

PATENT TERM EXTENSIONS AND ADJUSTMENTS



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Patent Term Extensions and Adjustments

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Comparative Summary

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This report surveys the law on extensions and adjustments of patents in nine jurisdictions: Australia, Canada, the European Union, France, Germany, Israel, Japan, South Korea, and the United Kingdom.

All of the surveyed jurisdictions provide for a standard patent term of twenty years, and all of them except Canada provide for extensions of protection for certain products that are subject to regulatory approval before they can be marketed. For the European Union and France, Germany, and the United Kingdom, supplementary protection certificates (SPCs) are available that extend the protections of patents for medicinal and plant protection products to cover the period needed for regulatory approval of the product, typically to a maximum of five years. Australia similarly provides for extensions of patent protections for pharmaceutical substances to account for the period needed for regulatory approval up to five years. Israel permits the term of basic pharmaceutical patents to be extended for a period equal to the time between submission and granting of the marketing license application, up to five years. Israel also permits extension of related patents held in the United States, Italy, Britain, Germany, Spain, and France where there is patent extension or SPC in the country of origin. Japan allows an extension of the duration of a patent right by up to five years when the patented invention is subject to certain regulatory approval processes that take a considerable time to complete, including those for agrochemicals and pharmaceuticals. South Korea likewise allows for the extension of patent terms for up to five years with respect to medicines and agricultural chemicals to account for the period of product registration.

In addition, South Korea provides for adjustment of patent terms due to delayed patent registrations.

While Canada currently does not have legislation providing for extensions of patent protection, it is currently negotiating a trade agreement with the European Union that in draft form provides for patent term extensions of two to five years for qualifying pharmaceutical products.

Australia

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I. Extension of Term Provisions in the Patents Act 1990 (Cth)

The Patents Act 1990 (Cth) provides that the term for a standard patent is twenty years.¹ However, part 3 of chapter 6 of the Patents Act provides for the extension of the term of standard patents for pharmaceutical substances. The provisions were added by legislation enacted in 1998.²

Note that, in order to be imported into, supplied in, or exported from Australia, pharmaceutical products must be approved by the Therapeutic Goods Administration for entry in the Australian Register of Therapeutic Goods (ARTG).³

Section 70 of the Patents Act 1990 (Cth) allows a holder of a standard patent to apply for one extension of term of the patent where the following conditions are satisfied:

- One or more “pharmaceutical substances *per se*,” or 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”;⁴
- The goods “containing, or consisting of, the substance” must be included in the ARTG;⁵ and
- The “period beginning on the date of the patent and ending on the first regulatory approval date for the substance must be at least 5 years.”⁶

¹ Patents Act 1990 (Cth), s 67, <https://www.comlaw.gov.au/Details/C2015C00484>, archived at <https://perma.cc/MQQ3-FX57>.

² Intellectual Property Laws Amendment Act 1998 (Cth) sch 1 div 2, <https://www.comlaw.gov.au/Details/C2004A00356>, archived at <https://perma.cc/TER5-BLJP>.

³ See *Australian Register of Therapeutic Goods*, THERAPEUTIC GOODS ADMINISTRATION (TGA) (July 5, 2013), <https://www.tga.gov.au/australian-register-therapeutic-goods>, archived at <https://perma.cc/N657-8J38>; *Australian Regulation of Prescription Medical Products*, TGA (Oct. 14, 2015), <https://www.tga.gov.au/australian-regulation-prescription-medical-products>, archived at <https://perma.cc/DU7D-MEWJ>. Pharmaceutical products and other “therapeutic goods” are regulated under the Therapeutic Goods Act 1989 (Cth), <https://www.comlaw.gov.au/Details/C2015C00471>, archived at <https://perma.cc/W9JX-EPWD>.

⁴ Patents Act 1990 (Cth) s 70(2).

⁵ *Id.* s 70(3)(a).

⁶ *Id.* s 70(3)(b).

An application for an extension of term must be made within six months of either the date the patent was granted or the date of commencement of the first inclusion of goods containing the substance in the ARTG, whichever date is later.⁷

The term of the extension cannot be longer than five years.⁸ The exact term is calculated by subtracting five years from the period beginning on the date of the patent and ending on the earliest first regulatory approval of a substance.⁹

If an extension of term is granted, the legislation provides that the exclusive rights of the patentee during the term of the extension are not considered to have been infringed where another person exploits the pharmaceutical substance for a purpose other than therapeutic use, or exploits any form of the invention that does not include the substance.¹⁰

II. Additional Information

A. Australia-United States Free Trade Agreement

In 2004, the Australian and the United States governments signed the Australia-United States Free Trade Agreement (AUSFTA), which includes a provision requiring that “[w]ith respect to a pharmaceutical product that is subject to a patent, each Party shall make available an adjustment of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process.”¹¹

The AUSFTA also requires that

[i]f there are unreasonable delays in a Party’s issuance of patents, that Party shall provide the means to, and at the request of a patent owner, shall, adjust the term of the patent to compensate for such delays. An unreasonable delay shall at least include a delay in the issuance of a patent of more than four years from the date of filing of the application in the Party, or two years after a request for examination of the application has been made, whichever is later. For the purposes of this paragraph, any delays that occur in the issuance of a patent due to periods attributable to actions of the patent applicant or any opposing third person need not be included in the determination of such delay.¹²

⁷ *Id.* s 71(2). The High Court of Australia held in a 2014 decision that the extension-of-time provisions in the Patents Act could be applied to extension-of-term applications: *Alphapharm Pty Ltd v H Lundbeck A-S* [2014] HCA 42, <http://www.austlii.edu.au/au/cases/cth/HCA/2014/42.html>, archived at <https://perma.cc/X65S-TTKS>.

⁸ Patents Act 1990 (Cth) s 77(2).

⁹ *Id.* s 77(1).

