinal products: concept of active ingredient*

Patents for reformulations of known pharmaceuticals, Swiss-type claims or dosage claims would not qualify for patent-term extension.[268] This is because patent-term extension would only be available to pharmaceutical substances and not products, and because the application for extension would have to be with reference that substance's first marketing approval (see 6.5.1.2). This was MBIE's recommendation,[269] which noted that there are no "significant benefits" in providing patent term extension for products (rather than substances), but "significant disadvantages".[270]

That the patentee would only be able to apply for patent-term extension with respect to the first marketing approval would also prevent patentees from choosing the market approval application with the longest application process and that would give them the longest extension. It would also stop patentees from choosing the application closest to the expiry of the patent term, which would create uncertainty for generic companies and for Pharmac.[271] To support this, there might be a prescribed time limit in the Patent Regulations.[272]

### 6.5.2 Conditions for granting an patent term extension

A patentee would be able to request term extension if:[273]

a) 1 or more pharmaceutical substances per se or biologics were disclosed in the complete specification relating to the patent and were wholly within the scope of the claim or claims of that specification; and
b) the patentee made a marketing approval application to distribute a product containing or consisting of a substance or biologic that is one of those referred to in paragraph a. and marketing approval of that product has been granted; and
c) that marketing approval is the first marketing approval for a product that contains or consists of any of the substances or biologics referred to in paragraph (a); and
d) the term of the patent has not been previously extended under section 111E.

Under the TPP Agreement Amendment Act, the Commissioner *must* grant term extension if the Commissioner is satisfied that there is "unreasonable curtailment of

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265 Medicines Act 1981, s 3A.
266 TPP Agreement Amendment Act 2016, s 75, introducing s 111D(1)(a).
267 TPP Agreement Amendment Act 2016, s 75, introducing s 111D(1)(c).
268 This is unless the original pharmaceutical was never marketed in New Zealand.
269 MBIE (n 258) paras 58-61.
270 *Ibid.* para 64.
271 *Ibid*. paras 116-18.
272 TPP Agreement Amendment Act 2016, s 75, introducing s 111D(2)(b).
273 TPP Agreement Amendment Act 2016, s 75, introducing s 111D.

the effective patent term as a result of the marketing approval process".[274] "Unreasonable curtailment" is specified as existing where marketing approval is obtained after the patent is granted, *and* the time between the application for marketing approval and marketing approval is notified in the *Gazette is more than five years for biologics and three years for other pharmaceutical substances (not including periods that* were outside the direction or control of the Regulator).[275] Extension would not be automatic because "unreasonable" indicates that some curtailment by the marketing process is contemplated and reasonable.[276]

Term extension would only be able to be granted once and would have to be applied for during the patent term,[277] in order to minimise the impact if extension were granted.[278]

## 6.6 RIGHT TO REQUEST AND OBTAIN A PATENT TERM EXTENSION

The patentee would have to have made the first successful marketing approval application for a product containing or consisting of the pharmaceutical substance or biologic, in order to apply for term extension.[279]

## 6.7 PERIOD OF PATENT TERM EXTENSION (CALCULATION OF TERM)

The term of extension would be the shorter of:[280]

a) the period equivalent to the interval between the date of grant of the patent and the date on which the marketing approval is notified in the *Gazette*;
b) the period by which period A in section 111F(1)(b) exceeds 5 years in the case of a biologic and 3 years in the case of any other pharmaceutical substance;
c) 2 years.

The TPP Agreement Amendment Act 2016 provides the following example:

A convention application [made in accordance with the Patent Convention Treaty] for a pharmaceutical substance other than a biologic is made on 1 April 2026, the request for examination is made on 1 April 2029, the application for marketing approval is made on 1 April 2030, the patent is granted on 1 October 2030 with a patent date of 1 April 2026 (so the patent term will expire on 1 April 2046), and marketing approval is notified on 1 April 2036.

Two years of the marketing approval process is taken by the applicant in responding to requests for information by the Regulator.

The term of the extension is 1 year, calculated as the shortest of the following periods:

- 5.5 years, being 1 October 2030 to 1 April 2036;

274 TPP Agreement Amendment Act 2016, s 75, introducing s 111E(a)-(b).
275 TPP Agreement Amendment Act 2016, s 75, introducing s 111F.
276 MBIE (n 258) para 48.
277 TPP Agreement Amendment Act 2016, s 75, introducing s 111D(1)(d) and (2)(a).
278 MBIE (n 258) para 102.
279 TPP Agreement Amendment Act 2016, s 75, introducing s 111D(1) and 111I.
280 TPP Agreement Amendment Act 2016, s 111G.

- 1 year, being the period by which 4 years (6-year interval between 1 April 2030 and 1 April 2036 minus 2 years) exceeds 3 years;
- 2 years.

## 6.8 SCOPE OF PROTECTION

The extended rights of the patentee would be limited to the therapeutic use(s) for which marketing approval was granted and to which the unreasonable curtailment is related to (i.e. the first marketing approval).[281] This means that third parties could exploit any form of the invention for a purpose other than the registered therapeutic uses related to the term extension.[282]

The grant of patent-term extension to a parent patent would not automatically extend to the term of a patent of addition.[283] The patent term of a patent of addition could also be extended apart from the parent patent; the extension would begin at the end of the unextended term of the parent patent, at which point the patent of addition would become an independent patent.[284]

## 6.9 RIGHTS CONFERRED BY THE EXTENDED PATENT

Patentees would have the same rights in the period of extended term. However, this would only cover the subject matter relating to the therapeutic uses covered by the connected marketing approval.

## 6.10 PROCEDURAL ASPECTS

Term extension applications would only be able to be made while the patent is still in term.[285]

The Commissioner would have some discretion to refuse to grant an extension if there were opposition to the grant or the grant is on appeal.[286] Anyone would be able to oppose the grant of a patent-term extension on the grounds that one of the above mentioned conditions (see 6.5.2) are not met or there was not unreasonable curtailment of the effective patent term.[287]

Decisions of the Commissioner can be appealed to the court, namely to the High Court.[288]

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281 TPP Agreement Amendment Act 2016, s 75, introducing s 111I.
282 In New Zealand, one must have regulatory approval for each therapeutic use.
283 TPP Agreement Amendment Act 2016, s 75, introducing s 111O(1) and (4).
284 TPP Agreement Amendment Act 2016, s 75, introducing s 111O(2)-(3).
285 TPP Agreement Amendment Act 2016, s 75, introducing s 111D(2)(a).
286 TPP Agreement Amendment Act 2016, s 75, introducing s 111E(c).
287 TPP Agreement Amendment Act 2016, s 75, introducing s 111H.
288 Patents Act 2013, s 214.

## 6.11 INTERPLAY WITH OTHER FORMS OF EXCLUSIVITY

New Zealand currently has regulatory-data exclusivity for medicines for humans for five years.[289] Protection for regulatory data submitted under the ACVM is for ten years.[290] However the TPP also requires more extensive regulatory data exclusivity of medicines for humans, which together with the potential for patent-term extension would reflect a significant ratcheting-up of protection for pharmaceuticals in New Zealand.[291]

## 6.12 EXCEPTIONS FROM INFRINGEMENT

New Zealand has an experimental-use exception, which states:[292]

> (1) It is not an infringement of a patent for a person to do an act for experimental purposes relating to the subject matter of an invention.
>
> (2) In this section, act for experimental purposes relating to the subject matter of an invention includes an act for the purpose of—
>
> a. determining how the invention works:
> b. determining the scope of the invention:
> c. determining the validity of the claims:
> d. seeking an improvement of the invention (for example, determining new properties, or new uses, of the invention).

The commercial nature of the use should not matter, so long as the use is experimental and for one of the prescribed purposes.

New Zealand also has a regulatory review exception, which provides:[293]

It is not an infringement of a patent for a person to make, use, import, sell, hire, or otherwise dispose of the invention solely for uses reasonably related to the development and submission of information required under any law (whether in New Zealand or elsewhere) that regulates the manufacture, construction, use, importation, sale, hire, or disposal of any product.

This allows generic manufacturers to enter the market sooner rather than later and thus, in theory, provide competition, which ought to eventually lower prices.

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289 Medicines Act 1981, s 23B.
290 ACVM Act 1997, ss 74A-74G. Resulting from to changes introduced in the ACVM Amendment Act 2016.
291 The potential increased protection and the interplay between the two regimes is examined in extensively in Frankel and Lai (n 247) ch 10.
292 Patents Act 2013, s 143. For more on this, see Frankel and Lai (n 247) 256-67.
293 Patents Act 2013, s 145.

# 7 SINGAPORE

*Prof. Elizabeth Siew-Kuan Ng* ***

## 7.1 SOURCES OF LAW

In Singapore, there are generally two sources of legislative provisions: primary and subsidiary legislation. Primary legislation is found in acts passed by Parliament, while subsidiary legislation is found in the associated rules, regulations and orders made by a Minister to the extent of the powers conferred by each specific act. Both are equally binding sources of law, except that the latter cannot contradict the former.

Under the Patents Act (Cap 221, 2005 Rev Ed), the standard term of protection for a patent in Singapore is twenty years, subject to the timely payment of renewal fees. In 2004, the Patents Act was amended by the Patents (Amendment) Act 2004 (No 19 of 2004)[294], which, inter alia, introduced a new section 36A to allow a patent proprietor to apply for an extension of a patent term.

Section 36A of the Patents Act (as amended) [295] provides that:

(1) The proprietor of a patent may apply to the Registrar to extend the term of the patent on any of the following grounds:

(a) that there was an unreasonable delay by the Registrar in granting the patent;

(b) where the patent was granted on the basis of any prescribed documents referred to in section 29(1)(d) relating to one corresponding application or related national phase application, that —

(i) there was an unreasonable delay in the issue of the corresponding patent or related national phase patent (as the case may be); and

(ii) the patent office that granted the corresponding patent or related national phase patent (as the case may be) has extended the term of the corresponding patent or related national phase patent (as the case may be) on the basis of such delay;

(c) where the subject of the patent includes any substance which is an active ingredient of any pharmaceutical product, that —

(i) there was an unreasonable curtailment of the opportunity to exploit the patent caused by the process of obtaining marketing approval for a pharmaceutical product, being the first pharmaceutical product to

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294 The 2004 Amendment Act came into force on 1st July 2004.

295 The Patents (Amendment) Act 2012 (No 15 of 2012) further amended s 36A of the Patents Act and came into effect on 14th February 2014.

obtain marketing approval which uses the substance as an active ingredient; and

(ii) the term of the patent has not previously been extended on this ground.

...

(5) A curtailment of the opportunity to exploit a patent, the subject of which includes a substance which is an active ingredient of any pharmaceutical product, caused by the process of obtaining marketing approval for a pharmaceutical product, being the first pharmaceutical product to obtain marketing approval which uses the substance as an active ingredient, shall not be treated as an unreasonable curtailment under subsection (1)(c) unless such requirements as may be prescribed are satisfied.

(6) Subject to subsections (7), (8) and (9), where the proprietor of a patent has made an application under subsection (1)(c) and has satisfied the Registrar that there was in fact an unreasonable curtailment of the opportunity to exploit the patent under subsection (1)(c), the Registrar shall extend the term of the patent by such period as may be prescribed.

(7) The Registrar shall not extend the term of the patent under subsection (6) unless the applicant has procured and submitted to the Registrar a certificate from the relevant authority stating such matters as may be prescribed.

(8) In determining the period by which to extend the term of the patent under subsection (6), the Registrar shall rely on, and shall not be concerned to inquire into the truth of, the statements contained in the certificate from the relevant authority under subsection (7).

(9) Where the term of a patent has been extended under subsection (6), the protection conferred by the patent during the term of the extension shall apply only to the substance referred to in subsection (1)(c).

(10) Every application to extend the term of a patent shall be —

(a) made by the proprietor of the patent in the prescribed form within the prescribed period;

(b) filed in the prescribed manner; and

(c) accompanied by the prescribed fee and any prescribed documents, and the Registrar may reject any application that fails to comply with any requirement under this subsection.

(11) As soon as practicable after the Registrar has extended the term of a patent, he shall —

(a) send to the proprietor of the patent a certificate of extension of patent term in the prescribed form specifying —

(i) the period of the extension; and

(ii) any limitation on the protection conferred by the patent during the term of the extension; and

(b) publish in the journal a notice of the extension.

(12) The proprietor of a patent who has made an application under subsection (1) may withdraw the application by informing the Registrar in writing of the withdrawal of the application, and any such withdrawal shall not be revocable.

Apart from this main statutory provision, rule 51A of the Patents Rules (Cap 221, R1, 2007 Rev Ed) goes on to prescribe the applicable procedural requirements for a patent term extension. Other relevant legislation include those related to the grant of marketing approval for medicinal and health products, such as the Medicines Act (Cap 176, 1985 Rev Ed) and the Health Products Act (Cap 122D, 2008 Rev Ed), and their associated subsidiary legislation.

This chapter will focus only on the extension of patent term under section 36A(1)(c), which is based on an unreasonable curtailment of the opportunity to exploit a patent caused by the process of obtaining marketing approval (hereinafter referred to as 'patent term extension(s)'). It will not cover any of the other grounds, such as those based on unreasonable delays in the grant of the patent under sections 36A(1)(a) or 36A(1)(b), although some parts of the discussion may be equally applicable to them.

## 7.2 LEGAL NATURE OF EXTENSION OF THE TERM OF THE PATENT

The extension of patent term in Singapore does not create any *sui generis* right independent of the patent for which the extension is sought. Indeed, section 36A of the Patents Act expressly provides that the patent proprietor may apply 'to extend the term of the patent'. Consequently, if the patent is no longer in force (e.g. where the patent has been revoked), then any extended term will also expire.

