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ВСЕМИРНАЯ ОРГАНИЗАЦИЯ ИНТЕЛЛЕКТУАЛЬНОЙ СОБСТВЕННОСТИ

C. SCIT 2539
06

July 6, 2001

Subject: Survey on the grant and publication of supplementary protection certificates for medicinal and phytopharmaceutical products or equivalent industrial property rights (SPCs) – SCIT Task No. 28

Madam,
Sir,

On the basis of information provided by industrial property offices and organizations, in response to Circular SCIT 2505 of March 31, 2000, the International Bureau has completed its updating of the above-mentioned Survey.

Prior to publishing the Survey on the WIPO Handbook on Industrial Property Information and Documentation CD-ROM, you are kindly invited to arrange for the accuracy of the information given in the attached Survey that relates to your Office/Organization to be checked by your specialists. Any comments you wish to make should preferably be sent by e-mail to our address: *scit.mail@wipo.int*, and should reach the International Bureau by September 20, 2001, at the latest.

Sincerely yours,

Klaus-Peter Wittig
Deputy Director
Standards and Documentation Service

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SURVEY OF THE GRANT AND PUBLICATION OF "SUPPLEMENTARY PROTECTION CERTIFICATES" FOR MEDICINAL AND PHYTOPHARMACEUTICAL PRODUCTS OR EQUIVALENT INDUSTRIAL PROPERTY RIGHTS (SPCs)

[adopted by the PCIPI Executive Coordination Committee at its fourteenth session on May 20, 1994, and further updated by the International Bureau]

INTRODUCTION

1. The Survey reflects information on the grant and publication of SPCs provided by industrial property offices and organizations in 52 countries.

2. A summary of the data contained in the Survey and specimens of announcements regarding applications for SPCs and their grant are given on pages 7.2.23 and 7.2.24 and in the Appendices to the Survey.

3. For a definition of an SPC, please refer to the "*Glossary of Terms Concerning Industrial Property Information and Documentation,*" published in Volume IV, Part 10 of the WIPO Handbook CD-ROM on Industrial Property Information and Documentation.

Question 1: **Does your Office grant "supplementary protection certificates" or equivalent industrial property rights (SPCs) that extend the validity of patents covering medicinal, pharmaceutical, agrochemical or cognate products and phytopharmaceutical products?**

(a) in the field of medicinal products

Yes: AT, AU, BE, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, IE, IT, JP, KR, LU, LV, MD, MX, NL, NO, SE, US (25)

No: BG, BY, CL, CN, EA, EP, HU, JO, KZ, LT, MA; MK, MX, MY, NZ, OM, OA, PA, PL, PT, QA, RU, SI, SK, TM, TR, UA (27)

Remarks:

UA: Although there is no SPC protection as such, an amendment to the Law of Ukraine on the Protection of Inventions and Utility Models provides for the extension of the term of patent protection for medicinal, animal or plant protection (phytopharmaceutical) products, the use of which is subject to an authorization issued by the competent authority. At the request of the patentee, the term of protection may be extended for the period that has elapsed from the filing of the application until the date of the authorization, up to a maximum of five years (Art. 6. of the amended Law referred to).

SI: The current legislation provides for an extension of not more than five years immediately on expiry of patents for which protection was sought on or after January 1, 1993.

(b) in the field of phytopharmaceutical products

Yes: AT, AU, BE, BG, CH, CZ, DE, DK, EE, ES, FI, FR, GB, IE, IT, JP, KR, LU, LV, MD, MX, NL, NO, SE, US (25)

No: AP, BG, BY, CN, CY, EA, EP, FI, HU, JO, KZ, LT, MA, MK, MX, MY, NO, NZ, OM, OA, PA, PL, PT, QA, RU, SI, SK, TM, TR, (UA) (30)

Remarks:

MD: Legislation not yet in force (see below, answer to Question 3).

UA: See explanation given in connection with question 1(a).

SI: See explanation given in connection with question 1(a).

Question 2: **Will your Office start granting SPCs in the future?**

(a) in the field of medicinal products

Yes: BG, KZ, LT, SI (4)

No: AP, BY, CA, CN, EP, MK, MX, MY, NZ, OM, PA, PL, SK, QA, (14)

(b) in the field of phytopharmaceutical products

Yes: BG, CY, KZ, LT, NZ, SI, SK, (7)

No: AP, CL, CN, MK, MX, MY, OM, PA, PL, QA, (9)

Remarks:

EP: With regard to the EPO, it should be noted that the grant and publication of SPCs for medicinal and for phytopharmaceutical products would be a matter for Contracting States under the European Patent Convention.

SI: New draft legislation is under consideration by the Slovenian Parliament.

Question 3: **Please specify the legal basis for granting SPCs (national law, regional regulation, etc.).**

(a) in the field of medicinal products

AT: Council Regulation (EEC) No. 1768/92 of June 18, 1992, and national legislation: Federal Law on Supplementary Protection Certificates 1996, N°11/1997.