¹⁰ *Id.* s 78.

¹¹ Australia-United States Free Trade Agreement, ch 17 art 17.9.8(b), <http://dfat.gov.au/about-us/publications/trade-investment/australia-united-states-free-trade-agreement/Pages/chapter-seventeen-intellectual-property-rights.aspx>, archived at <https://perma.cc/9UJR-HN5X>.

¹² *Id.* art 17.9.8(a).

No amendments were made to the Patents Act 1990 (Cth) in relation to this provision in the AUSFTA.¹³ The Australian Department of Foreign Affairs and Trade has recently stated, in relation to a similar provision in the Trans-Pacific Partnership Agreement (TPP Agreement), that

TPP Parties commit to the efficient and timely processing of patent applications by patent offices, with a view to avoiding unreasonable or unnecessary delays. Where there are systemic unreasonable delays in issuing patents, TPP Parties will provide the means to adjust the term of a patent to compensate for those delays. Australia is not experiencing such delays in issuing patents.¹⁴

Upon the entry into force of the TPP Agreement, the relevant provisions in that agreement that address the matters in both of the above provisions of the AUSFTA will apply with respect to the relationship between the United States and Australia.¹⁵

B. Review Panel Recommendations

In 2012, the previous government established a panel to review the Australian pharmaceutical patents system. A central focus of the review was the extension of term provisions in the Patents Act.¹⁶ The panel's final report, presented to the government in May 2013,¹⁷ was critical of the current provisions and recommended alternative approaches to meeting stated policy objectives.¹⁸

The government has stated that it “has no plans to respond to the report at this stage but may take information in the report into account when considering future policy. The views expressed and recommendations made in the report are those of the review panel and do not necessarily reflect government policy.”¹⁹

¹³ See US Free Trade Agreement Implementation Act 2004 (Cth) sch 8, <https://www.comlaw.gov.au/Details/C2004A01355/>, archived at <https://perma.cc/FRL8-VFNT>.

¹⁴ DEPARTMENT OF FOREIGN AFFAIRS AND TRADE, TRANS-PACIFIC PARTNERSHIP AGREEMENT: CHAPTER SUMMARY: INTELLECTUAL PROPERTY 4–5 (last updated Mar. 2, 2016), <http://dfat.gov.au/trade/agreements/tpp/summaries/Documents/intellectual-property.DOCX>, archived at <https://perma.cc/TSH4-GTGF>.

¹⁵ Exchange of Letters between Andrew Robb (Australian Minister for Trade and Investment) and Michael Froman (United States Trade Representative), February 4, 2016, available at <http://dfat.gov.au/trade/agreements/tpp/official-documents/Documents/australia-us-intellectual-property-regulatory-review-exception-technical-protection-measures-patent-office-delays.PDF>, archived at <https://perma.cc/6H2C-DTRY>.

¹⁶ *Review of Pharmaceutical Patents in Australia*, IP AUSTRALIA, <http://www.ipaustralia.gov.au/about-us/ip-legislation/ip-legislation-changes/review-pharmaceutical-patents> (last updated Mar. 20, 2014), archived at <https://perma.cc/AJY3-MU6F>.

¹⁷ The report was not publicly released until March 2014.

¹⁸ T. HARRIS, D. NICOL & N. GRUEN, PHARMACEUTICAL PATENTS REVIEW REPORT 2013, at 60–104 (2013), available at http://www.ipaustralia.gov.au/pdfs/2013-05-27_PPR_Final_Report.pdf, archived at <https://perma.cc/NHE9-4GK3>.

¹⁹ Government Statement on the Pharmaceutical Patent Review Final Report (undated, likely around Mar. 2014), http://www.ipaustralia.gov.au/pdfs/Government_statement_on_the_Pharmaceutical_Patent_Review_final_report.pdf (last visited Feb. 25, 2016), archived at <https://perma.cc/DY2S-C4VU>.

Canada

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I. Patent Term Extension in Canada

Canada, in compliance with its obligations under the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights,¹ has established a standard patent term of up to twenty years from the date on which a patent application is filed.² Canada does not have patent term extension legislation pertaining to pharmaceutical products or otherwise.³

II. Canada-European Union Comprehensive Economic and Trade Agreement (CETA)

The Canada-European Union Comprehensive Economic and Trade Agreement (CETA),⁴ which has not yet been concluded, signed, or ratified, is “a wide-ranging trade agreement” covering such diverse topics as foreign ownership and investments, access to public procurement contracts, automobiles, food, agriculture, and pharmaceuticals.⁵ The Agreement would provide for patent term restoration (which the Agreement describes as *sui generis* protection) for qualifying new pharmaceutical products. The duration of the restoration, which is to be established by each party to the Agreement, “may not exceed a period of two to five years.”⁶ The Canadian government has reportedly said that extensions will be capped at two years.⁷

¹ See David E. Schwartz, *Patent Term Extension Bill Tabled in the Canadian Senate*, SMART & BIGGAR / FETHERSTONHAUGH (Feb. 28, 2001), http://www.smart-biggar.ca/en/articles_detail.cfm?news_id=69, archived at <https://perma.cc/WR4M-CKY9>.

² Patent Act, R.S.C. 1985, c. P-4, § 44, <http://www.laws-lois.justice.gc.ca/PDF/P-4.pdf>, archived at <https://perma.cc/UNB9-4AEX>.

³ Brian Lee Crowley & Kristina Lybecker, *Improving Canada’s Drug Patent Protection: Good For Canada, Good For Trade*, 33(3) POL’Y OPTIONS 69, 70 (Mar. 2012), <http://policyoptions.irpp.org/wp-content/uploads/sites/2/assets/po/the-liberal-renewal/crowley.pdf>, archived at <https://perma.cc/AWP9-FKKQ>; MARGARET SMITH, PARLIAMENTARY RESEARCH BRANCH, LAW AND GOVERNMENT DIVISION, PATENT TERM EXTENSIONS FOR PHARMACEUTICAL PRODUCTS (MR-144E, Feb. 20, 1997), <http://publications.gc.ca/Collection-R/LoPBdP/MR/mr144-e.htm>, archived at <https://perma.cc/5GK4-F8AY>.