Moreover, the protection conferred during the extended term is generally the same as that conferred by the patent during the usual non-extended term, subject to certain exceptions. For example, in cases where the patent term extension has been granted due to the unreasonable curtailment of patent exploitation opportunity caused by delays in the marketing approval process under s 36A(1)(c), the scope of patent protection during the extended term has been expressly restricted to the substance which is an active ingredient of a pharmaceutical product that has been included in the subject-matter of the patent.

## 7.3 RATIONALE OF PATENT TERM EXTENSION

Patent term extensions were introduced partly as a result of Singapore's obligations under the US-Singapore Free Trade Agreement (**USSFTA**). Nonetheless, the rationale was also to strengthen the overall patent ecosystem in order to support the growth of the biomedical and pharmaceutical industries and generally encourage innovation and research development in Singapore.

It was aimed at compensating a patent owner for unreasonable delays that may occur in the process of granting a patent or, in the case of pharmaceutical products, a delay

in the process of obtaining marketing approval that results in any unreasonable curtailment of the opportunity to exploit the patent.

Like many developed countries, most pharmaceutical products cannot be marketed in Singapore until they have been granted marketing approval[296], notwithstanding that a patent has already been granted. The process of obtaining this marketing approval can sometimes be lengthy, and any unreasonable delay may negatively impact the ability to exploit the patent by shortening its market exclusivity period. Thus, patent term extensions strive to ensure that patent owners are not unfairly prejudiced by these delays.

## 7.4 GRANTING AUTHORITY

The authority that grants patent term extensions is the Intellectual Property Office of Singapore (**IPOS**)[297], and the authority that grants marketing approval is the Health Sciences Authority (**HSA**).[298] The HSA regulates medicinal and health products to make certain that they meet safety, quality and efficacy standards.[299] Where the patent owner is applying to extend the patent under section 36A(1)(c), the burden is on the applicant to procure and submit to the Registrar (IPOS) a certificate from the HSA stating:[300]

a) the date the application for marketing approval was filed;
b) the date marketing approval was obtained; and
c) for each period attributable to an act or omission of the applicant for marketing approval, the dates on which the period started and ended.

The Registrar (IPOS) relies on the statements contained in the certificate issued by the HSA, and does not inquire into the truth of the statements contained in any certificate so issued.

## 7.5 SUBSTANTIVE ASPECTS

### 7.5.1 Subject matter eligible for patent term extension

#### *7.5.1.1 Technical fields where PTE is possible*

Where patent term extension is sought under section 36A(1)(c), an application can only be made in respect of a patent where the subject 'includes any substance which

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296 'Marketing approval' in respect of a pharmaceutical product is defined in s 2 of the Patents Act as '(a) a product licence under section 5 of the Medicines Act (Cap. 176) granted before the date of commencement of section 2(d) of the Patents (Amendment) Act 2012; or (b) a registration under Part VII of the Health Products Act (Cap. 122D) granted on or after the date of commencement of section 2(d) of the Patents (Amendment) Act 2012.

297 It was established and incorporated in 2001 under the Intellectual Property Office of Singapore Act (Cap 140, 2002 Rev Ed).

298 It was established under the Health Sciences Authority Act (Cap 122C, 2002 Rev Ed) in 2001 as a statutory board of the Singapore Ministry of Health.

299 See the Corporate Profile of HSA <http://www.hsa.gov.sg/content/hsa/en/About_HSA/ Corporate_ Profile.html> accessed 8 July 2017.

300 Patents Rules, r 51A(9).

is an active ingredient of any pharmaceutical product'.[301] This provision has not yet been interpreted by the courts in Singapore and its precise scope remains unclear.

On a plain reading of the provision, it appears that the technical scope of patent term extensions will turn largely on the term 'pharmaceutical product'. Although the Patents Act does provide us with its definition, its scope remains ambiguous. Under section 2(1), 'pharmaceutical product' is defined as:

> … a medicinal product which is a substance used wholly or mainly by being administered to a human being for the purpose of treating or preventing disease, but does not include —
> (a) any substance which is used solely —
> (i) for diagnosis or testing; or
> (ii) as a device or mechanism, or an instrument, apparatus or appliance; or
> (b) any substance or class of substances specified in paragraph 2 or 3 of the Schedule.'

Medicinal product is further defined as a medicinal product (within the meaning of the Medicines Act) or a health product (within the meaning of the Health Products Act) prescribed as a medicinal health product.[302]

Thus, under the Patents Act a 'pharmaceutical product' is a medicinal product for human use, namely a substance used wholly or mainly by being administered to a human being for the purpose of treating or preventing diseases, subject to specific exceptions set out in the Patents Act. The following, inter alia, are not eligible for patent term extension since they are excluded from the definition of pharmaceutical products:

a) a medicinal product for veterinary use;
b) a substance used solely for diagnosis or testing;
c) a substance used solely as a device, mechanism, instrument, apparatus or appliance;
d) traditional medicine;
e) homoeopathic medicine;[303]
f) quasi-medicinal product;[304]
g) any raw material which is used as an ingredients in the preparation or manufacture of any medicinal product;
h) medicated oil or balm;[305]
i) a substance which is a type of food, a food additive or a food supplement;
j) a substance that occurs naturally in any plant, animal or mineral.[306]

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301 Patents Act, s 36A(1)(c).

302 Note also that the Patents (Medicinal Health Products) Rules 2016 (Cap 221, S 493/2016) states that a health product is prescribed as a medicinal health product if the health product is a therapeutic product as defined in the Health Products Act, First Schedule.

303 'Homoeopathic medicine' means any substance used in the system of therapeutics in which a disease is treated by the use of minute amounts of one or more substances which, in their undiluted forms, are capable of producing in a healthy human being symptoms similar to those of the disease being treated; see Patents Act, The Schedule.

304 'Quasi-medicinal product' means — (a) any anti-dandruff preparation; (b) any medicated cosmetic product for the treatment of pimples or acne, except any preparation containing etretinate or 13-cisretinoic acid; (c) any medicated soap; (d) any sweet for relieving coughs or throat irritations; (e) any medicated plaster; (f) any sunscreen or suntan preparation; (g) any medicated beverage; (h) any vitamin or nutritional preparation from any plant, animal or mineral, or any combination thereof; or (i) any medicated toothpaste. See the Patents Act, The Schedule.

305 'Medicated oil or balm' means any external medicated embrocation, medicated cream, ointment or inhalant — (a) which is used mainly for soothing purposes; and (b) which contains one or more of the following substances as an active ingredient or as active ingredients: (i) any essential oil; (ii) any fixed oil derived from a plant; (iii) methyl salicylate; (iv) menthol; (v) camphor; (vi) peppermint. See Patent Act, The Schedule.

The first issue to be highlighted is that the definition of 'pharmaceutical product' under the Patents Act does not have the same meaning as 'medicinal product' under the Medicines Act, or 'medicinal health product' in the Health Products Act. Hence, it may be possible that a delay in the grant of marketing approval for a 'medicinal product' or 'medicinal health product' by the HSA, may still not be eligible for patent term extension if it does not fall within the definition of a 'pharmaceutical product' under the Patents Act. For example, under the Medicines Act a 'medicinal product' includes any substance which is manufactured for use wholly or mainly (a) by being administered to one or more human beings or animals for a medicinal purpose; or (b) as an ingredient in the preparation of a substance or article which is to be administered to one or more human beings or animals for a medicinal purpose. 'Medicinal purpose' includes '*treating or preventing disease*', '*diagnosing disease* or ascertaining the existence, degree or extent of a physiological condition' etc. In contrast, 'pharmaceutical product' under the Patents Act is more limited in scope, it covers 'substance used wholly or mainly by being administered to a human being for the purpose of *treating or preventing disease*.' Indeed, substances used solely for diagnosis are explicitly excluded as 'pharmaceutical products' under the Patents Act. Hence, any delay in the grant of marketing approval by HSA for medicinal product that is used as a substance wholly for diagnosing diseases will not be eligible for patent term extension.

Similarly, any substance which is used solely as a device or mechanism, or an instrument, apparatus or appliance will fall outside the definition of a 'pharmaceutical product' under the Patents Act and will not be eligible for patent term extension.

The second issue of whether plant or animal products are pharmaceutical products and thus eligible for patent term extension under the Patents Act is less straightforward. As can be inferred from the provision above, the *prima facie* position is that plant or animal products are not treated differently and in order to be eligible for patent term extension they will, inter alia, have to fall within the definition of pharmaceutical products. However, several substances that have been expressly excluded from the definition of pharmaceutical products make reference to plant or animal products. It may be worth examining the scope of some of these exclusions.

(a) *Substance that occurs naturally in any plant, animal or mineral*

Naturally-occurring substances in any plant, animal or mineral have been expressly excluded from the definition of pharmaceutical product. However, the precise meaning of a naturally-occurring substance is unclear. On the one hand, a substance that occurs in a plant, animal or mineral in its natural state/form may be considered as naturally-occurring. On the other, where the substance has been modified or synthetically manufactured, it may be argued that it is not naturally-occurring. Beyond this, the line between substances that are naturally occurring and non-naturally occurring remains amorphous. For example, it is unclear whether a substance that is derived from a plant or animal, or is a derivative thereof, would be considered as naturally-occurring. It may depend, inter alia, on the extent to which the end product has been altered or modified.

[306] For items 4 – 10, see Patents Act, The Schedule.

(b) *Traditional medicine*

Traditional medicine has also been explicitly excluded from the definition of pharmaceutical product. It is defined under the Patents Act as:[307]

> …any medicinal product consisting of one or more substances derived from any plant, animal or mineral, or any combination thereof, but does not include the following:
> (a) any medicinal product to be administered by injection into a human body;
> (b) any vaccine to be administered to a human being;
> (c) any product derived from human blood;
> (d) any item specified in the Poisons List in the Schedule to the Poisons Act (Cap. 234);
> (e) any Chinese proprietary medicine.

Here, Chinese proprietary medicine is defined as:

> …any medicinal product used in the system of therapeutics according to the traditional Chinese method, that is to say, any medicinal product —
> (a) which has been manufactured into a finished product;
> (b) which contains one or more active substances derived wholly from any plant, animal or mineral, or any combination thereof; and
> (c) which is, or all of the active substances of which are, described in the current edition of 'A Dictionary of Chinese Pharmacy' <<中药大辞典>> or 'The Chinese Herbal Medicine Materia Medica' <<本草纲目>>,
>
> but does not include —
> (i) any medicinal product to be administered by injection into a human body; or
> (ii) any medicinal product which contains as an active substance any chemically-defined isolated constituent of any plant, animal or mineral, or any combination thereof.

The statutory language used in defining Chinese proprietary medicine under the Patents Act seems rather convoluted. A slightly clearer and more recent iteration of what constitutes Chinese proprietary medicine may be found in the Health Products Act, which clarifies that sub-paragraphs (i) and (ii) above should be read cumulatively with paragraphs (a) – (c) as follows:[308]

> (d) which does not contain as an active substance any chemically defined isolated constituent of any plant, animal or mineral, or any combination thereof; and
> (e) which is not intended to be administered by injection into a human body.

Notably, there is no apparent reason why the definition of Chinese proprietary medicine should differ between the two statutes. Therefore, it is arguable that the amendment under the Health Products Act was simply meant to clarify the earlier definition – it provides greater conceptual clarity and yet does not materially change the substance of the meaning of Chinese proprietary medicine. Hence, it is submitted that for the purposes of the Patents Act, the scope of Chinese proprietary medicine should be similar to that under the Health Products Act.

Be that as it may, from the preceding discussion it can be seen that in determining whether plant or animal products fall within the definition of pharmaceutical product under the Patents Act, tensions and overlaps exist between substances that:

a) occur naturally in any plant, animal or mineral;
b) are derived from any plant, animal or mineral;
c) are derived wholly from any plant, animal or mineral; and

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307 For the definitions of both traditional medicine and Chinese proprietary medicine, see Patents Act, The Schedule.

308 Health Products Act, First Schedule.

d) contain chemically-defined isolated constituents of any plant, animal or mineral, or any combination thereof.

Unfortunately, there is no clear guidance in the statute, case-law or administrative guidelines on the precise scope of any of the substances referred to above. In addition, there does not seem to be any clearly discernible principles that can be used to delineate and conclusively determine when a plant or animal product may be eligible for patent term extension. Nonetheless, it may be worth noting that some animal and plant products are exempted from marketing approval. In such cases, whether or not they will be treated as a pharmaceutical product under the Patents Act may not ultimately be a crucial issue.

From the preceding discussion, it seems at least clear that the approach to defining the technical scope of patent term extensions in Singapore is different from an SPC in Europe. Furthermore, it can be seen that Singapore does not deal specifically with patent term extensions for plant products *per se*. Instead, as discussed above, plant and animal products are broadly dealt with under the scope of what constitutes a pharmaceutical product.

#### *7.5.1.2 In the field of medicinal products: concept of active ingredient*

There is no definition of what constitutes an 'active ingredient' under the Patents Act. However, it may be useful to look at other relevant legislation, such as the Medicines Act and the Health Products Act for guidance. Under section 2(1) of the Health Products Act, "active ingredient" is defined as "any substance or compound that is usable in the manufacture of a health product as a pharmacologically active constituent"; and "ingredient" in relation to the manufacture or preparation of a substance under section 2(1) of the Medicines Act includes "anything which is the sole active ingredient of that substance as manufactured or prepared". It is unclear whether the same meaning will be attributed to "active ingredient" under the Patents Act.