AU: Australian Patents Act of 1990 (Sections 70 to 79 and Schedule 1); Australian Patents Regulations of 1991 (Regulation 6.7-6-11).

BE: Royal Decree of January 5, 1993, concerning applications and grants of supplementary protection certificates for medicinal products (in French: "Arrêté royal du 05 janvier 1993, relatif à la demande et à la délivrance des certificats complémentaires de protection pour les médicaments) and Council Regulation (EEC) No. 1768/92 of June 18, 1992, (concerning the creation of a supplementary protection certificate for medicinal products).

CH: Federal Law on Patents for Invention of June 25, 1954 (amended on February 3, 1995). Ordinance on Patents for Invention of October 19, 1977 (amended on May 17, 1995). The amendments concerning SPCs entered into force on September 1, 1995. SPCs are granted for Switzerland and for the Principality of Liechtenstein.

CY: Patent Law 16(I)/98 as amended by Law 21(I)/99 and Patent Regulations and P.I. N° 46/99.

CZ: Collection of Laws N° 527/1990, Law on Inventions, Industrial Designs and Rationalization Proposals as amended by the Law amending some laws on the protection of industrial property, N°116/2000.

DE: Council Regulation (EEC) No. 1768/92 of June 18, 1992, and Amendment to the German Patent Law of March 23, 1993.

DK: Council Regulation (EEC) No. 1768/92 of June 18, 1992, concerning the creation of a supplementary protection certificate for medicinal products, and the following national legislation: Consolidated Patents Act No. 587 of July 2, 1993, and Order on Patents and Supplementary Protection Certificates No. 1193 of December 23, 1992.

ES: Regulation (EEC) N° 1768/92 of June 18, 1992.

EE: Patent Act of 1994 as amended in 1999 (the amendments came into force on January 1, 2000) and the Regulations under the Patent Act of 1994.

FI: Patents Act, Chapter 9a; Patents Decree, Section 52d-52p and the European Parliament and Council Regulation (EEC) No. 1768/92 of June 18, 1992.

FR: Council Regulation (EEC) No. 1768/92 of June 18, 1992.

GB: Regional Regulation EEC No. 1768/92.

IE: Council Regulation (EEC) No. 1768/92 of June 18, 1992, and European Communities (Supplementary Protection Certificate) Regulations, 1993 (S.I. No. 125 1993).

IT: National and Community laws (Reg. EEC n° 1768/92).

JP: Patent Law, Sections 67/2, 67bis, 67ter.

KR: Patent Law (Sections 53 and 89 to 93).

KZ: The Patent Law of 1999, Astana, Art. 5.

LU: Council Regulation (EEC) No. 1768/92 of June 18, 1992; Ministerial Circular of December 31, 1992, concerning application of Regulation (EEC) No. 1768/92.
LV: Patent Law of 1995, Articles 7(9) and 31(5).
MD: Law N°461-XIII, of May 18,1995, Art.20.1, on Patents for Invention of Supplementary Protection for pharmaceutical products, and Regulations under that law[1].
MX: Law for the Development and Protection of Industrial Property (Article 23).
NL: Regulation (EEC) No. 1768/92 of June 18, 1992 and the Netherlands Patents Act of 1995 and its Regulations.
NO: Act N° 9 of December 15, 1967, as amended by Act N° 40 of June 24, 1994, and N° 98 of December 19, 1997 (Chapter 9a, Sections 62a and 62b).
PT: Council Regulation (EEC) No. 1768/92 of June 18, 1992.
SE: Council Regulation (EEC) No. 1768/92 of June 18, 1992.
US: United Sates Code (USC), Title 35 Patents, Sections 155, 155A and 156 on Extension of Patent Term: 35 USC °155-156 (2000) and Code of Federal Regulations (CFR) Rules of Practice in Patent cases, Extension of Patent Term: 37 CFR , §1710-1785 /2000).