⁴ Comprehensive Economic and Trade Agreement (CETA), Can.-E.U., Sept. 26, 2014, available at <http://www.international.gc.ca/trade-agreements-accords-commerciaux/agr-acc/ceta-aecg/text-texte/toc-tdm.aspx?lang=eng>, archived at <https://perma.cc/D9A8-BAFU>.

⁵ NOEL COURAGE, CANADIAN PATENT TERM EXTENSION – THE TREATY TEXT IS RELEASED 1 (BERESKIN & PARR Dec. 2, 2014), <http://www.bereskinparr.com/index.cfm?cm=Doc&ce=downloadPDF&primaryKey=481>, archived at <https://perma.cc/QRT5-EVWC>.

⁶ CETA, *supra* note 4, § 22, art. 9.2(4).

⁷ COURAGE, *supra* note 5, at 1.

According to the draft treaty, the *sui generis* protection would be available at “the request of the holder of the patent or his successor in title,” subject to certain limitations or conditions.⁸ The product could not have already been the subject of a period of *sui generis* protection.⁹ The restoration would be “available upon request of the brand name company, provided the drug is being approved by Health Canada for the first time.”¹⁰ The extended protection would also be “limited to a single patent for any new pharmaceutical product. Where the approved product is protected by multiple patents, the patentee must select just one to be the subject of its application for additional protection.”¹¹

The actual term of the protection would be “calculated on a product-by-product basis.”¹² The *sui generis* protection would extend only to the pharmaceutical product “covered by the authorisation to place that product on the market and for any use of that product as a pharmaceutical product that has been authorized before the expiry of the *sui generis* protection.”¹³ In other words, “additional protection of patent term restoration will be limited to the specific compound and its approved uses, not the entirety of the patent.”¹⁴ Also, this extension would be available only to drugs entering the market after the new rules came into effect.¹⁵ However, “[t]he draft CETA text provides an exception under the patent term extension for generic drugs to be exported, which was a carve-out promised by Canada to benefit its generic drug industry.”¹⁶

⁸ CETA, *supra* note 4, § 22, art. 9.2(2).

⁹ *Id.* § 22, art. 9.2(2)(b).

¹⁰ COURAGE, *supra* note 5, at 1.

¹¹ Geoffrey Mowatt & Ryan Evans, *Patent Term Restoration Under CETA – A Game-Changer for Canadian Pharma?*, DIMOCK STRATTON LLP (Jan. 23, 2015), <http://www.dimock.com/publications.php?article=102>, archived at <https://perma.cc/BA9L-8XWQ>.

¹² *Id.* CETA provides that

[e]ach Party shall provide that the period of *sui generis* protection shall be for a period equal to the period which elapsed between the date on which the application for a patent was filed and the date of the first authorisation to place the product on the market of that Party as a pharmaceutical product reduced by a period of five years. CETA, *supra* note 4, § 22, art. 9.2(4).

¹³ CETA, *supra* note 4, § 22, art. 9.2(5).

¹⁴ COURAGE, *supra* note 5, at 1.

¹⁵ *Id.*

¹⁶ *Id.*

European Union

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SUMMARY In the European Union, extensions of patent protection can be obtained for medicinal and plant protection products through supplementary protection certificates (SPCs). SPCs are governed by three regulations that are directly applicable in the national legal systems of the Member States.

I. Introduction

In the European Union (EU), patents are granted by either the competent national authorities or the European Patent Office.¹ Three EU regulations that are directly applicable in the national legal systems of the Member States and to European Economic Area (EEA) countries² provide for supplementary protection certificates (SPCs) that extend the protections of patents for medicinal and plant protection products, in most cases to a maximum of five years.³

II. Legal Framework

A. Products Covered by SPCs

1. Medicinal Products

Regulation No. 469/2009 Concerning the Supplementary Protection Certificate for Medicinal Products⁴ applies to any product that has already been protected by a patent within the territory of a Member State and is subject to an authorization procedure before it is placed on the market.⁵

¹ *Patent Protection in the EU*, EUROPEAN COMMISSION, http://ec.europa.eu/growth/industry/intellectual-property/patents/index_en.htm (last visited Mar. 4, 2016), archived at <https://perma.cc/4JVC-CHEB>.

² The European Economic Area (EEA) is composed of the EU Member States and three of the European Free Trade Association (EFTA) States (Iceland, Liechtenstein, and Norway). The EEA was established by the EEA Agreement, an international agreement that enables these three States to participate fully in the EU's single market. *Basic Features of the EEA Agreement*, EFTA, <http://www.efta.int/eea/eea-agreement/eea-basic-features#1> (last visited Mar. 4, 2016), archived at <https://perma.cc/9GHE-TFXW>.

³ *Supplementary Protection Certificates for Pharmaceutical and Plant Protection Products*, EUROPEAN COMMISSION, http://ec.europa.eu/growth/industry/intellectual-property/patents/supplementary-protection-certificates/index_en.htm (last visited Mar. 4, 2016), archived at <https://perma.cc/276V-TNNH>.

⁴ Regulation (EC) No. 469/2009 of the European Parliament and of the Council of May 6, 2009 Concerning the Supplementary Protection Certificate for Medicinal Products (Codified version), 2009 O.J. (L 152) 1, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:152:0001:0010:en:PDF>, archived at <https://perma.cc/3KM5-BJ8J>.