### 7.5.2 Conditions for granting patent term extension

#### *7.5.2.1 Premise*

Patent term extension is not automatic and must be applied for by the patent proprietor. In the case of a patent term extension under s 36A(1)(c), several conditions must be cumulatively fulfilled, namely:

a) The subject of the patent includes any substance which is an active ingredient of any pharmaceutical product;
b) That there was an unreasonable curtailment of the opportunity to exploit the patent caused by the process of obtaining marketing approval for a pharmaceutical product;
c) That the pharmaceutical product was the first pharmaceutical product to obtain marketing approval which uses the substance as an active ingredient;

d) That the term of the patent has not previously been extended on this ground.[309]

#### *7.5.2.2 First requirement – 'the subject of the patent includes any substance which is an active ingredient of any pharmaceutical product'*

There is no judicial interpretation of this provision. Nonetheless, several points are worth highlighting based on a plain reading of the provision.

First, similar to Europe, an application to extend the patent term under section 36A(1)(c) of the Patents Act can only be made while the patent is still in force.

Second, it would seem that where a patent in force has a subject that includes *any* substance which is an active ingredient of *any* pharmaceutical product, it may be eligible for patent term extension. To put it another way, so long as a substance which is an active ingredient of a pharmaceutical product is included in the subject of a patent, the patent may be eligible for patent term extension. For example, if the subject of the patent covers A, B and C, but only C is a substance which is an active ingredient of a pharmaceutical product, the patent would still be eligible for term extension provided the other conditions are met. Note, however, that the protection conferred by the patent during the extended term pertains only to the substance which is an active ingredient of a pharmaceutical product (i.e. substance C) and not to any other substance in the patent (i.e. A or B).

Yet, it should be emphasized that the precise scope and meaning of 'subject of the patent' is also unclear. For example, is it sufficient if the substance which is an active ingredient of a pharmaceutical product has been disclosed in the patent but has not been claimed? Or must the patent claim the said substance in order to constitute 'subject of the patent'? There is no case-law to provide guidance on this. However, some useful guidance may be obtained from section 36A(9) of the Patents Act which provides that where a patent term extension has been granted, the *protection conferred by the patent during the extended term* shall '*apply only to the substance*' which is an active ingredient of any pharmaceutical product. Hence, the author proffers that the substance which is an active ingredient of that pharmaceutical product must logically already be protected by the patent. Consequently, in the author's view 'subject of a patent' means the subject protected by a patent in force in Singapore. It is beyond the scope of this chapter to provide a detailed discussion on how to determine the scope of patent protection in Singapore, save to highlight that the extent of protection conferred by a patent 'shall, unless the context otherwise requires, be taken to be that specified in a claim of the specification of the application or patent, as the case may be, as interpreted by the description and any drawings contained in that specification.'[310] This is similar to section 125(1) of the United Kingdom Patents Act which corresponds to article 69 of the European Patent Convention.

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309 Patents Act, s 36A.

310 See s 113 of the Patents Act.

Third, the definitions of 'pharmaceutical product' and 'active ingredient' are also significant. However, these have been discussed in the preceding sections and will not be repeated here.[311]

Fourth, patent term extension is available only for products and not processes.

#### *7.5.2.3 Second requirement – 'there was an unreasonable curtailment of the opportunity to exploit the patent caused by the process of obtaining marketing approval for a pharmaceutical product'*

Unlike the other grounds for the grant of patent term extension, such as those based on an unreasonable delay by the Registrar in the grant of a patent; the extension of patent term under s 36A(1)(c) is contingent on the fact that there was an unreasonable curtailment of the opportunity for patent exploitation caused by the marketing approval process.

As stated above, marketing approval in respect of a pharmaceutical product denotes either a product licence under section 5 of the Medicines Act; or a registration under Part VII of the Health Products Act. Note however that the applicable limb will depend on the date on which the licensing or registration occurred.[312]

The scope of what constitutes 'unreasonable curtailment' is prescribed under the Patent Rules as one where the marketing approval was granted by HSA after the date of issue of the certificate of grant; and the time interval between the date of filing of the application for marketing approval and the date of grant of marketing approval exceeds 2 year, excluding any period attributable to an act or omission of the applicant for marketing approval.[313] In addition, the applicant for patent term extension must procure and submit to the Registrar a certificate from HSA stating –

a) The date of filing the application for marketing approval;
b) The date of grant of marketing approval; and
c) For every period that is attributable to an act or omission of the applicant for marketing approval, specify the dates on which the period commenced and ended.[314]

#### *7.5.2.4 Third requirement – 'pharmaceutical product was the first pharmaceutical product to obtain marketing approval which uses the substance as an active ingredient'*

Again, this requirement has not been subject to judicial interpretation. Based on a plain reading of the statutory provision, the pharmaceutical product must have been granted marketing approval and must be the first pharmaceutical product to be granted marketing approval that uses the substance as an active ingredient.

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311 See under heading '7.5.1.1 Technical fields where extension is possible' and '7.5.1.2 In the field of medicinal products: concept of active ingredient.'
312 See n 6.
313 See Patents Rules, r 51A(7). See r 51A(11) of the Patents Rules on what constitutes 'period attributable to an act or omission of the applicant for marketing approval.'
314 See Patents Act, s 36A(7) and Patents Rules, r 51A(9).

Example: Patent subject includes substance A which is an active ingredient of a pharmaceutical product. The first marketing authorization covers a medicinal product including A-B. Based on a reading of the statutory provision, it seems that the third requirement may be satisfied. If the patent term is extended, then the patent protection conferred during the extended term would apply to substance A only.

#### *7.5.2.5 Fourth requirement – 'term of the patent has not previously been extended on this ground'*

This requirement simply suggests that it must be the first time that the term of a particular patent is sought to be extended on the basis that there was unreasonable curtailment of opportunity to exploit the patent caused by the process of obtaining marketing approval for any pharmaceutical product. In other words, a patent cannot be extended more than once under this ground.

## 7.6 RIGHT TO REQUEST AND OBTAIN A PATENT TERM EXTENSION

The Patents Act provides that the proprietor of a patent is the one who is entitled to apply to extend the patent term.[315] In addition, the patent proprietor also has to procure and submit to the Registrar (IPOS) an HSA certification relating to certain timelines of the marketing approval process.[316] Where the patent proprietor is also the marketing authorization holder, the situation is unproblematic and the patent proprietor will clearly be entitled to rely on the marketing authorization in applying for a patent term extension. However, the position is less clear as to whether a patent proprietor may rely on a third party marketing authorization. In this situation what can be said is that there is no express requirement under the Patents Act and Patent Rules that the patent proprietor must also be the holder of the marketing authorization, or that a third party holder of the marketing authorization must consent to the use of the marketing authorization for the purpose of a patent term extension application. Nonetheless, it should be noted that Singapore has introduced patent linkage into its laws, which restricts the ability of third parties to apply for marketing approval if the pharmaceutical product will infringe on a patent.

## 7.7 PERIOD OF EXTENSION (CALCULATION OF TERM)

Where the Registrar (IPOS) is satisfied that there was in fact an unreasonable curtailment of the opportunity to exploit the patent, the term of the patent shall be extended by the shortest of the following periods:

a) a period equivalent to the interval between the date of issue of the certificate of grant and the date marketing approval was granted;
b) the period by which the interval referred to in paragraph (7)(b) exceeds 2 years;[317]
c) a period of 5 years.

[315] See Patents Act, s 36A.
[316] See discussion below in '1.9 Procedural aspect'.
[317] The 'interval referred to in paragraph 7(b)' denotes the interval between the date the application for marketing approval was filed and the date the marketing approval was obtained, exceeds 2 year (excluding any period attributable to an act or omission of the applicant for marketing approval).

In short, the patent term can be extended up to a maximum of 5 years based on the ground prescribed under section 36A(1)(c) of the Patents Act.

## 7.8 RIGHTS CONFERRED BY THE EXTENDED PATENT AND SCOPE OF PROTECTION

Although patent term extensions in Singapore are basically an extension of the period of protection granted by a patent, the scope of protection conferred during the extended term may not necessarily be the same as that conferred during the usual (non-extended) patent term. As has been emphasized above, where the term of a patent is extended under s 36A(1)(c), the protection conferred by the patent during the extended term is limited only to the substance which is an active ingredient of a pharmaceutical product included in the subject of the patent.

Example: Patent subject covers A, B and C. Only C is a substance which is an active ingredient of a pharmaceutical patent. During the extended term of the patent, the patent protection conferred is only to substance C.

Furthermore, in granting the patent term extension, the Registrar may specify in the certificate of extension any limitation on the protection conferred by the patent during the extended the term of the patent.

## 7.9 PROCEDURAL ASPECTS

An application for patent term extension under section 36A(1)(c) must be made on Patents Form 54:

a) within 6 months from the date of the grant of the patent, or date marketing approval was obtained (whichever is the later);
b) not later than 6 months before the end of the period of 20 years from the date of filing the patent application or with such other date as may be prescribed; and
c) while the patent is still in force.

These timelines must be strictly adhered to as the Registrar has no discretion to extend the time or period prescribed above.

In addition, the application for patent term extension must be accompanied by:

a) the prescribed fee;
b) a certificate from HSA stating (i) the date the application for marketing approval was filed; (ii) the date marketing approval was obtained; and (iii) for each period attributable to an act or omission of the applicant for marketing approval, the dates on which the period started and ended. As previously discussed, the Registrar (IPOS) relies on the statements contained in the certificate issued by the HSA, and is not concerned to inquire into the truth of the statements contained in the certificate so issued; and
c) all other documentary evidence that the applicant wishes to rely on in support of the application for patent term extension.

Apart from the matters prescribed above, the Registrar may also direct the applicant for patent term extension to furnish additional evidence in support of the application. In the event of non-compliance with the Registrar's direction, the application will be treated as abandoned.

## 7.10 INTERPLAY WITH DATA EXCLUSIVITY

Data exclusivity protection has been instituted in Singapore since 1998.[318] Under section 19A of the Medicines Act, the HSA is required to protect confidential supporting information (e.g. trade secrets) that have been submitted in respect of an innovative medicinal product application and is not to use that confidential supporting information for the purposes of determining whether to grant any other application (subject to certain exceptions) for a period of 5 years from the date of receipt of the innovative medicinal product application.[319]

The Medicines Act was subsequently amended in 2004 to provide that where information pertaining to the safety or efficacy of a medicinal product has been submitted to HSA by the applicant for a product licence, and a product licence has been granted in respect of the medicinal product, then for a period of 5 years from the date of grant of the product licence, HSA may not grant marketing authorization to another person in respect of that or a similar medicinal product on the basis of the grant of that earlier licence, except with the consent of the holder of the earlier licence.[320]

In respect of health products, similar provisions exist to protect the confidential information that has been submitted to HSA in respect of innovative therapeutic product applications. Again, the period of protection is 5 years.

## 7.11 BOLAR EXEMPTION

Singapore introduced the Bolar exemption as part of its obligation under the USSFTA in 2004. It was aimed at counterbalancing the introduction of patent term extensions into the Singapore patent regime, as well as to facilitate the manufacture and sale of generic pharmaceutical products immediately upon the expiry of the patent in respect of such products.

The Bolar exception basically exempts from patent infringement any act which would otherwise constitute an infringement of a patent if the act is done in relation to the subject-matter of the patent to support any application for marketing approval for a pharmaceutical product, provided that any thing produced to support the application is not made, used or sold in Singapore, or exported outside Singapore, other than for purposes related to meeting the requirements for marketing approval for that pharmaceutical product.

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318 Section 19A was introduced by the Medicines (Amendment) Act 1998 (No. 7 of 1998).
319 See Medicines Act, s 19A.
320 See Medicines Act, s 19D.

# 8 THE USA

*Prof. John R Thomas**

## 8.1 SOURCES OF LAW

In the USA, patent term extension to account for regulatory approval delays is governed entirely by federal law. That law consists principally of the Drug Price Competition and Patent Term Restoration Act of 1984,[321] more commonly known as the Hatch-Waxman Act. The specific provision of the Hatch-Waxman pertaining to patent term extensions, section 156 of Title 35 of the United States Code, is referenced as 35 U.S.C. §156. That legislation provides two federal agencies, the US Patent & Trademark Office (**USPTO**) and Food & Drug Administration (**FDA**) with responsibility for administering grants of patent term extension. These two agencies have issued regulations and guidance documents in keeping with this authority. Notably, the individual US states lack authority either to grant patents or to approve drugs for marketing, and therefore play no role in this endeavor.

Patent term extensions form just one component of the complex provisions of the Hatch-Waxman Act. That statute also provides provisions governing the mechanisms through which a generic manufacturer may obtain marketing approval that has been patented by another; a statutory exemption from claims of patent infringement based on acts reasonably related to seeking FDA approval (the so-called "*Bolar* exemption"); special provisions for challenging the enforceability, validity, and infringement of patents on approved drugs, and regulatory exclusivities that act to preclude generic competition for a period of time. Through amendments to both the patent law and the food and drug law, the Hatch-Waxman Act established several practices intended to facilitate the marketing of generic pharmaceuticals while providing brand-name firms with incentives to innovate.[322]

## 8.2 LEGAL NATURE

As indicated by the title of 35 U.S.C. §156, "Extension of patent term," a patent term extension under the Hatch-Waxman Act does not act as a *sui generis* right. It instead acts as an accessory to the patent although, as discussed in sections 8.8 and 8.9 below, the scope of protection afforded during the period of extension may be more limited than the scope of the patent claims themselves. Because the patent term extension acts as an adjunct to the patent, no separate revocation action is needed to remove it. In particular, if the patent on which the extension is based is deemed to be invalid, the extension under 35 U.S.C. §156 will fail as well.