(b) in the field of phytopharmaceutical products

AT: Council Regulation (EEC) No. 1610/96 of July 23,1996, and Federal Law on Supplementary Protection Certificates 1996, N°11/1997..
AU: Australian Patents Act of 1990 (Sections 70 to 79 and Schedule 1); Australian Patents Regulations of 1991 (Regulation 6.7-6-11).
BE: Royal Decree of November 08, 1998, concerning applications and grants of supplementary protection certificates for plant protection products (in French: "Arrêté royal du 8 novembre 1998, relatif à la demande et à la délivrance des certificats complémentaires de protection pour les produits phytopharmaceutiques) and Council Regulation (EEC) No. 1610/96 of July 23, 1996, concerning the creation of a supplementary protection certificate for plant protection products.
CZ: Collection of Laws N° 527/1990, Law on Inventions, Industrial Designs and Rationalization Proposals as amended by the Law amending some laws on the protection of industrial property, N°116/2000 (an unofficial translation can be found on the Czech Office website: http://www.upc.cz/english/index.html).
DE: Council Regulation (EEC) N°1610/96 of the European Parliament and Amendment to the German Patent Law of March 23, 1993 (insertion of Sections 16a and 49a).
DK: Council Regulation No. 1610/96 of July 23, 1996, concerning the creation of a supplementary protection certificate for plant protection products.
EE: Patent Act of 1994, as amended in 1999 (the amendments came into force on January 1, 2000) and the Regulations under the Patent Act of 1994.
ES: Regulation (EEC) No.1610/96 of the European Parliament and the Council of July 23, 1996 .
FI: Patents Act, Chapter 9a, Patents Decree, Section 52d-52p and the European Parliament and Council Regulation (EEC) No. 1610/96.
FR: Regulation (EEC) No.1610/96 of the European Parliament and the Council of July 23, 1996, for the creation of a supplementary protection certificate for plant protection products.
GB: Regional Regulation (EEC) No. 1610/96.
IE: Council Regulation (EEC) No. 1610/96 of the European Parliament and of the Council of July 23, 1996.
IT: National and Community laws (Reg. EEC n°1610/96).
JP: Patent Law, Sections 67/2, 67bis, 67ter.
KZ: Patent Law of 1999, Astana, Art. 5.
LV: Patent Law of 1995, articles 7(9) and 31(5).
NL: Council Regulation (EEC) No. 1610/96 and the Netherlands Patents Act of 1995 and its Regulations (Ordinance 1997/42).
NO: Act N° 9 of December 15, 1967, as amended by Act N° 40 of June 24, 1994, and N° 98 of December 19, 1997 (Chapter 9a, Section 62a) and 62b).
PT: Council Regulation (EEC), N° 1610/96 of July 23, 1996.
SE: Council Regulation (EEC), N° 1610/96 of July 23, 1996.

1 *This law enters into force when published in the Official Gazette (not yet done at the time of establishing this updated Survey).*

US: The United Sates Code (USC), Title 35 Patents, Sections 155, 155A and 156 on Extension of Patent Term: 35 USC °155-156 (2000) and Code of Federal Regulations (CFR) Rules of Practice in Patent cases, Extension of Patent Term: 37 CFR §1710-1785 /2000).

Remarks:
JP: Phytopharmaceutical products are protected and treated in the same way as medicinal products.

Question 4: Please give the name of the SPC granted by your Office.

(a) in the field of medicinal products

AT: Supplementary Protection Certificate (in German:"Ergänzendes Schutzzertifikat").
AU: No special name given, merely a patent with an extended term of protection (four additional years extension).
BE: Supplementary Protection Certificate for Medicinal Products (in French: "Certificat complémentaire de protection pour les médicaments").
CH: Supplementary Protection Certificate for Medicinal Products (in French: "Certificat complémentaire de protection pour les médicaments"; in German: "Ergänzendes Schutzzertifikat für Arzneimittel"; in Italian: "Certificato protettivo complementare per medicinali").
CY: Supplementary Protection Certificate for medicinal products.
CZ: Supplementary Protection Certificate to Patent (in Czech, "Dodatkové ochranné osvedcenik patentu").
DE: Supplementary Protection Certificate (in German: "Ergänzendes Schutzzertifikat").
DK: Supplementary Protection Certificate for Medicinal Products (in Danish: "Supplerende beskyttelsescertifikat for laegemidler").
EE: Supplementary Protection Certificate (in Estonian:"Täiendava Kaiste Tuenmistus").
ES: Supplementary Protection Certificate for Medicinal Products (in Spanish: "Certificado Complementario de Protección para medicamentos").
FI: Supplementary Protection Certificate for Medicinal Products (in Finnish: "Lääkeaineiden lisäsuojatodistus").
FR: Supplementary Protection Certificate for Medicinal Products (in French: "Certificat complémentaire de protection pour les médicaments").
GB: Supplementary Protection Certificate.
IE: Supplementary Protection Certificate.
IT: Supplementary Protection Certificate.
JP: No special name given ("Registration of extension of term of patent right").
KR: Extension of Term of Patent Right.
LU: Supplementary Protection Certificate for Medicinal Products.
LV: No special name given.
MX: No special name given.
NL: Supplementary Protection Certificate, (in Dutch:"aanvullend beschermingscertifcaat voor geneesmiddelen").
NO: Supplementary Protection Certificate (in Norwegian: "Supplerende beskyttelsessertifikat").
PT: Supplementary Protection Certificate (in Portuguese: "Certificado complementar de protecao para os medicamentos).
SE: Supplementary Protection for Medicinal Products (in Swedish: "Tilläggsskydd för läkemedel").
US: Certificate Extending Patent Term Under 35 U.S.C. 156.