⁵ The authorization procedure is regulated by Directive 2001/83/EC of the Community Code Relating to Medicinal Products for Human Use, 2001 O.J. (L 311) 67, <http://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX:32001L0083>, archived at <https://perma.cc/G4W3-VCU6>, and Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code Relating to Veterinary Medicinal Products, 2001 O.J.

Medicinal products are defined as

any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals.

2. Medicinal Products for Children

Regulation (EC) No. 1901/2006 provides that SPCs apply to medicinal products for children for which data have been submitted according to a Paediatric Investigation Plan (PIP).⁶ PIPs are required to support the authorization of medicines for children. The Regulation provides for a six-month additional extension for SPCs concerning such medicinal products reviewed under a PIP.⁷

3. Plant Protection Products

Regulation (EC) No. 1610/96 governs the creation of an SPC for plant protection products.⁸ On the basis of Regulation No. 1610/96, any product that is protected by a patent in the territory of a Member State and is subject, prior to being placed on the market as a plant protection product, to an administrative authorization procedure as established in Directive 91/414/EEC,⁹ or pursuant to an equivalent provision of national law, may be the subject of a certificate.¹⁰

The Regulation defines “plant protection products” as

. . . active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to:

- 1.1. protect plants or plant products against all harmful organisms or prevent the action of such organisms, in so far as such substances or preparations are not otherwise defined below;

(L 311) 1, <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32001L0082>, archived at <https://perma.cc/EFS7-92BR>.

⁶ Regulation (EC) No. 1901/2006 of the European Parliament and of the Council of December 12, 2006, on Medicinal Products for Paediatric Use and Amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No. 726/2004, 2006 O.J. (L 376) 1, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:378:0001:0019:en:PDF>, archived at <https://perma.cc/LC2S-8PNZ>.

⁷*Id.* art. 36.

⁸ 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, 1996 O.J. (L 198) 30, <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A31996R1610>, archived at <https://perma.cc/29QK-2GRA>.

⁹ Council Directive 91/414/EEC of 15 July 1991 Concerning the Placing of Plant Protection Products on the Market art. 4, 1991 O.J. (L 230) 1, <http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:31991L0414>, archived at <https://perma.cc/9VVA-8DZ6>.

¹⁰ Regulation 1610/96, art. 2.

- 1.2. influence the life processes of plants, other than as a nutrient (e.g. growth regulators);
- 1.3. preserve plant products, in so far as such substances or products are not subject to special Council or Commission provisions on preservatives;
- 1.4. destroy undesirable plants; or
- 1.5. destroy parts of plants, check or prevent undesirable growth of plants[.]¹¹

“Substances” are defined as “chemical elements and their compounds, as they occur naturally or by manufacture, including any impurity inevitably resulting from the manufacturing process.” “Active substances” are defined as those “substances or micro-organisms including viruses, having general or specific action . . . against harmful organisms; or . . . on plants, parts of plants or plant products.” “Preparations” are defined as “mixtures or solutions composed of two or more substances of which at least one is an active substance, intended for use as plant protection products.”¹²

B. Applications

The application for a certificate for a medicinal or a plant protection product must be filed with the competent industrial property office of the Member State that granted the basic patent and where the authorization was obtained. A Member State may designate another authority responsible for the filing of an application.¹³

The conditions for applying for an SPC for a medicinal or plant protection product are the same. The applicant must meet the following criteria:

- Have a valid patent
- Have valid authorization to place the product on the market
- Show that the product has not already been the subject of a certificate
- Show that the marketing authorization is the first authorization to place the product on the market as a medicinal product or a plant protection product¹⁴

The certificate is granted to the holder of the basic patent or his/her successor in title,¹⁵ grants the same rights, limitations, and obligations as those conferred by the basic patent, except that the protection only extends to the product covered by the authorization to place the product on the market.¹⁶

¹¹ *Id.* art. 2, para. 1.

¹² *Id.* art. 1, paras. 2–5.

¹³ *Id.* art. 9, para. 1; Regulation 469/2009, art. 9.

¹⁴ Regulation No. 469/2009, art. 3; Regulation No. 1610/96, art. 3.

¹⁵ *Id.* art. 6; Regulation No. 1610/96, art. 6.

¹⁶ Regulation No. 469/2009, arts. 4 & 5; Regulation No. 1610/96, arts. 4 & 5.

An application for an SPC must be filed within six months of the date the product was authorized to be marketed as a medicinal product¹⁷ or as a plant protection product.¹⁸ If the authorization to place the product on the market is granted before the basic patent is granted, the application for a certificate must be filed within six months of the date on which the patent is granted.¹⁹

An application to extend the duration of a certificate that has been already granted must be filed no later than two years before the expiration of the certificate.²⁰

C. Calculation of Duration

The following rules are provided for calculating the duration of a medicinal or plant protection product SPC:

- It becomes valid at the end of the lawful term of the basic patent for a period equal to the period that elapsed between the date on which the application for a basic patent was filed and the date the product was first authorized to be placed on the European Community market, reduced by a period of five years.
- The duration of a certificate for a medicinal or plant protection product may not exceed five years from the date on which it takes effect.
- Account is taken of a provisional first marketing authorization only if it is directly followed by a definitive authorization concerning the same product.²¹

¹⁷ Regulation No. 469/2009, art. 7.

¹⁸ Regulation No. 1610/96, art. 7.

¹⁹ *Id.* art. 7, paras. 1 & 2; Regulation No. 469/2009, art. 7, paras. 1 & 2.

²⁰ Regulation No. 1610/96, art. 7, para. 4; Regulation No. 469/2009, art. 7, para. 4.

²¹ Regulation No. 1610/96, art. 13; Regulation No. 469/2009, art. 13.