Many US patents are also subject to patent term "adjustments" in keeping with 35 U.S.C. §154(b). This legislation provides certain deadlines that, if not met by the USPTO, result in an automatic "adjustment" of the term of an individual patent. In particular, each day of USPTO delay results in one additional day of patent term.

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321 Public Law No. 84-417, 98 Stat. 1585 (1984).

322 John R. Thomas, *Pharmaceutical Patent Law* 13 (3d edn, 2015).

Among the more significant of these deadlines are 14 months for the issuance of an initial "Office Action" responding to the application, as well as four months for a reply to subsequent communications by the applicant. Patent term adjustments are cumulative with the patent term extensions offered by 35 U.S.C. §156.

## 8.3 RATIONALE OF PATENT EXTENSION

The particular rationale for a patent term extension has not been the subject to extensive discussion in the USA. Some academic commentators assert that patent term extensions—along with other regulatory exclusivities afforded by the FDA—act as a direct promoter of innovation. As explained by Professor Rebecca S. Eisenberg with respect to patent term extensions and related food and drug laws:

> Each may be better understood as an economic measure designed to promote costly investments in innovation than as a consumer protection measure designed to keep unsafe or ineffective products off the market. Considered together, they show a trend toward directing the FDA to use its gatekeeper role in timing approval of pharmaceutical products to serve a function traditionally relegated to the patent system: promoting and rewarding innovation by granting valuable exclusionary rights.
> Other provisions of the Hatch-Waxman Act . . . further blur the functional distinction between drug regulation and patents, directing PTO to take regulation into account in determining patent term and directing FDA to take patents into account in approving drugs. The Hatch-Waxman Act allows the PTO to grant patent term extensions of up to five years to compensate for marketing delays during the regulatory review period prior to the first permitted commercial marketing of a new drug.[323]

On the other hand, other commentators argue that patent term extensions should instead be viewed not as promoting innovation *per se*, but rather as encouraging efforts to obtain marketing approval from the FDA. As the author of this contribution has asserted elsewhere:

> [R]egulatory exclusivities are best viewed as promoting the pursuit of activities that the patent system, through its essential doctrinal framework, is unable to encourage. The patent law has never in its long history served as a mechanism for encouraging the entire spectrum of technological activity. In particular, the Patent Act does not extend its protections to the extensive quantity of information brand-name firms must generate in order to obtain marketing approval. Regulatory exclusivities are therefore best seen as addressing the patent system's shortcomings with respect to the modern administrative state.[324]

The debate has largely been confined to academic circles in the United States. As noted by Professor Yaniv Heled, "the incentivizing of technological innovation and the production of socially valuable data are not mutually exclusive and may well coincide" in this setting.[325]

## 8.4 GRANTING AUTHORITY

The USPTO grants patent term extensions under 35 U.S.C. §156. However, that statute requires the USPTO to consult with the FDA or the US Department of Agriculture, depending upon the subject matter of the extended patent, to confirm the

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323 Rebecca S. Eisenberg, 'Patents, Product Exclusivity, and Information Dissemination: How Law Directs Biopharmaceutical Research and Development' [2003] 72 Fordham Law Review 477, 483.

324 John R. Thomas, 'The End of "Patent Medicines?" Thoughts on the Rise of Regulatory Exclusivities' [2015] 70 Food & Drug Law Journal 39, 46-47.

325 Yaniv Heled, 'Regulatory Competitive Shelters' [2015] 76 Ohio State Law Journal 299, 308 n.29.

period of regulatory delay encountered by the applicant. The USPTO maintains a list of term-extended patents on its website.[326] The specific procedures employed by that agency are discussed below in section 8.10.

## 8.5 SUBSTANTIVE ASPECTS

### 8.5.1 Subject matter eligible for patent term extension

#### *8.5.1.1 Technical fields where PTE is possible*

For a patent to be eligible for term extension, it must claim a "product" that includes the following categories:

(1) The term "product" means:
  (A) A drug product.
  (B) Any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act.
(2) The term "drug product" means the active ingredient of—
  (A) a new drug, antibiotic drug, or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act), or
  (B) a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Virus-Serum-Toxin Act) which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques,

including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.[327]

As a result, patents may be subject to term extension if they claim a new drug product, antibiotic drug, or human biological product; food additive or colour additive; medical device; or a new animal drug or veterinary biological product. As a result, term extensions under 35 U.S.C. §156 are widely available in the USA for essentially every product subject to regulatory review under US law.

#### *8.5.1.2 Category of patents eligible for PTE (§ 156a)*

35 U.S.C. §156(a) stipulates that the patent may claim a "product, a method of using a product, or a method of manufacturing a product." As a result, a patent with any sort of claim format may be extended under the Hatch-Waxman Act.

#### *8.5.1.3 In the field of medicinal products: concept of active ingredient*

Most judicial activity concerning 35 U.S.C. §156 has dealt with pharmaceuticals. As such, the notion of what "product" qualifies as an "active ingredient" of a

[326] USPTO, Patent Terms Extended Under 35 U.S.C. §156 (available at https://www.uspto.gov/patent/laws-and-regulations/patent-term-extension/patent-terms-extended-under-35-usc-156).
[327] *Ibid.,* §156(f).

pharmaceutical has been addressed on several occasions. The reason for this focus is that 35 U.S.C. §156 dictates, with emphasis added, that "the permission for the commercial marketing or use of the product after such regulatory review period [must have been] the first permitted commercial marketing or use of *the product* under the provision of law under which such regulatory review period occurred." 35 U.S.C. §156 defines the term "product" in part as a "drug product," which the statute in turn defined as "the active ingredient . . . of a new drug . . . including any salt or ester of the active ingredient."[328]

The term "active ingredient" is not further defined in 35 U.S.C. §156 and is arguably ambiguous. An "active ingredient" may be the "active moiety" of the drug, which is to say the component of a drug compound that provides pharmacological activity. Under this concept, the term "product" in 35 U.S.C. §156 includes both the salt and ester formulations, among others, of the primary molecule. On the other hand, the term "active ingredient" could be limited to only the specific compound in an FDA-approved drug, and in particular the precise derivative form used in that drug.[329] The leading US cases, which are provided below in chronological order, have arguably issued inconsistent rulings with respect to this issue.

In its 1989 decision in *Fisons PLC v Quigg,*[330] the US Court of Appeals for the Federal Circuit ("Federal Circuit") considered three Fisons patents involving cromolyn sodium. Each patent claimed an innovative use or dosage form of this compound. The FDA had first allowed commercial marketing of cromolyn sodium in inhalation capsule form in 1973. Subsequently, the FDA also issued marketing approvals for the new uses and dosage forms of cromolyn sodium that Fisons had patented. Fisons then sought term extension under 35 U.S.C. §156 for its three patents relating to the new uses and dosage forms, asserting that the term "product" in 35 U.S.C. §156(a)(5)(A) meant a particular drug product that the FDA had approved. The USPTO and district court disagreed, reasoning that 35 U.S.C. §156(f) expressly defined the term "product" to mean "the *active ingredient* of a new drug."[331]

Following an appeal to the Federal Circuit, Judge Nies agreed that the three Fisons patents were not eligible for term extension. Under the plain language of the statute, she reasoned, extensions to the term of a drug product patent are limited to the first marketing or commercial use of a particular active ingredient.[332] Given this express statutory language, Judge Nies was not persuaded by the "policy argument" that the development of new uses and doses for existing drugs was potentially just as medically significant as the development of new chemical entities, and therefore just as worthy of patent term extension. "Matters of policy are for Congress, not courts, to decide," she concluded.[333] The *Fisons v Quigg* ruling appears to establish that a drug product patent is not eligible for term extension based upon any subsequent FDA approval for commercial marketing or use of a drug product containing the identical active ingredient, or salt or ester of that active ingredient.

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328 *Ibid.*
329 Ann Kotze, 'Reigning in Patent Term Extensions for Related Pharmaceutical Products Post-*Photocure* and *Ortho-McNeil'* [2012] 106 Northwestern University Law Review 1419, 1435-36.
330 876 F.2d 99 (Fed. Cir. 1989).
331 *Ibid.,* at 100 (emphasis in original).
332 *Ibid.,* at 101.
333 *Ibid.,* at 101.

The subsequent Federal Circuit opinion in *Glaxo Operations UK Ltd. v Quigg*[334] addressed the same issue, this time with more favourable results for the patent proprietor. In this case, Glaxo was the owner of two patents relating to the antibiotic cefuroxime.[335] One of these patents claimed cefuroxime and its salts, which were FDA approved and sold under the trademarks ZINACEF® and KERUROX®. The other patent claimed cefuroxime axetil, an ester of cefuroxime, which was also an FDA-approved product sold under the trademark CEFTIN®.[336] The former compounds were therapeutically active antibiotics only when administered intramuscularly or intravenously, while cefuroxime axetil could be administered orally.[337]

Litigation arose when the PTO denied Glaxo's request for term extension for its cefuroxime axetil patent. In reaching its decision, the PTO observed that the FDA had previously approved ZINACEF® and KERUROX®, two products employing salts of cefuroxime. The PTO reasoned that the FDA approval of cefuroxime axetil was not the "first permitted commercial marketing or use of the product" by the FDA, as 35 U.S.C. §156(a)(5)(A) required. Put differently, the PTO took the position that the statutory use of the term "drug product" incorporated any "'new chemical entity,' i.e., 'new active moiety,' which would encompass *all* acid, salt, or ester forms of a single therapeutically active substance even if the drug before being administered contained only other substances."[338]

Glaxo instead took the position that the patent for which extension was sought claimed cefuroxime axetil. Glaxo conceded that the previously approved products, ZINACEF® and KERUROX®, consisted of salts of cefuroxime. Glaxo further observed, however, that neither of these products contained salts or esters of cefuroxime axetil, as required by 35 U.S.C. §156(f). As a result, Glaxo contended that CEFTIN® was properly considered the "first commercial marketing or use" of the patented drug product.[339]

On appeal, the Federal Circuit rejected the PTO's interpretation of the statutory term "drug product" and instead sided with Glaxo. According to the court of appeals, the US Congress had used words with well-established, ordinary, and common meanings—"active ingredient," "salt," and "ester"—in defining which drug products were eligible for patent term extension under 35 U.S.C. §156.[340] Judge Michel further reasoned that the US Congress specifically selected these well-established scientific terms over other options, such as "new molecular entity" or "active moiety," that had a broader meaning.[341] The result of the decision was that Glaxo received a term extension for its cefuroxime axetil patent, even though the FDA had previously approved products incorporating salts of cefuroxime as their active ingredient.

In its 2003 decision in *Merck & Co. v Teva Pharmaceuticals USA, Inc.,*[342] the Federal Circuit majority also upheld a patent term extension under 35 U.S.C. §156. *Merck v Teva* concerned Merck's patent on a method of treating osteoporosis through the

334 894 F.2d 392 (Fed. Cir. 1990).
335 *Ibid.,* at 393.
336 *Ibid.,* at 393–94.
337 *Ibid.,* at 393–94.
338 *Ibid.,* at 394 (emphasis in original).
339 *Ibid.*
340 *Ibid.,* at 395.
341 *Ibid.,* at 399 n.10.
342 347 F.3d 1367 (Fed. Cir. 2003).

administration of 4-amnio-1-hydroxybutane-1, 1-biphosphonic acid. Merck's product, FOSAMAX®, had been approved by the FDA for use in treating osteoporosis and Paget's disease. FOSAMAX® consisted of 4-amnio-1-hydroxybutane-1, 1-biphosphonic acid monosodium salt trihydrate, which is more concisely known as alendronate salt.[343] Due to significant delays that Merck had experienced in obtaining FDA marketing approval for FOSAMAX®, Merck's patent had been subject to term extension under 35 U.S.C. §156.[344]

Teva subsequently filed an ANDA with the FDA, proposing to market a generic version of FOSAMAX®. Teva's proposed product employed the salt form of the acid as its active ingredient.[345] Merck responded by filing a suit for patent infringement under the procedures established by the Hatch-Waxman Act. Although Teva argued that it did not infringe the claims of the Merck patent, the district court concluded that Merck's claims encompassed the salt as well as the acid version of the active acid agent. The district court observed that the patent's specification referred to the acid active agent as encompassing both the acid and "salt forms," and experts in the field testified that bone disorder treatments commonly include the acid salt form of whatever active agent is administered.[346]

Teva appealed to the Federal Circuit, in part asserting that: (1) its proposed product did not infringe the Merck patent; and (2) the term extension granted by the PTO was invalid because Merck's patent claimed an acid, while the FDA approval concerned the salt. The Federal Circuit disagreed with Teva on both counts. With respect to the argument of noninfringement, Judge Newman concluded that skilled pharmacologists would understand that when 4-amino-1-hydroxybutane-1, 1-bisphosponic acid is administered to treat urolithiasis and to inhibit bone reabsorption, that administration encompasses the acid salt.[347] Turning to the term extension issue, the Federal Circuit majority observed that 35 U.S.C. §156 expressly contemplated the extensions for "any salt or ester of the active ingredient" in the drug product. As a result, the PTO had appropriately granted term extension to Merck's patent.[348]

Chief Judge Mayer issued a brief dissenting opinion. In his view, Teva's proposed product did not infringe Merck's patent because the term "acid" should not be read to encompass both acids and salts. He also concluded that term extension was inappropriate because the patent claimed only the acid form of the compound, rather than the FDA-approved salt form of the compound.[349]

Most recently, in *Photocure ASA v Kappos*,[350] the Federal Circuit also held that term extension under the Hatch-Waxman Act was appropriate. Photocure sold methyl aminolevulinate hydrochloride ("MAL hydrochloride") under the brand name METVIXIA®. MAL is the methyl ester of amino-levulinic acid (ALA). The FDA had previously awarded marketing approval to ALA hydrochloride for the same therapeutic use as MAL hydrochloride—namely, to treat precancerous cell growths on the skin. Photocure requested an extension of term for U.S. Patent No. 6,034,267, which

343 *Ibid.,* at 1369.
344 *Ibid.,* at 1373.
345 *Ibid.,* at 1369.
346 228 F. Supp. 2d 480 (D. Del. 2002).
347 347 F.3d at 1371–72.
348 *Ibid.*, at 1373–74.
349 *Ibid.,* at 1374–75.
350 603 F.3d 1372 (Fed. Cir. 2010).

covered MAL hydrochloride. The PTO denied the request, reasoning that MAL hydrochloride was the "same 'product'" as ALA hydrochloride because the "underlying molecule" of MAL is ALA, and, in the view of the agency, "ALA is simply formulated differently in the two different drugs."[351]

Judge Liam O'Grady of the U.S. District Court for the Eastern District of Virginia reversed the PTO determination,[352] and on appeal the Federal Circuit affirmed his holding. Writing for a three-judge panel, Judge Newman explained that: the MAL hydrochloride was a "separate" chemical composition with a distinct patent from ALA hydrochloride; it had been subject to a separate FDA approval; it had been subject to a full period of FDA regulatory review; and this review permitted the first commercial marketing and use of the MAL hydrochloride product.[353] Notably, although MAL hydrochloride is the ester of ALA hydrochloride, ALA hydrochloride is neither the salt nor ester of MAL hydrochloride. As a result, the '267 patent claiming MAL hydrochloride was deemed eligible for term extension.