(b) in the field of phytopharmaceutical products

AT: Supplementary Protection Certificate ("Ergänzendes Schutzzertifikat").
AU: No special name given, merely a patent with an extended term of protection (four additional years extension).
CZ: Supplementary Protection Certificate to Patent (in Czech, "Dodatkové ochranné osvedcenik patentu").
BE: Supplementary Protection Certificate for Phytopharmaceutical Products (in French :"Certificat complémentaire de protection pour les produits phytopharmaceutiques").

DE: Supplementary Protection Certificate (in German: “Ergänzendes Schutzzertifikat”).
EE: Supplementary Protection Certificate (in Estonian:”Täiendava Kaiste Tuenmistus”).
ES: Supplementary Protection Certificate for Medicinal Products (in Spanish: ”Certificado Complementario de Protección para productos fitosanitarios”).
FI: Supplementary Protection Certificate for Plant Products (in Finnish: “Kasvinsuojeluaineiden lisäsuojatodistus“).
FR: Supplementary Protection Certificate for Phytopharmaceutical Products (in French: “Certificat complémentaire de protection pour les produits phytopharmaceutiques”).
GB: Supplementary Protection Certificate.
IE: Supplementary Protection Certificate.
IT: Supplementary Protection Certificate for Phytopharmaceutical Products.
JP: No special name given (“Registration of extension of term of patent right”).
LV: No special name given.
NO: Supplementary Protection Certificate (in Norwegian: ”Supplerende beskyttelsessertifikat”).
NL: Supplementary Protection Certificate, (in Dutch:”aanvullend beschermingscertifcaat voor gewasbeschermingsmiddelen”).
PT: Supplementary Protection Certificate (in Portuguese: “Certificado complementar de protecao para os produtos fitopharmaêuticos.
SE: Supplementary Protection for Plant Protection Products (in Swedish: “Tilläggsskydd för växtskyddsmedel”).
US: Certificate Extending Patent Term Under 35 U.S.C. 156.

Question 5: **Please specify for which fields of technology or which products an SPC can be obtained (for example, medicinal products, pharmaceutical products, phytopharmaceutical products, herbicides, agro-chemicals, all products subject to regulatory approval for marketing, etc.).**

(a) in the field of medicinal products

AT: Medicinal products and plant protection products.
AU: Pharmaceutical products including phytopharmaceuticals.
BE: Medicinal products.
CH: Active ingredients or combinations of active ingredients of a medicinal product.
CY: Medicinal products only.
CZ: All medicinal products with marketing approval.
DE: Medicinal products as defined by EEC Council Regulation N°1768/92, Art. 1(a).
DK: Medicinal products.
EE: Medicinal products.
ES: Medicinal products as defined by EEC Council Regulation N°1768/92.
FI: Medicinal products as defined by EEC Council Regulation N°1768/92.
FR: Any product protected by a patent which has been granted marketing approval (applicable to medicinal and phytopharmaceutical products).
GB: Products marketd on the marked as plant protection products subject to authorization in accordance with Directives 65/65/EEC or 81/851/EEC.
IE: As defined in Council Regulation (EEC) No. 1768/92 of June 18, 1992.
IT: Medicinal products.
JP: Phytopharmaceutical products are protected and treated in the same way as medicinal products.
KR: Pharmaceutical products, agrochemicals, herbicides and veterinary drugs.
KZ: All products for which marketing approval has been given.
LU: Medicinal products as defined in EEC Regulation No. 1768/92.
LV: Medicinal or veterinary products covered by the provisions of laws in force on pharmaceuticals requiring obligatory testing and registration of the product prior to its being marketd on the market in the Republic of Latvia.
MD: Medicinal products.
MX: Pharmaceutical products and processes.
NL: Medicinal products subject to regulatory approval for marketing.

NO: Medicinal products and phytopharmaceutical products, including herbicides.
PT: Medicines.
SE: Medicinal products.
US: Human drugs, antibiotic drugs or human biological products (as those terms are used in the US Federal Food Drug, and Cosmetic and the Public Health Services Act), new animal drugs or veterinary biological products(as those terms are used in the US Federal Food, Drug, and Cosmetic and the Virus-Serum-Toxin Act) which are 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, and any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act.