France

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The standard length of patent protection under French law is twenty years, beginning from the date on which the patent application is submitted.¹

Pharmaceutical products and plant protection products are eligible for a supplemental protection certificate (SPC) under European Union regulations that are directly applicable to French law.² In both cases, the SPC extends protection “for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorization to place the product on the market in the Community, reduced by a period of five years,” but not to exceed five years from the date on which it took effect.³

Furthermore, under a 2006 European Union regulation, pediatric pharmaceutical products for which data has been submitted according to a pediatric investigation plan as part of the regulatory authorization process are eligible for an additional six-month extension beyond the above-mentioned five years.⁴

Council Regulation (EEC) No. 1768/92 of June 18, 1992, entered into force on January 2, 1993 (six months after its publication in the *Official Journal of the European Communities*).⁵ Before that date, French law provided for a version of the SPC that extended protection for a period not to exceed either seven years from the end of the standard twenty-year patent period, or seventeen years from the date of the authorization to sell the product in question.⁶ It appears that there may

¹ CODE DE LA PROPRIETE INTELLECTUELLE [INTELLECTUAL PROPERTY CODE] art. L611-2, https://www.legifrance.gouv.fr/affichCodeArticle.do;jsessionid=9D5EDDC702E7AE19ADF607D69CB0193F.tpdila07v_3?idArticle=LEGIARTI000006279394&cidTexte=LEGITEXT000006069414&dateTexte=20160225, archived at <https://perma.cc/DH7A-LV73>.

² Council Regulation (EEC) No. 1768/92 of 18 June 1992 Concerning the Creation of a Supplementary Protection Certificate for Medicinal Products, 1992 O.J. (L 182) 1, <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31992R1768&from=EN>, archived at <https://perma.cc/GG28-VE6V>; 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, 1996 O.J. (L 198) 30, <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31996R1610&from=EN>, archived at <https://perma.cc/2U4F-7MU7>.

³ Council Regulation (EEC) No. 1768/92, *supra* note 2, art. 13; Regulation (EC) No. 1610/96, *supra* note 2, art. 13.

⁴ Regulation (EC) No. 1901/2006 of the European Parliament and of the Council of 12 December 2006 on Medicinal Products for Paediatric Use and Amending Regulation (EEC) No. 1768/92, Directive No. 2001/20/EC, Directive No. 2001/83/EC and Regulation (EC) No. 726/2004, art. 36, 2006 O.J. (L 378) 1, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:378:0001:0019:en:PDF>, archived at <https://perma.cc/AL5A-FVGM>.

⁵ Council Regulation (EEC) No. 1768/92, *supra* note 2, art. 23.

⁶ CODE DE LA PROPRIETE INTELLECTUELLE art. L611-3, https://www.legifrance.gouv.fr/affichCodeArticle.do;jsessionid=9D5EDDC702E7AE19ADF607D69CB0193F.tpdila07v_3?idArticle=LEGIARTI000006279396&cidTexte=LEGITEXT000006069414&dateTexte=20160225, archived at <https://perma.cc/U8JE-PA9F>.

still be some products currently protected by certificates granted under French law before January 2, 1993.⁷

⁷ *Quelle est la procédure de délivrance d'un certificat complémentaire de protection?* [What is the Procedure for Granting a Supplemental Protection Certificate?], INSTITUT NATIONAL DE LA PROPRIÉTÉ INDUSTRIELLE [NATIONAL INDUSTRIAL PROPERTY INSTITUTE] (French equivalent of the Patent Office), [https://www.inpi.fr/fr/faq/ quelle-est-la-procedure-de-delivrance-d-un-certificat-complementaire-de-protection-ccp](https://www.inpi.fr/fr/faq/quelle-est-la-procedure-de-delivrance-d-un-certificat-complementaire-de-protection-ccp) (last visited Feb. 25, 2016), archived at <https://perma.cc/2P6Z-BGAH>.

Germany

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Section 16 of the German Patent Act generally provides that the patent term is twenty years.¹ The period starts the day after the application has been filed. An extension or adjustment of the patent term is not possible.

As an exception, if the patent is covered by the European Union (EU) Regulations concerning the creation of supplementary protection certificates (SPC) for pharmaceutical and plant protection products,² an application for supplementary protection can be filed.³ The EU Regulations are directly applicable in Germany. The amendment to the German Patent Act was inserted in 1993.⁴

The period of supplementary protection commences immediately after the expiration of the general patent term.⁵ The SPC can extend the patent for a maximum of five years.⁶ An additional six-month extension can be granted if the SPC concerns a medicinal product for children for which data has been submitted according to a Paediatric Investigation Plan.⁷

¹ Patentgesetz [PatentG] [Patent Act], Dec. 16, 1980, 1981 BUNDESGESETZBLATT [BGBl.] I at 1, as amended, § 16, <http://www.gesetze-im-internet.de/bundesrecht/patg/gesamt.pdf>, archived at <http://perma.cc/6KRL-Q6LGö>, unofficial English translation available at http://www.gesetze-im-internet.de/englisch_patg/patent_act_patent_gesetz_patg_.pdf, archived at <http://perma.cc/P9RA-P9FM>.

² Regulation (EC) No. 469/2009 of the European Parliament and of the Council of 6 May 2009 Concerning the Supplementary Protection Certificate for Medicinal Products (Codified Version), 2009 O.J. (L 152) 1, http://ec.europa.eu/health/files/eudralex/vol-1/reg_469_2009/reg_469_2009_en.pdf, archived at <http://perma.cc/Y9D2-QWDXö>; Regulation (EC) No. 1610/96 of the European Parliament and of the Council Concerning the Creation of a Supplementary Protection Certificate for Plant Protection Products, 1996 O.J. (L 198) 30, <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31996R1610&from=EN>, archived at <http://perma.cc/YG2Q-DRHE>.

³ Patent Act § 16a, para. 1.

⁴ Gesetz zur Änderung des Patentgesetzes und anderer Gesetze [Act to Amend the Patent Act and Other Acts], Mar. 23, 1993, BGBl. I at 366, http://www.bgbl.de/xaver/bgbl/start.xav?startbk=Bundesanzeiger_BGBl&jumpTo=bgbl193s0366.pdf, archived at <http://perma.cc/8BW3-DZU6>.