The Federal Circuit has also held that metabolite patents are not eligible for term extension under 35 U.S.C. §156 based upon regulatory approval delays associated with review of the chemical precursor to the metabolite. The litigation in *Hoechst-Roussel Pharmaceuticals, Inc. v Lehman,*[354] concerned COGNEX®, a medication for treating Alzheimer's disease. The active ingredient in COGNEX® is tacrine hydrochloride. Hoechst-Roussel sought term extension under 35 U.S.C. §156 for U.S. Patent No. 4,631,286, which did not itself claim tacrine hydrochloride. The '286 patent instead claimed 1-hydroxy-tacrine—a compound into which tacrine hydrochloride metabolized after digestion—as well as a method of treating memory loss using 1-hydroxy-tacrine.[355] The USPTO denied Hoechst-Roussel's request, reasoning in part that the '286 patent did not itself claim tacrine hydrochloride.[356]

The Federal Circuit affirmed the USPTO's decision on appeal. Judge Clevenger observed that 35 U.S.C. §156(a) stated that the "term of a patent *which claims* a product . . . shall be extended in accordance with this section from the original expiration date if . . . the product has been subject to a regulatory review period before its commercial marketing or use."[357] He further reasoned that the claims of the '286 patent were directed neither to the active ingredient that received FDA approval, tacrine hydrochloride, nor to a method of using that ingredient.[358] As a result, the '286 patent failed to qualify for term extension under 35 U.S.C. §156.

On the other hand, a patent claiming an enantiomer of a previously FDA-approved racemate may be awarded term extension under 35 U.S.C. §156 under the reasoning of *Ortho-McNeil Pharmaceutical, Inc. v Lupin Pharmaceuticals, Inc*.[359] In reaching this conclusion, the Federal Circuit deferred to the FDA practice of viewing an enantiomer as a single active ingredient distinct from the racemate.[360] As a result, if the other

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351 *Ibid*., at 1375.
352 622 F.Supp.2d 338 (E.D. Va. 2009).
353 603 F.3d at 1375.
354 109 F.3d 756 (Fed. Cir. 1997).
355 *Ibid.,* at 757.
356 *Ibid.,* at 757–78.
357 35 U.S.C. §156(a)(4) (emphasis added).
358 109 F.3d at 759.
359 603 F.3d 1377 (Fed. Cir. 2010).
360 *Ibid.,* at 1380.

requirements of the statute are met, then the fact that an enantiomer was previously marketed in its racemic form does not bar the award of patent term extension.

The patent term extension of 35 U.S.C. §156 may be available for combination products. This state of affairs results from the Federal Circuit's 2004 decision in *Arnold Partnership v Dudas.*[361] In that case, the Arnold Partnership (Arnold) held a patent claiming compositions containing hydrocodone (or a salt thereof) and ibuprofen (or a salt thereof), as well as methods of treating pain using these compositions. This product was available commercially as VICOPROFEN®, which specifically combined hydrocodone bitartrate and ibuprofen. Although these two components had previously been available separately, the FDA required Arnold to file a New Drug Application (NDA) in order to market the combined product.[362]

Arnold subsequently sought term extension from the USPTO under 35 U.S.C. §156 in order to compensate for regulatory review delays. The USPTO rejected Arnold's application, however, on the basis that VICOPROFEN® did not comply with the "first commercial marketing" requirement of 35 U.S.C. §156(a)(5)(A). Arnold therefore commenced litigation in the U.S. District Court for the Eastern District of Virginia, which sided with the USPTO.[363]

Arnold then appealed to the Federal Circuit, which affirmed. The appeals court observed that 35 U.S.C. §156(a)(5)(A) stipulated that term extension is appropriate only where "the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under which such regulatory review occurred. . . ." This statute further defined the term "product" to mean "drug product,"[364] with "drug product" in turn defined as "the active ingredient of . . . a new drug . . . including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient."[365] According to Judge Dyk, this statutory language expressly indicated that a drug product's eligibility for extension depended upon an analysis of its individual ingredients, rather than the compound as a whole. As the district court had previously explained:

> Even though a drug may contain two or more active ingredients in combination with each other, for the purpose of the patent extension that drug is defined through reference to only one of those active ingredients; the other active ingredient or ingredients are merely "in combination" with this first active ingredient.[366]

Under this interpretation, if a patent claimed a composition comprising two ingredients, A and B, the patent was eligible for term extension if either A or B had not been previously marketed. In a case such as this, however, where both ingredients had been subject to prior commercial marketing, the combination patent could not benefit from the term extension provisions of the Hatch-Waxman Act.[367]

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361 362 F.3d 1338 (Fed. Cir. 2004).
362 *Ibid.,* at 1339.
363 246 F. Supp. 2d 460 (E.D. Va. 2003).
364 35 U.S.C. §156(f)(1).
365 *Ibid.,* §156(f)(2).
366 246 F. Supp. 2d at 464–65.
367 362 F.3d at 1341.

## 8.5.2 Conditions for granting a patent term extension

### *8.5.2.1 Premise*

The conditions for obtaining a patent term extension in the United States via the Hatch-Waxman Act are, in broad outline, similar to those for obtaining an SPC. In a nutshell, a patent proprietor who wishes to obtain the term extension offered by the Hatch-Waxman Act must submit an application to the USPTO.[368] That application must be filed prior to the expiration of that patent,[369] and within 60 days of receiving FDA marketing approval.[370] Only one patent can be extended based upon an approval for commercial marketing use. In the event multiple patents cover that product, the proprietor must choose one.[371] The maximum extension period is capped at five years, or a total effective patent term after the extension of not more than 14 years.[372] The scope of rights during the period of extension is generally limited to the subject matter claimed in the patent that is put to the use approved for the product that subjected it to regulatory delay.[373]

### *8.5.2.2 First requirement "the product is protected by a basic patent in force" art. 3(a) Regulations versus "the patent claims a product" "the term of the patent has not expired before an application for patent term extension is submitted" § 156*

Pursuant to its regulatory authority, the USPTO has identified an extension-eligible patent as one that "claims a product . . . either alone or in combination with other ingredients that read on a composition that received permission for commercial marketing or use, or a method of using such a product, or a method of manufacturing such a product, and meets all other conditions and requirements of this subpart."[374] The agency has further explained that a "patent is considered to claim the product at least in those situations where the patent claims the active ingredient *per se*, or claims a composition or formulation which contains the active ingredient(s) and reads on the composition or formulation approved for commercial marketing or use."[375]

The USPTO has previously granted term extensions under the Hatch-Waxman Act for patents incorporating Markush groups, in which one member of the Markush group is the subject of FDA approval. For example, U.S. Patent No. 6,054,297, which generally calls for a humanized antibody variable domain having a functional antigen binding region with an amino acid substitution at one of numerous identified sites, was afforded a term extension by the USPTO.

Case law has established that the term "claims a product" is not synonymous with "infringed by a product." As discussed previously in this contribution, a patent that

368 35 U.S.C. §156(d)(1).
369 *Ibid.,* §156(a)(1).
370 *Ibid.,* §156(d)(1).
371 *Ibid.,* 156(c)(4).
372 *Ibid.,* §156(b), (c).
373 *Ibid.,* §156(b)(1).
374 37 C.F.R. §1.710.
375 USPTO, Manual of Patent Examining Procedure §2751 (9th ed. November 2015).

claims a metabolite of an approved drug is not deemed to claim the approved drug within the meaning of the Hatch-Waxman Act.[376]

In addition, the Hatch-Waxman Act stipulates that an extension of patent term is proper only if the patent has not expired before the application is submitted to the USPTO.[377] This rule potentially creates difficulties for patent proprietors who face lengthy periods of FDA approval. The possibility exists that a patent could expire prior to the issuance of a certificate of extension, thus denying the patent proprietor a term extension to which it would otherwise be entitled.

The US Congress provided for the issuance of a "certificate of interim extension" to address this circumstance. According to 35 U.S.C. §156(d)(5), if a patent owner or its agent reasonably expects that the federal regulatory review period for the product in that patent may extend beyond the expiration of the patent term, that individual may request an interim extension during the period beginning six months, and ending 15 days, before the patent's expiration date.[378] If the patent would otherwise be eligible for extension, then the USPTO Director must issue a certificate of interim extension for a period of not more than one year.[379] A patent owner who has procured one interim extension may apply for up to four subsequent extensions,[380] although the interim extensions may not be longer than the maximum period for extension to which the applicant would be eligible.[381] Any interim extension granted will end 60 days after the FDA grants regulatory approval, unless the patentee or its agent files further information.[382] In any case, the extension may not extend past a total of five years from the expiration of the original patent term.[383] During the period of interim term extension, the rights provided by the patent are limited to the specific use then under regulatory review.[384]

#### *8.5.2.3 The product has been subject to a regulatory review period before its commercial marketing or use*

The Hatch-Waxman Act awards patent term extension only if the patented product "has been subject to a regulatory review period before its commercial marketing or use."[385] 35 U.S.C. §156 defines the term "regulatory review period" in a detailed fashion that depends upon the nature of the regulated product and the particular practices of the relevant federal agency. For example, for a human drug, antibiotic, or human biological product, the testing period begins on the date the Investigational New Drug (**IND**) application is filed, while the approval phase period starts on the date of filing of either the New Drug Application (**NDA**) or Product License Application (**PLA**).

376 *Hoechst-Roussel Pharmaceuticals Inc. v Lehman*, 109 F.3d 756, 759 (Fed. Cir. 1997).
377 35 U.S.C. §156(a)(1).
378 *Ibid.,* §156(d)(5)(A). For further discussion of interim extensions under the Hatch-Waxman Act, see *Somerset Pharms., Inc. v Dudas,* 500 F.3d 1344, 84 USPQ2d 2023 (Fed. Cir. 2007).
379 *Ibid.,* §156(d)(5)(B).
380 *Ibid.,* §156(d)(5)(C).
381 37 C.F.R. §1.760.
382 35 U.S.C. §156(d)(5)(E).
383 *Ibid.,* §156(d)(5)(E)(i).
384 *Ibid.,* §156(d)(5)(F).
385 *Ibid.,* §156(a)(4).

#### *8.5.2.4 "the term of the patent has never been extended"*

The Hatch-Waxman Act dictates that a single patent may not receive more than one term extension under that statute.[386] As succinctly explained by the US Court of Appeals for the Federal Circuit: "Clearly, a patent may receive only one restoration extension."[387]

#### *8.5.2.5 "no more than one patent may be extended for the same marketing authorisation period for any product"*

A patent proprietor may not obtain more than one patent term extension under the Hatch-Waxman Act for a given regulatory review of a product. If multiple patents cover the FDA-approved product, the proprietor must select one of them for extension.[388] The administrative carriage of the application does not matter, so patents that arose from continuation, reissue, re-examination, or other procedures available under US law may be extended via the Hatch-Waxman Act.

#### *8.5.2.6 "the authorisation . . . is the first authorisation to place the product on the market"*

The Hatch-Waxman Act requires a drug to be classified as "new" to be eligible for term extension.[389] In turn, the statute defines the term "new" to mean a drug that has not previously been approved for marketing by the FDA.[390] As a result, a single product can ordinarily be subject to only a single term extension under the Hatch-Waxman Act.