(b) in the field of phytopharmaceutical products

AT: Medicinal products and plant protection products.
AU: Pharmaceutical products including phytopharmaceuticals.
CZ: All medicinal phytopharmaceutical products with marketing approval.
BE: Phytopharmaceutical products.
DE: Medicinal products as defined by EEC Council Regulation No. 1610/96 of the European Parliament and the Council, Art.1 N°1,on phytopharmaceutical products.
DK: Plant products.
EE: Medicinal products.
ES: Phytopharmaceutical products as defined by EEC Council Regulation No. 1610/96 of the European Parliament and the Council.
FI: Plant products as defined in European Parliament and Council Regulation (EC) No.1610/96.
FR: Any product protected by a patent that has been granted marketing approval (applicable to medicinal and phytopharmaceutical products).
GB: Products marketd on the marked as plant protection products subject to authorization in accordance with Article 4 of Directive 91/414/EEC.
IE: As defined in Council Regulation (EEC) No. 1610/96 of the European Parliament and of the Council of July 23, 1996.
IT: Phytopharmaceutical products.
JP: Drugs made from plants.
KZ: All products for which marketing approval has been given.
LV: Medicinal or veterinary products covered by the provisions of laws in force on pharmaceuticals requiring obligatory testing and registration of the product prior to its being marketd on the market in the Republic of Latvia.
MD: Phytopharmaceutical products.
NL: Plant protection products subject to regulatory approval for marketing.
NO: Medicinal products and phytopharmaceutical products including herbicides.
PT: Phytopharmaceutical products.
SE: Phytopharmaceutical products.
US: Human drugs, antibiotic drugs or human biological products (as those terms are used in the US Federal Food Drug, and Cosmetic and the Public Health Services Act), new animal drugs or veterinary biological products (as those terms are used in the US Federal Food Drug, and Cosmetic and the Virus-Serum-Toxin Act) which are 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, and any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act.

Question 6: **Does your Office publish or intend to publish the receipt of an application for an SPC? (If "Yes," please attach specimen of a front page of an SPC and/or of announcements regarding SPCs made in an Official Gazette.)**

(a) in the field of medicinal products

Yes: AT, AU, BE, CH, CZ, DE, DK, EE, ES, FI, FR, GB, IE, IT, JP, KR, LU, LV, NL, NO, PT, SE, (22)
No: AP, CN, KZ, MY, OA, US, (6)

Remarks:
CY: Intends to publish the receipts of SPC applications when its system is fully operational.
BE: See Appendix 3.
GB: See Appendix 11.
IT: The Office does publish the receipts of SPC applications.
LU: A notice is published either of the filing and refusal of an SPC application or of the filing and grant of an SPC.
PT: The application and mention of the grant.
US: However, the Food and Drug Administration publishes a determination related to the filing of an application for patent term extension, including the approval date of the product and the new drug application (or other application) number. See the attached Federal Register Notice (Appendix 21).

(b) in the field of phytopharmaceutical products

Yes: AT, AU, CZ, BE, DE, DK, EE, ES, FR, FI, GB, IE, IT, JP, LV, NL, NO, SE (18)
No: AP,CN, KZ, MY, OA, US (5)

Remarks:
BE: See Appendix 3.
FI: For specimen announcement in the Patent Gazette, please see FIPO website: http://patinfo.prh.fi/julkaisut/patenttilehti/2000/pl-11-2000.pdf, Section D, unter "Tehtyjä lisäsuojatodistushakemuksia – Ingivna ansökningar om tilläggsskydd."
GB: See Appendix 11.
JP: Phytopharmaceutical products are protected and treated in the same way as medicinal products.
PT: The application and mention of the grant.
US: However, the Food and Drug Administration publishes a determination related to the filing of an application for patent term extension, including the approval date of the product and the new drug application (or other application) number. See the attached Federal Register Notice (Appendix 21).

Question 7: **If your reply to question 6 is "Yes," please state the minimum elements that a publication must contain**

(a) in the field of medicinal products

(i) Number assigned to receipt of the application
Yes: AT, AU, CH, CY, CZ, BE, DK, EE, ES, FI, FR, GB, IE, IT, JP, LU, LV, NL, NO, PT, SE (21)
No: DE (1)

Remarks:
AU: Application number is identical to patent number.

(ii) Date of receipt
Yes: AT, BE, CH, CZ, DK, EE, ES, FI, FR, GB, IE, IT, KR, LU, LV, NL, NO, PT, PT (19)
No: AU, DE, JP, SE (4)

Remarks:
CY: See comment under question 6(a).

(iii) Name and address of the applicant
Yes: AT, AU, BE, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, IE, IT, JP,KR, LU, LV, NL, NO, PT, SE (23)

Remarks:
AU: Name but not address of applicant is published.

(iv) Number of the basic patent
Yes: AT, AU, BE, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, IE, IT, JP, KR, LU, LV, NL, NO, PT, SE (23)

(v) Title of the invention
Yes: AT, BE, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, IE, IT, KR, LU, LV, NL, NO, PT, SE (20)
No: AU, JP, KR (3)

(vi) Number of any marketing authorization, including the product identified in the authorization
Yes: AT, BE, CH, CZ, DE, DK, EE, ES, FI, FR, IE, IT, JP, KR, LU, LV, NL, NO, PT, SE (20)
No: AU, CY (2)