⁵ *Id.*

⁶ Regulation (EC) No. 469/2009, *supra* note 2, art. 13, para. 1; Regulation (EC) No. 1610/96, *supra* note 2, art. 13, para. 2.

⁷ Regulation (EC) No. 1901/2006 of the European Parliament and of the Council of 12 December 2006 on Medicinal Products for Paediatric Use and Amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No. 726/2004, 2006 O.J. (L 378) 1, art. 36, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:378:0001:0019:en:PDF>, archived at <http://perma.cc/TE84-ZH59>.

Israel

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SUMMARY The term for patents in Israel is generally up to twenty years. However, the term of basic pharmaceutical patents may be extended for up to an additional five years. Related patents held in certain recognized countries also enjoy protection in Israel for up to fourteen years from the date of first licensing for marketing in such countries. The extension of term for these related patents generally depends on the existence of a pending patent term extension in the US, or a supplementary protection certificate in Italy, Britain, Germany, Spain, and France.

I. Patent Protection Period

Under the Patents Law, 5727-1967, as amended, the term for patents in Israel is generally up to twenty years from the date of filing,¹ subject to the timely payment of fees.² However, basic pharmaceutical patents may be extended for up to an additional five years for a total term of twenty-five years from the date of filing.³

The Law also ensures related patents held in the United States, Italy, Britain, Germany, Spain, and France (“recognized countries”) are protected in Israel for fourteen years following regulatory approval in those countries.⁴ The fourteen-year term is calculated from the date the first marketing permit is granted in the recognized countries.⁵ The term of protection for related patents can only be extended if the patents are subject to relevant orders or certificates in the recognized countries.

II. Extended Terms for Basic and Related Pharmaceutical Patents

A. Type of Patents That May Be Extended

Protection terms may be extended for both basic and related patents. For the purpose of extending patent protection, a “basic patent” is defined as

¹ Patents Law, 5727-1967, § 52, available by subscription in the Nevo Legal Database, at <http://www.nevo.co.il> (in Hebrew; last visited Feb. 23, 2016), archived at <https://perma.cc/FWZ7-ZUWU>.

² *Id.* §§ 56 & 57.

³ *Id.* § 64J(1).

⁴ *Id.* § 64J(2). The definition of “recognized countries” in which marketing permits were issued is provided in § 64A and makes reference to the list in Appendix 1.

⁵ *Id.* § 64J(2); see also Michael Factor, *Can a Patent Term Be Extended in Israel on the Basis of a Patent Term Adjustment in the US?*, THE IP FACTOR, <http://blog.ipfactor.co.il/2016/02/08/can-a-patent-term-be-extended-in-israel-on-the-basis-of-a-patent-term-adjustment-in-the-us> (last visited Feb. 24, 2016), archived at <https://perma.cc/DV72-KQWR>.

the patent that protects any material, a process for the production of a material, use of a material, a medical preparation that incorporates a material, a process for the production of a medical preparation that incorporates a material or medical equipment that requires a license in Israel.⁶

A “material” is defined as “the active component of a medical preparation or salts, esters, hydrates or crystal forms of that component.”⁷

For the purpose of extending the term of protection for related patents issued in recognized countries, a “related patent” is defined as

any patent whatsoever in a recognized state, which protects the material, the process for the production of the material or the use of the material, or the medical preparation that incorporates the material, or the process for the production of the medical preparation that incorporates the material, or the medical equipment, which is claimed in a basic patent in Israel, whether or not the aforementioned patent parallels the Israel patent[.]⁸

B. Conditions for Granting Extension Orders

An extension order may be issued only for patents that have not yet expired and if the following conditions are met:

- (1) the material, the process for its production or its use, the medical preparation that incorporates the material or the process for its production, or the medical equipment was claimed in the basic patent and the basic patent remains in effect;
- (2) in respect of a medical preparation – a medical preparation that incorporates the material is registered in the Register of Medical Preparations . . . ;
- (3) the registration mentioned in paragraph (2) is the first registration that allows the material to be used in Israel for medical purposes;
- (4) no extension order was previously granted in respect of the basic patent or in respect of the material;
- (5) if a marketing permit was granted in the United States of America – an extension order for the related patent has been issued in that country and has not expired;
- (6) if a marketing permit was granted in Italy, Britain, Germany, Spain and France – an order for the extension of the related patent was made in the aforementioned states and has not yet expired;
- (7) if marketing permits have been issued in both the United States and the aforementioned European countries – and orders extending the related patents were also issued in those countries and have not yet expired.⁹

⁶ Patents Law § 64A (all translations by author, R.L.).

⁷ *Id.*

⁸ *Id.*

⁹ *Id.* § 64D.

C. Orders Extending Related Patents in Recognized Countries

Authorization of term extensions for related patents may be granted only for patents that are subject to orders of extension in the recognized countries.