The literature describes a single instance where arguably one product was subject to two patent term extensions. In one case, the FDA approved on the same day two separate New Drug Applications (NDAs) to the same applicant for the same drug, LYRICA, with respect to two indications: (1) diabetes-related neuropathic pain, and (2) herpes-zoster-related neuropathic pain. The patent proprietor requested that the USPTO grant a term extension under 35 U.S.C. §156 for two of its patents, one relating to diabetes and the other to herpes-zoster. The agency agreed that the FDA had not previously approved the same drug and granted an extension for the two patents. The rare circumstances that allowed the award of dual patent term extensions are unlikely to recur frequently in the future.[391]

## 8.6 RIGHT TO REQUEST AND OBTAIN A PATENT TERM EXTENSION

In the USA, the patent proprietor that seeks term extension is usually also the NDA holder. An applicant for term extension may refer to a third-party authorization only in one limited circumstance. In particular, the applicant must have established a legal relationship with the NDA holder—for example, by granting a license of the patent—in

386 35 U.S.C. §156(a)(2).
387 *Merck & Co. v Kessler*, 80 F.3d 1543, 1551 (Fed. Cir. 1996).
388 35 U.S.C. § 156(c)(4) ("[I]n no event shall more than one patent be extended . . . for the same regulatory review period for any product.").
389 35 U.S.C. §156(f)(2)(A).
390 *Ibid.,* §156(a)(5)(A).
391 Stephanie Plamondon Bair, 'Adjustments, Extensions, Disclaimers, and Continuations: When Do Patent Term Adjustments Make Sense?' [2013] 41 Capital University Law Review 445.

order to obtain an extension of the patent under the Hatch-Waxman Act. As explained by the Federal Circuit, albeit in a concurring opinion, "§ 156 is satisfied if the holder of the regulatory market approval acts as the agent of the patentee in apply for extension of the patent term; it is the holder of the market approval that is the primary intended beneficiary of § 156."[392]

The relevant statutory language supports this conclusion in the following way. Only the "owner of record of the patent or its agent"[393] may submit an application to the USPTO requesting patent term extension. The statute then requires the application to include a description of activities undertaken "by the applicant" to seek marketing approval.[394] Compliance with this provision through reference to third party activities does not seem plausible. In keeping with this interpretation, USPTO regulations indicate that when the Hatch-Waxman Act allows the "agent" of the patent proprietor to file an application for marketing approval, the legislation has equated the term "agent" with the patent owner's "licensee."[395]

## 8.7 PERIOD OF EXTENSION (CALCULATION OF TERM): § 156(C)

Under the Hatch-Waxman Act, the period of patent term extension is set to the "regulatory review period."[396] Generally speaking, 35 U.S.C. §156(c) defines the term "regulatory review period" as one-half of what may be termed the "testing phase" of the product, plus the entirety of what may be termed the "approval phase" at the FDA.[397] To illustrate this basic formula of 35 U.S.C. §156(c) through a simple example, suppose that clinical trials consumed three years, while FDA approval took an additional two years. If none of the statute's numerous qualifications applied, then the patent term would be extended by (1/2 × 3) + 2 = 3.5 years.

The nature of the regulated product sets the precise dates that commence the testing and approval phases that together comprise the regulatory review period. For a human drug, antibiotic, or human biological product, the testing period begins on the date the Investigational New Drug (IND) application is filed, while the approval phase period starts on the date of filing of either the New Drug Application (NDA) or Product License Application (PLA).[398] With respect to a patent claiming a new animal drug, the testing period begins on the date a major health or environmental effects test on the drug was initiated, or the date of an exemption under subsection (j) of Section 512 of the Federal Food, Drug, and Cosmetic Act, with the approval phase set to the date a New Animal Drug Application (NADA) was submitted.[399] For a patent claiming a veterinary biological product, the testing period commences on the date on which the authority to prepare an experimental biological product under the Virus-Serum-Toxin Act became effective, while the approval date is the date on which an application for a license was submitted under the Virus-Serum-Toxin Act.[400]

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392 Hoechst-Roussel Pharmaceuticals, 109 F.3d 756, 761 (Fed. Cir. 1997) (Newman, J., concurring).
393 35 U.S.C. §256(d)(1).
394 35 U.S.C. §256(d)(1)(D).
395 37 C.F.R. §1.730(c).
396 35 U.S.C. §156(c).
397 *Ibid.,* §156(c)(2).
398 37 CFR §1.740(a)(10)(i).
399 *Ibid.,* §1.740(a)(10)(ii).
400 *Ibid.,* §1.740(a)(10)(iii).

The relevant dates for a patent claiming a food or colour additive are, for the testing period, the date that a major health or environmental effects test on the additive was initiated and, for the approval phase, the date on which a petition for product approval under the Federal Food, Drug, and Cosmetic Act was initially submitted.[401] Finally, for a patent claiming a medical device, the testing date commences on the effective date of the Investigational Device Exemption (IDE) or, if no IDE was submitted, on the date on which the applicant began the first clinical investigation involving the device. The approval phase commences on the date on which the application for product approval or notice of completion of a product development protocol under Section 515 of the Federal Food, Drug, and Cosmetic Act was initially submitted.[402]

The Hatch-Waxman Act provides a number of exceptions to its basic term extension formula. First, if the applicant did not act with due diligence at any time during the regulatory review period, then the length of the regulatory review period is reduced by that number of days.[403] Second, for patents issued after the date of enactment of the Hatch-Waxman Act, September 24, 1984,[404] the maximum period of term extension is capped at five years.[405] In addition, the remaining patent term, combined with the period of term extension, may not exceed 14 years.[406] Finally, any part of the regulatory review period that took place prior to the issuance of the patent is not included in this calculation.[407]

## 8.8 SCOPE OF PROTECTION

The scope of protection afforded to a term-extended patent is founded upon the claims of the patent. US courts will apply the same rules with respect to the interpretation of the patent's claims as they do to other sorts of patents. In particular, they apply the "broadest reasonable construction" of the claims in keeping with the decision of the US Supreme Court in *Markman v Westview Instruments, Inc*.[408] In addition, in appropriate cases, the doctrine of equivalents may apply to the claims of patents that have been extended in keeping with the Hatch-Waxman Act.

One significant exception exists to this standard. The Hatch-Waxman Act does not go so far as to provide a patent term extension in the usual sense—that is to say, a temporal extension of the original right to exclude others from practising the patented invention. During the period of term extension, the rights provided by the patent are instead limited, generally speaking, to the specific use that the FDA has approved. This requirement is discussed at greater length immediately below.

401 *Ibid.,* §1.740(a)(10)(iv).
402 *Ibid.,* §1.740(a)(10)(v).
403 35 U.S.C. §156(c)(1).
404 The relevant date for animal drug products and veterinary biological products is November 16, 188, the date of enactment of the Generic Animal Drug and Patent Term Restoration Act.
405 35 U.S.C. § 156(g)(6). For a discussion of the statutory scheme for patents that issued prior to September 24, 1984, see *Hoechst AG v Quigg,* 917 F.2d 522, 16 USPQ2d 1549 (Fed. Cir. 1990).
406 35 U.S.C. §156(c)(3).
407 *Ibid.,* §156(c).
408 517 U.S. 370 (1996).

## 8.9 RIGHTS CONFERRED BY THE EXTENDED PATENT

More specifically, 35 U.S.C. §156 stipulates that in the case of an extended product patent, the patent's rights during the extension period are generally "limited to any use approved for the product" that subjected it to regulatory approval delays at the FDA.[409] In the case of a patent that claims a method of using a product, the patent's rights during the extension period are "limited to any use claimed by the patent and approved for the product" that subjected it to regulatory delays at the FDA.[410] Finally, in the case of a patent that claims a method of manufacturing a product, the patentee's rights during the extension period are "limited to the method of manufacturing as used to make . . . the approved product" that was subject to regulatory delays at the FDA.[411]

An example illustrates this situation. Suppose that Compound A, which is claimed in the US `123 patent, has two uses: (1) as an FDA-approved treatment for asthma; and (2) as a cleaning solution for coins. The application that matured into the `123 patent was filed on 1 March 1998, and would expire under its own terms on 1 March 2018. However, the `123 patent is subject to term extension under 35 U.S.C. §156 until 1 December 2020. During year 2019, anyone who tried to obtain FDA approval for Compound A as an anti-asthma agent would face infringement liability under the `123 patent. However, numismatists who used Compound A merely to clean their coins could do so free of infringement liability with respect to the `123 patent.

The courts have interpreted the scope of the "approved product" fairly broadly. In *Pfizer, Inc. v Dr. Reddy's Laboratories, Ltd.,*[412] the US Court of Appeals for the Federal Circuit interpreted this language broadly. In that case, Pfizer owned US Patent No. 4,572,909, which related to certain dihydropyridine compounds and their acid addition salts. The compound recited in claim 8 was commonly known as amlodipine.[413] Pfizer obtained FDA approval to sell an anti-hypertensive, anti-ischemic drug product whose active ingredient is amlodipine, as the besylate salt. Although Pfizer had submitted clinical data to the FDA with respect to both amlodipine besylate and amlodipine maleate, it chose the besylate salt due to ease of tableting.[414]

Although the '909 patent was set to expire on February 25, 2003, Pfizer obtained a term extension of 1,252 days under 35 U.S.C. §156. Dr. Reddy's subsequently filed a paper NDA proposing to market amlodipine maleate. Although certain claims of the '909 patent unquestionably read upon Dr. Reddy's proposed product, Dr. Reddy's argued that the term extension applied only to the registered product, the besylate salt.[415] In contrast, Pfizer cited 35 U.S.C. §156(f), which reads in relevant part:

> (1) The term "product" means: (A) A drug product.
>
> ***
>
> (2) The term "drug product" means the active ingredient of—
> (A) a new drug, antibiotic drug, or human biological product . . . *including any*

409 *Ibid.,* 156(b)(1).
410 *Ibid.,* §156(b)(2).
411 *Ibid.,* §156(b)(3).
412 359 F.3d 1361 (Fed. Cir. 2004).
413 *Ibid.,* at 1363.
414 *Ibid.,* at 1363–64.
415 *Ibid.,* at 1364.

> *salt or ester of the active ingredient, as a* single entity or in combination with another active ingredient.[416]

Pfizer observed that 35 U.S.C. §156(f) contemplated that a therapeutic product could be administered as a "salt or ester of the active ingredient," and the Hatch-Waxman Act's term extension is not defeated merely by changing the salt or ester. Although the district court sided with Dr. Reddy's,[417] the Federal Circuit reversed this holding on appeal.

In its opinion, the Federal Circuit reasoned that the stipulation in 35 U.S.C. §156(b) that any patent term extension be "limited to any use approved for the product" meant that "other, e.g., non-pharmaceutical uses, are not subject to the extension." This provision did not limit the form of the product subject to the extension.[418] Judge Newman further explained:

> We conclude that the active ingredient is amlodipine, and that it is the same whether administered as the besylate salt or the maleate salt. The statutory definition of "drug product" is met by amlodipine and its salts. Dr. Reddy's is proposing to market the "drug product," as defined in 35 U.S.C. §156(f), for the same approved uses. The statute foresaw variation in the salt or ester of an active ingredient, and guarded against the very loophole now urged.[419]

Judge Mayer dissented. In his view:

> As the court points out, section 156(f) defines a product as a new drug "including any salt or ester of the active ingredient." What the court fails to consider, however, is that regardless of how a product is defined in section 156(f), to be eligible for a patent term extension, that product must "ha[ve] been subject to a regulatory review period before its commercial marketing or use." 35 U.S.C. § 156(a)(4). In this case, the product that was subject to regulatory review was amlodipine besylate. It was not merely amlodipine, nor was it amlodipine maleate, the product that Dr. Reddy's seeks approval to market. As such, the product amlodipine maleate cannot qualify for a patent term extension; it does not comport with the statutory requirements for eligibility.

## 8.10 PROCEDURAL ASPECTS

Under 35 U.S.C. §156(d)(1), an application for term extension "may only be submitted within the sixty-day period beginning on the date the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use." An application for patent term extension under the Hatch-Waxman Act must be submitted by "the owner of record of the patent or its agent."[420]

Applications for term extension under 35 U.S.C. §156 must be filed at the USPTO. The USPTO requires that each application for term extension include 15 elements.[421] In addition to such expected components as the identity of the approved product and relevant patent, a statement of the relevant dates of FDA activity, and fee,[422] a complete application must incorporate the following notable items:

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416 35 U.S.C. §156(f) (emphasis added).
417 2002 WL 31833744 (D.N.J. 2002).
418 359 F.3d at 1366.
419 *Ibid.,* at 1366.
420 35 U.S.C. §156(d)(1).
421 *Ibid.,* §1.740(a).
422 As of July 1, 2017, the fee was US $1120.00. *Id.* §1.20(j).

- an identification of the applicable federal statute under which regulatory review occurred;
- in the case of a drug product, an identification of each active ingredient in the product and, as to each active ingredient, a statement that it has not been previously approved for commercial marketing or use;
- a statement that the application has been filed within the 60-day statutory period, including an identification of the last day on which the application could be submitted;
- a brief description of the significant activities undertaken by the marketing applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities;
- a calculation of the length of the extension claimed; and
- a statement that the applicant acknowledges a duty to disclose any material that is pertinent to the determination of entitlement to the extension sought.[423]

The USPTO will assign a filing date to an application for term extension that falls somewhat short of its regulatory standards, however. If the application (1) identifies the approved product; (2) identifies each federal statute under which regulatory review occurred; (3) identifies the patent for which an extension is being sought; (4) identifies each claim of the patent which claims the approved product or a method of using or manufacturing the approved product; (5) provides sufficient information to enable the USPTO to determine whether the patent is eligible for extension, and the rights that will be derived from the extension, and information to enable the Director and the Secretary of Health and Human Services or the Secretary of Agriculture to determine the length of the regulatory review period; and (6) includes a brief description of the activities undertaken by the marketing applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities, then the USPTO will accord the application a filing date.[424] This USPTO policy is based on the obligatory nature of these six elements in a term extension application under 35 U.S.C. §156(d)(1)(A)-(D), while the remainder of the USPTO requirements were established via regulation in keeping with 35 U.S.C. §156(d)(1)(E).