Remarks:
AT: The Office publishes the date and number of the first authorization to market the product in Austria as a medicinal product and the date, country and number of the first such authorization in the EEA.
BE: The Office publishes data concerning the placing of the product on the market in Belgium.
CH: The Office publishes the number and date of the first authorization to market the product as a medicinal product in Switzerland and Liechtenstein.
DE: The Office publishes the date and number of the first authorization to market the product in Germany and, if different, the country, number and date of the first authorization to market the product in the EEC.
ES: The number of the first authorization to market the product in Spain and in the European Union.
FI: The Office plans to publish data regarding the first authorization to market the product in Finland.
FR: The Office publishes the number and date of the first authorization to market the product in France as a medicinal product and number and date of the first authorization to market the product in the EEC as a medicinal product.
GB: The number(s) and date(s) of the first authorization in the United Kingdom and the first authorization in the Community are quoted. The medicinal product is not identified.
IE: Irish market authorization, and where relevant the number and date of the first authorization to market the product in the Community.
IT: The Office publishes the number and date of the first authorization to market the product in Italy as a medicinal product and number and date of the first authorization to market the product in the EEC as a medicinal product.
JP: In addition to the authorization and to the product identified therein, the Japanese Office gives information on the law under which the authorization was obtained, on the product and on the extent of its use.
LU: The Office publishes the number and date of the first authorization to market the product in Luxembourg as a medicinal product and number and date of the first authorization to market the product in the EEC as a medicinal product.
NL: Number of the first relevant authorization in the Netherlands and, where different, the number of the first relevant authorization concerned in the EC.
NO: The Office intends to publish, where applicable, the number and date of the first authorization to market the product in the EEC.

(vii) Date of the authorization
Yes: AT, BE, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, IE, IT, KR, LU, PT, SE (18).
No: AU, JP, LV (3)

Remarks
AT: See explanation given under question 7(a)(vi).
FR: See explanation given under question 7(a)(vi).
GB: See explanation given under question 7(a)(vi).

IT: See explanation given under question 7(a)(vi).
LU: The Office mentions the product as identified in the authorization to market the product in Luxembourg.
NL: See explanation given under question 7(a)(vi).

(viii) Other elements (please specify)

AT: The publication contains also the following elements: the application number, the application date and date of grant of the basic patent, its IPC classification symbols, its language (if it is a European patent), the PCT application number (if applicable), the priority of the basic patent (if applicable) and the inventor' s name (if applicable).

BE: Number and date of the first authorization to market the product in the EEC as a medicinal product.

CH: The Office also publishes a designation of the product covered by the authorization to market together with the name and address of the representative where applicable.

CZ: Product name.

DE: In addition to the minimum elements provided for in the ECC Regulation, the German Patent and Trademark Office publishes also the IPC main class symbol of the basic patent and the application number of the SPC.

DK: Including the EEA authorization (number and date) and the number in the Community Register of Medicinal Products.

EE: Identification data for the product specified in the authorization.

ES: Name of the product that has received the authorization.

FI: Name and address of the representative.

FR: Filing date, application number and date of grant of the basic patent.

GB: The product name and product type (i.e. medicinal or plant protection).

IE: Where the authorization to market the product in Ireland is not the first authorization in the EEC, the number and date of that first authorization are also published.

IT: Name and address of the representative, filing date and date of grant.

JP: The Office publishes information regarding the extension of the term of protection of the patent.

KR: Claims relating to the product authorized. The product should also be identified in the claims.

LU: The Office names the product as identified in the authorization to market the product in Luxembourg.

NL: Name and address of the agent, if any, and name of the active ingredient as mentioned in the first relevant authorization in the Netherlands.

SE: Where relevant, the number and date of the first authorization to market the product in the EEC.

(b) in the field of phytopharmaceutical products

(i) Number assigned to receipt of the application

Yes: AT, BE, CZ, DE, DK, EE, ES, FI , FR, GB, IE, IT, JP, LV, NL, NO, PT (17)

Remarks:

AU: Application number is identical to patent number.

(ii) Date of receipt

Yes: AT, BE, CZ, DE, DK, EE, ES, FI, FR, GB, IE, IT, LV, NL, NO, PT (16)

No: AU, JP (2)

(iii) Name and address of the applicant

Yes: AT, AU, BE, CZ, DE, DK, EE, ES, FI, FR, GB, IE, IT, JP, LV, NL, NO, PT, SE (19)

Remarks:

AU: Name but not address of applicant is published.