The Law defines “an order for extending a related patent” as

[a] decree or a license providing for the extension, by one day or longer, of the effectiveness of a related patent regarding a medical preparation that includes the material or regarding medical equipment, that is protected by the related patent, for which one of the following applies:

- (1) It was given in the United States of America (patent term extension) and the period of its effectiveness is determined by the responsible authority in accordance with the portion of the evaluation period for granting the first marketing permit by the agency authorized to grant marketing licenses that applies after the grant of a related patent, while deducting periods for which it has been held that the requestor of the extension orders did not apply appropriate urgency in the period of the aforementioned review, and in addition half of the period of clinical tests of a medical preparation or of equipment that is protected by the related patent;
- (2) It was given in a recognized European country (supplementary protection certificate), and its period of effectiveness is determined in consideration of the period that passed from the date of filing the request for a related patent until the date of the receipt of the first marketing license, with a deduction of five years;
- (3) It was given in a recognized country, and was designed to temporarily extend the effective [period] of the related patent until a determination regarding the granting of an order under subsections (1) or (2) or until an earlier date . . . [.]¹⁰

In a recent rejection of an extension request by Novartis AG, the Patent Registrar (PR) noted that the extension of a protection term for a related patent granted in the US cannot apply to a patent that is subject to a Notice of Final Determination that was granted in a patent term adjustment procedure in the US. The PR determined that the Notice, which is not an order for a patent term extension, does not meet the requirements for establishing that “an order for extending a related patent” was in effect in the US, as required under the Israeli Patent Law.¹¹

D. Calculation of the Term of an Extension Order

If a marketing license was applied for only in Israel, the extension order for a basic patent must be in effect for a period that is equal to the period covering the license application submission date to the date the license was granted, on the condition that the application was submitted and

¹⁰ *Id.* § 64A.

¹¹ Request for Patent Extension No. 154465 by Novartis AG (Jan. 27, 2016), available at <http://www.nevo.co.il> (in Hebrew; last visited Feb. 25, 2016), archived at <https://perma.cc/WD9Y-3V6N>.

handled in good faith and with appropriate expediency.¹² This is subject to the five-year limit for patent term extensions.

With respect to extending the term of related patents, an extension order must be in effect, subject to the five-year extension limit, during a period equal to the shortest extension period among the extension periods granted for the related patent in the recognized states, not including extensions unrelated to patent terms granted in the United States, and term extensions other than supplementary protection certificates granted in the recognized European countries.¹³

¹² Patents Law § 64 I(b).

¹³ *Id.* § 64I(a).

Japan

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The Japanese Patent Act states that the duration of a patent right expires twenty years after the filing date of the patent application.¹ The duration of a patent right may be extended by up to five years if there was a period during which the patented invention could not be worked due to the certain regulatory approval processes taking a “considerable time” to complete. Such processes, which are aimed at ensuring the safety of patented products, are prescribed by relevant Acts and designated by Cabinet Order.²

The relevant Cabinet Order, the Patent Act Enforcement Order, mandates the following regulatory approval processes:³

- Registration of agrochemicals under the Agrochemical Control Act;⁴ and
- Approval of pharmaceuticals and in-vitro diagnostics under the Act on Securing the Quality, Effectiveness and Safety of Pharmaceuticals and Medical Devices.⁵

Extending the duration of a patent right requires filing an application with the Japan Patent Office within a specified period.⁶

¹ Patent Act, Act No. 121 of 1959, art. 67, para. 1, *as amended by* Act No. 41 of 2009, English translation of the Act *as amended by* Act No. 109 of 2006 available at <http://www.japaneselawtranslation.go.jp/law/detail/?printID=&ft=2&re=02&dn=1&yo=patent&ia=03&x=0&y=0&ky=&page=1&vm=02>, archived at <https://perma.cc/YH5S-CB3K>.

² *Id.* art. 67, para. 2. See Japan Patent Office, Revised Examination Guidelines for “Patent Term Extension,” at 1 (Nov. 2014), https://www.jpo.go.jp/iken_e/pdf/pharmaceutical_141008_result/revised.pdf, archived at <https://perma.cc/6BNH-NLYL>.

³ Patent Act Enforcement Order, Cabinet Order No. 16 of 1960, art. 2.

⁴ Agrochemical Control Act, Act No. 82 of 1948.

⁵ Act on Securing Quality, Effectiveness and Safety of Pharmaceuticals and Medical Devices, Act No. 145 of 1960.

⁶ Patent Act arts. 67-2 & 67-2-2; Patent Act Enforcement Order art. 3.

South Korea

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I. Extension of Patent Term due to Delay in Regulatory Approval

The Korean Patent Act states that the term of a patent right commences upon registration of the patent right and lasts for twenty years from the filing date of the patent application.¹ The term of the relevant patent right may be extended up to five years when the acquisition of a permit or registration of the patented item, as required under other statutes and designated by Presidential Decree, takes a long time because of safety tests, etc.²

The relevant Presidential Decree, the Enforcement Decree of the Patent Act, allows term extensions for the following inventions:

1. Invention of a medicine for which a permit by item has been granted pursuant to . . . the Pharmaceutical Affairs Act³ to work a patented invention [limited to a medicine for which a permit by item has been granted first, among medicines manufactured with a new substance (referring to a substance whose chemical structure in the activated part having medicinal effects is new) as an effective ingredient];
2. Invention of an agricultural chemical or raw material registered pursuant to . . . the Agrochemicals Control Act⁴ to work a patented invention (limited to an agricultural chemical or raw material registered first, among agricultural chemicals and raw materials manufactured with a new substance as an effective ingredient).⁵

II. Adjustment of Patent Term due to Delayed Patent Registration

If a patent registration has taken longer than four years from the filing date, or three years from the examination request, due to a delay in the examination procedures of the Korean Patent Office, extra time may be added to the regular patent term upon request.⁶

¹ Patent Act, Act No. 950, Dec. 31, 1961, art. 88, *amended by* Act No. 6411, Feb. 3, 2001, English translation available on the Statutes of the Republic of Korea website, at http://elaw.klri.re.kr/eng_service/lawView.do?hseq=30412&lang=ENG, archived at <https://perma.cc/HS7L-SQNJ>.

² *Id.* art. 89(1), *amended by* Act No. 11117, Dec. 2, 2011.

³ Pharmaceutical Affairs Act, Act No. 300, Dec. 18, 1953, *as amended by* Act No. 12074, Aug. 13, 2013, arts. 31(2)–(3), 42(1), English translation available at http://elaw.klri.re.kr/kor_service/lawView.do?lang=ENG&hseq=29093&joseq=JO0031000, archived at <https://perma.cc/C647-QRGT>.