If the USPTO determines that the term extension application should be accorded a filing date, but that it does not fully comply with USPTO regulations, the applicant ordinarily has two months to complete the application.[425] The applicant may extend this period through the payment of additional surcharges in accordance with usual USPTO practice.[426]

The submission of a complete application for term extension under 35 U.S.C. §156 commences a fairly elaborate proceeding involving the USPTO, FDA, and patent proprietor, and possibly third parties as well. In short, within 60 days of receiving the application, the PTO will request either the Secretary of Agriculture (if the product is subject to the Virus-Serum-Toxin Act) or the Secretary of Health and Human Services

423 *Ibid.,* §1.740.
424 *Ibid.,* §1.741.
425 *Ibid.,* §1.741(b).
426 *Ibid.,* §1.136.

(in all other cases) to calculate the applicable "regulatory review period," which is then published in the Federal Register.[427]

The date of publication is followed by a 180-day period during which any interested party may file a petition contending that the applicant has not acted with due diligence.[428] For purposes of this determination, the Hatch-Waxman Act stipulates that the term "due diligence" is defined as "that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period."[429] The appropriate secretary must determine within 90 days of filing whether the applicant has acted with due diligence or not, and then publish this determination in the Federal Register.[430] An interested person may then request an informal hearing on this determination within 60 days of publication, which is held within 60 days of the request.[431] Following the hearing, the appropriate secretary is allotted 30 days to affirm or modify its original decision and then notify the USPTO Director.[432]

The USPTO then forwards a Notice of Final Determination to the applicant. The applicant may make a single request for reconsideration of the determination within one month, or such other time period set forth in the determination.[433] If no such request for reconsideration is filed, or upon the completion of its review of such a request, the USPTO will then issue a Certificate of Extension of Patent Term to the applicant.[434]

## 8.11 THE INTERPLAY WITH OTHER FORMS OF EXCLUSIVITY

In the USA, brand-name firms may qualify for a six-month paediatric exclusivity upon the completion of studies on the effects of a drug upon children.[435] This period of regulatory exclusivity is cumulative with the patent term extension afforded by 35 U.S.C. §156. This six-month period begins on the date that the existing patent or data exclusivity protection on the innovator drug would otherwise expire. Paediatric exclusivity extends to any drug product with the same active ingredient. The purpose of the paediatric regulatory exclusivity is to improve the availability of appropriate paediatric labelling on drug products.

The effect of a paediatric exclusivity is to extend the approved manufacturer's existing regulatory exclusivity or patent protection for an additional six months. If applied to a patent, that paediatric exclusivity does not actually extend the term of a patent in the manner of 35 U.S.C. §156. Rather, it is a regulatory exclusivity administered by the FDA.[436] As a result, the principal practical function of the paediatric exclusivity is to

427 35 U.S.C. §156(d)(2)(A). *See Aktiebolaget Astra v Lehman*, 71 F.3d 1578, 1580–81 (Fed. Cir. 1995).
428 35 U.S.C. §156(d)(2)(B)(i).
429 *Ibid.* §156(d)(3).
430 *Ibid.*
431 *Ibid.,* §156(d)(2)(B)(ii).
432 *Ibid.*
433 USPTO, Manual of Patent Examining Procedure §2755 (9th edn, November 2015).
434 37 C.F.R. §1.780.
435 21 U.S.C. §355a.
436 *Ibid.,* §355a(b)(1)(B).

preclude the FDA from approving applications for marketing approval filed by generic firms.[437]

## 8.12 THE US *BOLAR* EXEMPTION

The Hatch-Waxman Act created a statutory exemption from certain claims of patent infringement. As codified in 35 U.S.C. §271(e)(1), this provision mandates: "It shall not be an infringement to make, use, offer to sell, or sell within the United States a patented invention ... solely for uses reasonably related to the development and submission of information under a Federal Law which regulates the manufacture, use or sale of drugs or veterinary biological products." Under this provision, commonly known as the *Bolar* exemption, generic manufacturers may commence work on a generic version of an approved drug any time during the life of the patent, so long as that work furthers compliance with FDA regulations. This provision applies both to the original term of the patent and any extended term under the Hatch-Waxman Act.

Several particular situations have arisen in which the US courts have had to apply 35 U.S.C. §271(e)(1). One relates to efforts in the USA undertaken to obtain foreign regulatory approval. In general, efforts to obtain foreign regulatory approval will not infringe US patents if they occur outside the USA. In those cases, no infringement of a US patent occurs at all, and there is no need to refer to the *Bolar* exemption.

However, to the extent that potentially infringing activities occur within the USA, the pivotal determination is whether those activities lead to data that could be submitted to the FDA or not. If the accused infringer conducted the activity with the intention of submitted the resulting information to the FDA, then the 35 U.S.C. §271(e)(1) safe harbor applies. The fact that the information was also submitted to foreign agencies is irrelevant.[438]

On the other hand, if the infringing activity within the USA is not related to seeking FDA approval, then the *Bolar* exemption does not apply. For example, in *NeoRx Corp. v Immunomedics, Inc.*,[439] the accused infringer produced samples of the accused product in the USA and then shipped them to foreign regulatory authorities for purposes of obtaining marketing approval. Reasoning that these shipments were unrelated to FDA requirements for obtaining marketing approval, the court held that 35 U.S.C. §271(e)(1) did not apply.

Another distinctive situation relates to third party suppliers. The USA does not have a rich case law on whether the safe harbor of 35 U.S.C. §271(e)(1) applies to enterprises that supply products to a generic or follow-on competitor. However, the 2008 decision of the Federal Circuit in *Proveris Scientific Corp. v InnovaSystems Inc*.[440] suggests that third parties are not covered by the US version of the *Bolar* exemption.

In that case, the accused infringer sold an infringing optical spray analyzer (**OSA**) to various biopharmaceutical enterprises. Those enterprises then used the device to

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437 *AstraZeneca AB v Apotex Corp.*, 792 F.3d 1324 (Fed. Cir. 2015).
438 *Elan Transdermal Ltd. v Cygnus Therapeutic Systems*, 24 USPQ2d 1926 (N.D. Cal. 1992).
439 877 F. Supp. 202 (D.N.J. 1994).
440 536 F.3d 1256 (Fed. Cir. 2008).

conduct experiments needed to obtain FDA regulatory approval for their products. The Federal Circuit found that the defendant's activity was outside the scope of 35 U.S.C. §271(e)(1) because the device manufacturer was not the type of user that 35 U.S.C. § 271(e)(1) sought to protect. In particular, the court reasoned that 35 U.S.C. §271(e) was meant to mitigate distortions resulting from the time-limited patent term and the FDA approval process. However, this defendant faced no regulatory barriers to market entry upon patent expiration and was not itself involved in the FDA regulatory process. As a result, the accused infringer was not deemed to fall within the category of entities for whom the safe-harbor provision was designed to provide relief.[441]

[441] *Ibid.* at 1265-66.

# 9 TAIWAN

*Prof. Dr. Kung-Chung LIU* ***

## 9.1 SOURCES OF LAW

The relevant provisions for patent extensions in Taiwan are Articles 53(1) and 66 of Taiwanese Patent Act.

## 9.2 LEGAL NATURE

Unlike some European jurisdictions, Taiwan does not have a supplementary protection certificate that grants a patentee an independent, *sui generis* IP right. Rather, under Taiwan Patent Act, a patent term extension is available only on two occasions. Firstly, when a patentee of an invention of pharmaceuticals (excluding veterinary drugs), agrochemicals, or the manufacturing processes thereof, obtains the market authorization by another authority from the central government required by law for the exploitation of the patented invention after the patent was granted by the Taiwan IP Office (**TIPO**).[442] Secondly, Article 66 of Taiwan Patent Act allows a patentee of an invention unable to practice his/her patent due to war between Republic of China (**ROC** more commonly known as Taiwan) and other foreign countries to extend his/her patent term once for a period of between 5 to 10 years. However, patentees from the foreign county that is in war with Taiwan are not eligible for patent term extension. In patent practice the patent term extension regime is rarely used in Taiwan. Unless otherwise specified, patent term extension mentioned hereinafter refers only to extension for pharmaceutical and agrochemicals patents and the manufacturing processes thereof.

## 9.3 RATIONALE OF PATENT TERM EXTENSION

As the legislative reason for the revision of Article 53(1) in 2011 mentions,443 the legislative purpose of patent term extension is to "compensate the period of time in

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442 Article 53(1) of the Patent Act. According to Article 39 of Taiwan Pharmaceutical Act, anyone manufacturing/importing any pharmaceutical products will need prior market authorization by the health authority before this person is allowed to do so. Similarly, Article 9 of Taiwan's Statute Governing the Management of Pesticides, the same requirement applies to anyone who would like to process or import a pesticide product.

443 According to the general legislative reasoning for the 2011 amendment of the Patent Act (November 29, 2011), "In order to incentivize industrial innovation and R&D to boost the economic strength and industrial competiveness of the country, in order to promote domestic industries that are of vital importance to biotechnology, green technology and refined agriculture, which are included into the so-called Six Emerging Industries, and to enhance the quality of patent examination, and in order to cope with national and international competition, to respond to the impact of globalization, to harmonize patent system, which is international in nature, with international norms," the legislature amended the

which the patentees of pharmaceuticals, agrochemicals and their manufacturing processes cannot implement those patents due to the yet to be acquired marketing approval." In addition, pursuant to the TIPO's Patent Examination Guidelines ("**Examination Guidelines**"), patent extension protection was adopted to encourage research and development on new drugs.[444] In the context of patent extension for pharmaceuticals, agrochemicals and their manufacturing processes, the 2011 amendment relaxed the regulatory requirement by deleting the temporal requirement that the obtainment of market authorization by the patentee must be two years after the grant of the patent.

## 9.4 GRANTING AUTHORITY

The TIPO issues the Revised Regulations for Ratifying Extension of Patent Term (Extension Regulations) in 2012. A patent term extension will be granted by the TIPO, which cooperates with the "central competent authority in charge of the business," namely the Ministry of Health and Welfare (**MHW**) for pharmaceuticals and the Council of Agriculture (**CA**) for agrichemicals.[445]

In practice, the TIPO will request the Food and Drug Administration (**TFDA**) of the MHW to provide the documents and information related to the calculation of patent term extension. On the basis of these documents and information, the TIPO calculates the period of time in which the patentee was unable to implement the patent due to the procedure of marketing approval.

## 9.5 SUBSTANTIVE ASPECTS

### 9.5.1 Subject matter eligible for patent term extension

#### *9.5.1.1 Technical fields where PTE is possible*

Article 53(1) of the Patent Act allows patent term extension only for patented inventions of pharmaceuticals, agrochemicals and the manufacturing processes of these inventions. However, patents on veterinary drugs are not eligible. The TIPO made it clear in the Examination Guidelines that medical devices are not eligible for patent term extension.[446] As a result, when an invention involves a medical product that is administered through an implantable device, the patentee of this invention may be granted with a patent term extension only to the medicine, not to the device that is required to administer this medicine.

#### *9.5.1.2 Category of patents eligible for PTE*

Similarly as it is in Europe in Taiwan, according to Article 53(1) of the Patent Act both composition claims and process claims of a patented pharmaceutical/agrochemical

Patent Act. It is typical for Taiwanese legislature to pursue multiple goals that are loosely interrelated to each other, which sometimes makes the legislative purpose not easy to comprehend.

444 Examination Guidelines, 2-11-1, available at https://www.tipo.gov.tw/public/Attachment/742814402497.pdf (2013).

445 Article 2 of the Extension Regulations.

446 Examination Guidelines, 2-11-2.

invention are eligible for patent term extension. Moreover, a claim for a new use of a pharmaceutical/agrochemical product is also eligible for patent term extension, subject to the requirement that the said new use must be identified by the active ingredients and uses stated in the first market authorization (regulatory approval). For more see 9.5.1.3.[447]

#### *9.5.1.3 In the field of medicinal products: concept of active ingredient*

According to Article 56 of Taiwan Patent Act, which was first introduced into the Patent Act in 2011, the scope of a patent, of which a term extension has been granted, shall be limited to only the active ingredients **and** uses stated in the regulatory approval concerned. The legislative reasoning of Article 56 elaborates that the scope of a patent, of which a term extension has been granted, shall be limited to only the products, uses and processes corresponding to the active ingredients **and** uses stated in the regulatory approval concerned. Any ingredients, processes or uses that are specified in the claims but not identified in the market authorization will not be covered by the term extension protection.[448] In other words, for the purpose of being granted with extended patent term protection, active ingredients, processes and uses must be specified in the market authorization certificate. Any ingredients, processes and uses not specified in the certificate will not be eligible for patent term extension protection.

According to the Examination Guidelines, active ingredients mean ingredients of pharmaceutical or agrochemical formula that have pharmacological action.[449] There is no case law on active ingredients.

As noted earlier, only active ingredients and uses identified in the first regulatory approval (market authorization certificate) are eligible for patent extension. An adjuvant, even specified in a claim, will not be eligible for patent term extension.[450]

According to Article 7 of the Pharmaceutical Affairs Act (**PAA**) and Article 2 of Enforcement Rules of PAA, a combination of two active substances is a new product, regardless of whether any of the active substances has been approved by the TFDA as a new drug or not.

Whether a combination of an active ingredient with an adjuvant, new adjuvant plus active ingredient, an enantiomer versus a racemate, an enantiomer versus another enantiomer or salts versus basic forms of the substance are treated as different active ingredients and need to follow the approval procedure of new drugs, is decided by the TFDA on a case-by-case basis. However, with regard to the patent term extension, the free forms of the active ingredient, namely different enantiomers or salts, are treated as the same active ingredients. The TIPO will not grant more than one patent term extension based on the same basic form of active ingredient, even though their enantiomers or salts are different.