(iv) Number of the basic patent

Yes: AT, AU, CZ, BE, DE, DK, EE, ES, FR, GB, IE, IT, JP, LV, NL, NO, PT, SE (18)

(v) Title of the invention

Yes: AT, CZ, BE, DE, DK, EE, ES, FI, FR, GB, IE, IT, LV, NL, NO, PT, SE (17)

No: AU, JP (2)

(vi) Number of any authorization to market the product, including the product identified in that authorization
Yes: AT, CZ, BE; DE, DK, EE, ES, FI, FR, IE, IT, JP, LV, NO, PT, SE (16)
No: AU (1)

Remarks:
AT: The Office publishes the date and number of the first authorization to market the product in Austria as a plant protection product and the date, country and number of the first such authorization in the EEA.
DE: The German Patent Office publishes the date and number of the first authorization to market the product in Germany and, if different, the country, number and date of the first authorization to market the product in the EEC.
ES: The number of the first authorization to market the product in Spain and in the European Union.
GB: The number(s) and date(s) of the first authorization in the United Kingdom and the first authorization in the Community are quoted. The medicinal product is not identified.
IE: Irish market authorization, and where relevant, the number and date of the first authorization to market the product in the Community.
JP: In addition to the authorization and to the product identified therein, the Japanese Office gives information on the law under which the authorization was obtained, on the product and on the extent of its use.
NL: Number of the first relevant authorization in the Netherlands and, where different, the number of the first relevant authorization in the EC.

(vii) Date of the authorization
Yes: AT, CZ, BE, DE, DK, EE, FI, FR, GB, IE, IT, NL, NO, PT, SE (15)
No: AU, JP, LV (3)

Remarks:
AT: See explanation given under question 7(b) (vi).
DE: See explanation given under question (vi) above.

(viii) Other elements (please specify)
AT: See information given under question 7 (a) (vi).
BE: Number and date of the first authorization to market the product in the EEC as a phytopharmaceutical product.
CZ: Product name.
DE: In addition to the minimum elements prescribed by the EEC Regulation (the German Patent Office publishes also the IPC main class symbol of the basic patent ant the application number of the SPC.
DK: Including the EEA authorization (number and date) and the number in the Community Register of Medicinal Products.
EE: Identification data for the product specified in the authorization.
ES: Name of the product that has received the authorization.
FI: Name and address of the representative.
FR: Filing date, application number and date of grant of the basic patent.
GB: The product and product type (i.e. medicinal or plant protection).
IT: Name and address of the representative, filing date and date of grant.
NL: Name and address of the agent, if any, and name of the active ingredient as mentioned in the first relevant authorization in the Netherlands.
SE: Where relevant, the number and date of the first authorization to market the product in the EEC.

Question 8: **Does your Office publish or intend to publish the fact that an SPC has been granted? (If "Yes," please attach specimen of a front page of an SPC and/or of announcement regarding the grant of SPCs made in an Official Gazette.)**

(a) in the field of medicinal products

Yes: AT, AU, BE, CH, CZ, DE, DK, EE, ES, FI, FR, GB, IE, IT, JP, KR, LU, LV, MX, NL, NO, PT, SE, US (24)

No: MY, OM (2)

Remarks:
BE: See Appendix 3.
GB: See Appendix 11.
LU: A notice is published either of the filing and rejection of an SPC application or of the filing and grant of the SPC.
US: See sample of the Official Gazette notice attached to this Survey as Appendix 21.

b) in the field of phytopharmaceutical products
Yes: AT, AU, BE, CZ, DE, DK, EE, ES, FI, FR, GB, IE, IT, JP, LV, NL, NO, PT, SE, US (20)
No: MY, OM (2)

Remarks:
BE: See Appendix 3.
DK: Granted SPCs are not published.
FI: For specimen announcement in the Patent Gazette , please see FIPO Website: http://patinfo.prh.fi/julkaisut/patenttilehti/2000/pl-7-2000.pdf, Section D, under "My!önnettyjä lisäsuojatodistuksia-Ibeviljade tilläggsskydd."
GB: See Appendix 11.
US: See Appendix 21.

Question 9: **If your reply to question 8 is "Yes," please state the minimum elements that a publication must contain**

(a) in the field of medicinal products
(i) Registration number assigned to the granted SPC
Yes: AT, AU, BE, CH, CZ, DK, EE, ES, FI, FR, GB, IE, IT, JP, LU, LV, NL, NO, PT, SE (19)
No: CY, DE, SE, US (4)

Remarks:
AU: Application number is identical to patent number.
BE: No special registration number is given; the number of the application for an SPC is used.
CH: The Office uses the basic patent number with an addition ("CNNNNNN").
IE: No special registration number is given; the number of the application for an SPC is used.
IT: No special registration Number is given; the number of the application for an SPC is used.
JP: No special registration number is given; the patent number of the basic patent is used.
US: No specific registration number is given; the publication number of the patent is used.

(ii) Date of the registration of the granted SPC
Yes: AT, BE, CH, CZ, EE, ES, FR, GB, IE, IT, JP, KL, LV, NO, PT, SE, US (17)
No: AU, CY, DE, DK, FI, FR, IE, LU, NL, SE (10)

Remarks:
AT: The Office publishes the actual date of grant.
FR: The Office specifies in its Official Gazette the expiry date of the SPC.
GB: The Office publishes the actual date of grant, which is specified on the certificate.
IT: The Office publishes the actual date of grant, which is specified on the certificate.
NL: The Office publishes in the Official Gazette the date on which the SPC enters into force.