⁴ Agrochemicals Control Act, Act No. 445 of August 28, 1957, *as last amended by* Act No. 9658 of May 8, 2009, arts. 8(1), 16(1), 17(1), English translation available on the World Intellectual Property Organization's website, at http://www.wipo.int/edocs/lex_docs/laws/en/kr/kr098en.pdf, archived at <https://perma.cc/SQS3-SQVN>.

⁵ Enforcement Decree of the Patent Act, Presidential Decree No. 590, Mar. 27, 1962, *as amended by* Presidential Decree No. 24645, June 28, 2013, art. 7, available at http://elaw.klri.re.kr/eng_service/lawView.do?hseq=28853&lang=ENG, archived at <https://perma.cc/2P4X-5ASF>.

⁶ Patent Act, art. 92-2, *added by* Act No. 11117, Dec. 2, 2011.

United Kingdom

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SUMMARY The UK allows the extension of patent protection through a Supplemental Protection Certificate (SPC). This certificate only applies to certain pharmaceutical or plant protection products that require market authorization in the UK as the reason for the certificate is to compensate the patent holders for any delays caused by the requirement to obtain market authorization. The SPC enters into force upon the expiration of any patent and can last for up to five years.

I. Introduction

Patent protection is provided for in the United Kingdom Patents Act 1977 (as amended).¹ The UK implements European Union regulations providing for extending the protection that patents offer to pharmaceutical or plant protection products.² The extension takes the form of a Supplemental Protection Certificate (SPC).³ The purpose of the SPC is to compensate patent holders for delays caused as a result of the regulatory approval that must be obtained to sell the products in the UK.⁴ The SPC protects the specific pharmaceutical or plant protection product authorized, and any use of the active ingredient in an authorized pharmaceutical or plant protection product that was protected by a patent.⁵

II. Requirements for a Supplemental Protection Certificate

In order to be eligible to be granted an SPC, the individual must have both a valid UK patent that protects either the active ingredient, the process to obtain the active ingredient, or an application of the active ingredient, and a marketing authorization that allows the active ingredient to be placed on the UK market as a pharmaceutical or plant protection product. The SPC is granted to

¹ Patents Act 1977, c. 37, <http://www.legislation.gov.uk/ukpga/1977/37>, archived at <https://perma.cc/G7G4-PJVS>.

² Patents (Supplementary Protection Certificate for Medicinal Products) Regulations 1992, SI 1992/3091, <http://www.legislation.gov.uk/uksi/1992/3091/made>, archived at <https://perma.cc/Y3MP-JAZM>; Patents (Supplementary Protection Certificate for Plant Protection Products) Regulations 1996, SI 1996/3120, <http://www.legislation.gov.uk/uksi/1996/3120/made>, archived at <https://perma.cc/6BUM-NS82>; Patents (Compulsory Licensing and Supplementary Protection Certificates) Regulations 2007, SI 2007/3293, <http://www.legislation.gov.uk/uksi/2007/3293/made>, archived at <https://perma.cc/FS7B-FS7L>.

³ *Supplementary Protection Certificates: Guidance*, INTELLECTUAL PROPERTY OFFICE (May 16, 2014), <https://www.gov.uk/guidance/supplementary-protection-certificates>, archived at <https://perma.cc/LW74-ORTT>.

⁴ INTELLECTUAL PROPERTY OFFICE, MANUAL OF PATENT PRACTICE SP 0.01 (Feb. 19, 2016), <https://www.gov.uk/guidance/manual-of-patent-practice-mopp/supplementary-protection-certificates-for-medicinal-and-plant-protection-products>, archived at <https://perma.cc/XV4H-VV5Z>.

⁵ *Id.* SP 0.02.

the holder of the patent that protects the active ingredient, not the licensee or manufacturer of a pharmaceutical or plant protection product.⁶

The date of any marketing authorization, and any other marketing authorizations in effect in any other European Economic Area (EEA) Member States, affects the patent holder's ability to obtain an SPC. The marketing authorization must either be a national product license issued by the Medicines and Healthcare Products Regulatory Authority, the Veterinary Medicines Directorate, a valid UK plant protection product authorization, or an authorization issued through the European Agency for the Evaluation of Medicinal Products.⁷ The authorization must be the first one granted to place the active ingredient on the UK market. If an earlier authorization for the active ingredient of the product exists in another country of the EEA, the Intellectual Property Office must be notified of this as the date of the first valid authorization in the European Community will determine the length of the SPC.⁸

III. Duration

As noted above, the purpose of the SPC is to compensate the patent holder for the period of time between market authorization for the product and the start of the patent. To provide for this compensation, the SPC:

takes effect at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorization to place the product on the market in the Community.⁹

The maximum period that the SPC may be granted for is

a period of fifteen years from the date of the first authorization to place the product on the market in the Community; or

a period of five years from the date on which it takes effect,

whichever is the lesser.¹⁰

Thus, the maximum period a SPC may be granted for is five years. An SPC for a medicinal active ingredient may be extended for an additional six months if it has undergone the appropriate pediatric testing.

⁶ *Supplementary Protection Certificates: Guidance*, *supra* note 3.

⁷ MANUAL OF PATENT PRACTICE, *supra* note 4, SP 0.04 & SPM 2.01.

⁸ *Supplementary Protection Certificates: Guidance*, *supra* note 3.

⁹ MANUAL OF PATENT PRACTICE, *supra* note 4, SPM 13.00.

¹⁰ *Id.* SPM 13.04.

IV. Restrictions

As noted above, the SPC may only be granted to the holder of the patent that covers the active ingredients, and only those active ingredients if they are present in a medicinal or plant protection product. The protections of the SPC do not extend overseas and are only effective in the UK.¹¹

¹¹ Patents (Compulsory Licensing and Supplementary Protection Certificates) Regulations 2007, *supra* note 2.