In June 2017, the TIPO had initiated to amend the Examination Guidelines to allow several patent term extensions based on different free forms of the same basic active

447 Examination Guidelines, 2-11-2 & 2-11-3.
448 Examination Guidelines, 2-11-21.
449 Examination Guidelines, 2-11-3.
450 Examination Guidelines, 2-11-2.

ingredient. The TIPO believed R&D on new drugs and innovation in free form of active ingredients in recent years is one of the major areas of development of the domestic pharmaceutical industry. However, the TIPO withdrew the amendment, since most of the domestic industry were deeply concerned that the amendment would mainly benefited foreign big pharmaceutical companies.

### 9.5.2 Conditions for granting an patent term extension

#### *9.5.2.1 Premise*

In Taiwan the requirements to obtain an SPC are similar as in Europe stipulated in the Art. 3 of Reg. 469/2009.

(a) *"..basic patent in force"*

Regarding interim request Article 54 of the Patent Act (Deemed to have been extended) has such legal provision:

> Where a request for patent term extension is filed in accordance with the preceding article, the patent term shall be deemed to have been extended if the Specific Patent Agency has yet to render a decision before the original patent term expires. However, where such request for patent term extension is not allowed, the patent term shall expire on the original expiration date.

(b) *"a valid authorisation to place the product on the market as a medicinal product has been granted"*

The scope of a patent, of which a term extension has been granted, shall be limited to only the products, uses and processes corresponding to the active ingredients and uses stated in the first regulatory approval. Any ingredients, processes or uses that are specified in the claims but not identified in the market authorization will not be covered by the term extension protection. Therefore, the Examination Guidelines prescribe that an applicant must explain in the application form the relatedness (correspondence) between the patent claims and the active ingredients and uses, and further explain the relationship between the patent claims and the active ingredients and uses if they are not identical.[451]

The Examination Guidelines provide some illustration for the "corresponding relationship" between the patent claims and the effective ingredients and uses:

a) For invention patents on compounds, at least one of the claims must correspond to the effective ingredients stated in the market authorization certificate.[452]
b) For invention patents on combination that contain combination in the claims consisted of more than two effective ingredients, the effective ingredients stated in the market authorization certificate must also contain more than two effective ingredients. For example, if the market authorization certificate stated a combination of two effective ingredients, a and b, and yet there is only a or b in the patent claim, then there is no "corresponding relationship." Conversely, if the combination of a+b is the patent claim, and yet the market authorization

[451] Examination Guidelines, 2-11-5.
[452] *Ibid.*

certificate stated only the effective ingredient of a or b, then there is no "corresponding relationship" either.[453]

c) For invention patents on use, the content of at least one of the usage claims must correspond to the use of effective ingredients stated in the market authorization certificate.[454]

d) For process invention patents, at least one of the product that was manufactured by the process must correspond to the effective ingredients stated in the market authorization certificate, which does not state the process.[455]

(c) *"the product has not already been the subject of a certificate"*

To not to over-compensate patentees, there can be only one patent term extension for one granted patent. The legislative reasoning to Article 53(1) of the Patent Act gives detailed illustration: "One invention patent that has claim for germicide and pesticide respectively and was extended patent term based on market authorization for germicide, cannot be again extended patent term based on authorization for pesticide. The first regulatory approval is to be judged on the combination of active ingredients and uses, rather than by active ingredients alone, specified in the first regulatory approval. Therefore, (although) active ingredients can acquire separate regulatory approvals according to different uses, the patent can be extended only once based on one of the regulatory approvals, rather than being extended twice based on the two regulatory approvals. Patentees can extend their patents once based on one regulatory approval. Therefore if one regulatory approval has been used to extend patent term, the patentee may not apply to extend the term of the same or other patent based on the same regulatory approval. Consequently, the patentee who has acquired one regulatory approval that covers several patents can only choose to extend patent term for one from the multiple."

Since the market authorization identifies clearly the active ingredients and their use (the therapeutic indication), the patent protection covers the same substance and therapeutic indication, regardless of its formulation or dosage form. For example, if the market authorization identifies X as active ingredient for treating Y disease in a tablet form, the extended patent covers X active ingredient for treating Y disease in form of tablet, injection, capsule etc. It is then impossible to obtain another extension concerning the new formulation. In June 2017, the TIPO proposed to limit the scope of patent term extension and grant new formulation of an existing drug patent term extension. However, both foreign and domestic pharma industries disagree with the amendment.

With regard to the new therapeutic indication of an active ingredient, it is possible to obtain an extension, since the extended patent only covers the same active ingredient and the same therapeutic indication.

Principally it is not possible to obtain an extension for a combination product if one of the combined products has already been subject of an extension. However, if the

[453] Examination Guidelines, 2-11-7.
[454] *Ibid.*
[455] *Ibid.*

composition of the combination product is protected by another patent, it is then possible for the composition patent to obtain an extension.

## 9.6 RIGHT TO REQUEST AND OBTAIN A PATENT TERM EXTENSION

In Taiwan, the legislature does not envision the scenario in which the patent holder is not the same as the first market authorization holder. As a matter of fact, the wording of Article 53(1) states that only patent holders that have acquired "their" first market authorization are eligible to apply for patent term extension. The Examination Guidelines allow some flexibility that the exclusive patent licensee may also be the applicant for patent term extension if his/her license is duly recorded with the TIPO.[456] In addition, the first market authorization holder can be the patentee, his/her exclusive and non-exclusive licensee, whether registered with the TIPO or not, and the one which has the identical legal personality as the patentee (e.g. Taiwan branch office of a parent company).[457] The Examination Guidelines further elaborate that if the first market authorization holder is not the same as the patentee or the registered licensee, the TIPO shall ask the patentee to "revise the application or provide supplementary materials (to prove the license agreement) within designated time limit, which if not complied with will lead to the rejection of the application."[458] Under Taiwanese law it is not possible for a patentee to obtain an extension by referring to a third party authorization.

## 9.7 PERIOD OF EXTENSION

The TIPO may grant an applicant a patent term extension for a period of time that is equal to the period of time this patentee was not allowed to practice his/her patented invention because the market authorization has not yet been granted. However, the maximum term is five years.[459] According to the Extension Regulations, with respect to pharmaceuticals or the manufacturing processes thereof, the periods of time allowable for patent term extension include: 1. the period of domestic and/or foreign clinical trials conducted for obtaining a pharmaceutical approval from the MHW; and 2. the examining period for the domestic regulatory approval. The "domestic and/or foreign clinical trials" shall be limited to those referred by the TIPO to the MHW and confirmed by the MHW as necessary for issuing the pharmaceutical approval. Where the request for patent term extension is made, the time period attributable to the requester's omission of act, the overlapping time period between domestic and foreign clinical trials, and the overlapping period between the clinical trials and the examining period for the regulatory approval, should be deducted from the period to be granted extension.[460]

With respect to agrichemicals or the manufacturing processes thereof, the periods of time allowable for a request for patent term extension include: 1. the period of domestic and/or foreign field tests conducted for obtaining an agrichemical approval from the CA; and 2. the examining period for the domestic regulatory approval. The

456 Examination Guidelines, 2-11-2.
457 Examination Guidelines, 2-11-3.
458 Examination Guidelines, 2-11-13.
459 Article 53(2) of the Patent Act.
460 Article 4 of the Extension Regulations.

"domestic and/or foreign field tests" shall be limited to those referred by the TIPO to the CA and confirmed by the CA as necessary for issuing the agrichemical approval. Where the request for patent term extension is made, the time period attributable to the requester's omission of act, the overlapping time period between domestic and foreign field tests, and the overlapping time period between field tests and the examination period of the regulatory approval, should be deducted from the period to be granted extension.[461]

In June 2017, the TIPO proposed to amend the Patent Act to introduce a limitation on maximum protection term. According to the draft, the period between the first market authorization and the expiry of patent right shall not be longer than 15 years.

It has no effect on the calculation of the duration of an extension if the clinical trials were done abroad and not in Taiwan.

## 9.8 SCOPE OF PROTECTION

According to Article 56 of the Patent Act, the granted extension only covers active ingredients and uses that are identified in the first regulatory approval. Any ingredients and uses that are specified in the claim but not identified in the first regulatory approval will not be covered by the extension protection.[462]

As a rule, the equivalence doctrine applies in Taiwan too. However, whether such doctrine also applies to the scope of patent term extension, so far there is no case law on this. Some commentators argue that it should, while some argue otherwise.[463]

## 9.9 RIGHTS CONFERRED BY THE EXTENDED PATENT

A patent holder will enjoy his/her rights and protection conferred by a grant of patent term extension exactly the same as the rights and protection this patent holder has before the extension.

## 9.10 PROCEDURAL ASPECTS

According to Article 53(4) of Taiwan Patent Act, when requesting for patent term extension, a request form and document(s) of proof must be submitted to the TIPO within three months after obtaining the first regulatory approval; no request for patent term extension shall be filed within six months prior to the expiry of the original patent term. In the event that the patent holder obtains the certificate of market authorization after the actual issuance date of the market authorization, the Examination Guidelines prescribe that the three-month period starts to run from the

461 Article 6 of the Extension Regulations.
462 Examination Guidelines, 2-11-21.
463 Noteworthy is that the Tokyo IP High Court in a decision of January 20, 2017 opined that the doctrine of equivalence does not apply to the scope of patent term extension (*Debiopharm International S.A. v Towa Pharmaceutical Co., Ltd.*), which is available at http://www.saint-island.com.tw/report/data/IPR_201703_in_si.htm#a02

date when the patent holder or the registered licensee actually receives the first market authorization certificate.[464]

When making a decision on an application for patent term extension, the TIPO has to make substantive examination. The TIPO is required by Article 53(5) of the Patent Act to take into consideration the impact on public health and further required by Articles 4(2) and 6(2) of the Extension Regulations to decide which "domestic and/or foreign clinical trials" shall be referred to the MHW and CA to determine whether they are necessary. However, the findings of the MHW and the CA regarding the period of time spent on clinical trials will be respected by the TIPO. Taiwan Supreme Administrative Court (**SAC**) confirms in the 2011 Pan Tze no. 1534 (August 31, 2011) decision that the TIPO was correct in calculating the number of days that an applicant was delayed in obtaining market authorization, and upholds the TIPO's decision not to include certain period of time, based on the MHW's interpretations of regulations on clinical trials.

According to Article 57 of the Patent Act, anyone may object the TIPO's grant of patent term extension under any of the following circumstances: 1. where it is unnecessary to obtain the regulatory approval to exploit the invention patent concerned; 2. where neither the patentee nor licensee has obtained the regulatory approval; 3. where the granted term of extension exceeds the period during which the patent cannot be exploited; 4. where the requester of the patent term extension is not the patentee; 5. where the regulatory approval of extension request is not the first approval, or a request for extension based on the said regulatory approval has been made; 6. where the request for extension is based on the time spent on conducting trials or tests in a foreign country, the extended term granted by the Specific Patent Agency exceeds the period approved by the foreign patent authority; or 7. where the pharmaceuticals involved in the granted patent term extension are veterinary drugs.

If an invalidation decision revoking the patent term extension has become final and binding, the granted patent term extension shall be deemed non-existent *ab initio*. However, if such final and binding invalidation decision is rendered due to violation of the above-mentioned 3 or 6 circumstances, only the exceeding period of the extension shall be deemed non-existent. In addition, according to case law, an alleged infringer in a civil patent infringement lawsuit may challenge the patent term extension if infringement was made during the extended term of a patent. When the infringer raises this defense, the IP Court will have to determine whether the patent extension was legally granted. In the event of finding that the patent extension should not have been granted, the IP Court can refuse to enforce the patentee plaintiff's patent against such alleged infringer.[465]

If an application for patent term extension was rejected by the TIPO, the patentee applicant may file an administrative appeal with the Ministry of the Economic Affairs, which supervises the TIPO. An administrative review board will review and determine this appeal. The applicant may further file an administrative lawsuit with Taiwan Intellectual Property Court against the decision made by the review board. The

[464] Examination Guidance, 2.4 at 2-11-3.
[465] *See e.g.*, Taiwan Intellectual Property Court judgments 2014 Ming Juan Su Tze no. 55; 2015 Ming Juan Sheng Tze no. 41.

applicant may appeal against an unfavorable judgment of the IP Court to the SAC, whose judgment will be final.

## 9.11 THE INTERPLAY WITH OTHER FORMS OF EXCLUSIVITY

Data exclusivity is different from the patent term extension and will not be effected by the latter.

## 9.12 BOLAR EXEMPTION

The research exemption is available under Article 59(1) No.2 of the Patent Act, which prescribes that the effects of an invention patent right shall not extend to the necessary acts to exploit the invention for research or experimental purpose(s). [466] Apart from the above-mentioned research exemption, Article 60 of the Patent Act prescribes the "Bolar exemption": "The effects of the patent right shall not extend to research and trials, including their practical requirements, necessary for obtaining registration and market approval of drugs under the Pharmaceutical Affairs Act or obtaining market approval of pharmaceuticals from a foreign country." Not only the parties conducting research and trials, but also the parties supplying products necessarily related to research and trials are entitled to invoke the Bolar exemption.

Neither the Patent Act nor the Examination Guidelines or the Extension Regulations address how the research and experiment exemption interplays with the patent term extension protection. There is no case law on this.

[466] Prior than the 2011 amendment, the exemption was conditioned on "non-commercial." This condition was deleted in 2011.

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# Study on the Legal Aspects of Supplementary Protection Certificates in the EU

Annex II: International Reports

Publications Office

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