(iii) Name and address of the holder of the SPC
Yes: AT, BE, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, IE, IT, JP, KR, LU, LV, MX, NL, NO, PT, SE, US (24)
No: AU (1)

Remarks:
AU: Name but not address of applicant is published.

US: But the United Patent and Trademark Office publishes the name only.

(iv) Number of the basic patent
Yes: AT, AU, BE, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, IE, IT, JP, LU, LV, MX, NL, NO, PT SE, US (24)

Remarks:
IT: Name and address of the representative, filing date and date of grant.

(v) Title of the invention
Yes: AT, BE, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, IE, IT, LU, LV, MX, NL, NO, PT, SE, US (22)
No: AU, JP, KR (3)

(vi) Number of any marketing authorization, including the product identified in that authorization
Yes: AT, BE, CY, CZ, DE, DK, EE, ES, FI, FR, GB, IE, IT, JP, KR, LV, NL, NO, SE (20)
No: AU, US (2)

Remarks:
AT: See explanations given under question 7(a)(vi).
CH: The Office publishes the number and date of the first authorization to market the product as a medicinal product in Switzerland and Liechtenstein.
DE: The German Patent Office publishes the date and number of the first authorization to market the product in Germany and, if different, the country, number and date of the first authorization to market the product in the EEC.
ES: The number of the first authorization to market the product in Spain and in the European Union.
FI: As in question 7(a)(vi).
FR: As in question 7(a)(vi).
GB: The number(s) and date(s) of the first authorization in the United Kingdom and the first authorization in the Community are quoted. The medicinal product is not identified.
IE: Irish market authorization, and where relevant, the number and date of the first authorization to market the product in the Community.
IT: As in question 7(a)(vi).
JP: No special registration number is given; the patent number of the basic patent is used.
LU: As in question 7(a)(vi).
NL: Number of the first authorization in the Netherlands and, where different, the number of the first relevant authorization in the EC.
SE: As in question 7(a)(vi).

(vii) Date of the authorization
Yes: AT, BE, CH, CY, CZ, DE, DK, EE, ES, FI, GB, IE, IT, KR, LU, LV, NL, NO, PT, SE (20)
No: AU, JP, US (3)

(viii) Duration of the SPC
Yes: AT, AU, BE, CH, CZ, DE, DK, EE, ES, FI, FR, GB, IE, IT, JP, KR, NL, NO, PT, US (20)
No: LV, SE (2)

Remarks:
AT: The duration is identified by the expiry date of the maximum period.
CH: The Office specifies the expiry date of the SPC.
ES: Expiry date of validity.
IE: The duration is identified by the expiry date of the maximum period.
LV: The duration is identified by the expiry date of the SPC.

(ix) Other elements, e.g. patent classification, product name (please specify)
AT: See explanations given under question 7(a) (viii).
CH: The Office also publishes a designation of the product covered by the authorization to

market, the filing date of the application and the name and address of the representative where applicable.

CZ: Product name.
DE: In addition to the minimum elements prescribed by the EEC Regulation the German Patent Office publishes also the IPC main class symbol of the basic patent ant the application number of the SPC.
EE: Identification data for the product specified in the authorization.
ES: Name of the product that has received the authorization.
FI: Number and date of the corresponding application, name and address of the representative.
FR: Filing date, application number and date of grant of the basic patent.
GB: Product name and product type (i.e. medicinal or plant protection).
IE: Where necessary, the fact that the application has been rejected is also published.
IT: Name and address of the representative, filing date and date of grant.
KR: Product name approved by authorization.
LV: Product name.
NL: Name and address of the agent, if any, and name of the product for which the SPC has been granted.
SE: Where relevant number and date of the first authorization to market the product in the EEC.
US: Patent grant date, applicant, owner of record, patent classification and product trade name.

(b) in the field of phytopharmaceutical products

(i) Registration number assigned to the granted SPC
Yes: AT, AU, BE, CZ, DK, EE, ES, FI, FR, GB, IE, IT, JP, LV, NL, NO, PT (17)
No: DE, SE, US (3)

Remarks:
AU: Application number is identical to patent number.
BE: Application number.
IE: No special registration number is given; the number of the application for and SPC is used.
JP: No special registration number is given; the number of the basic patent is used.
US: No specific registration number is given; the publication number of the patent is used.

(ii) Date of registration of the granted SPC
Yes: AT, BE, CZ, EE, ES, FR, GB, IE, IT, JP, LV, NO, PT, US (14)
No: AU, DE, DK, FI, NL, SE (6)

(iii) Name and address of the holder of the SPC
Yes: AT, BE, CZ, DE, DK, EE, ES, FI, FR, GB, IE, IT, JP, LV, NL, NO, PT, SE, US (19)
No: AU (1)

Remarks:
AU: Name but not address of applicant is published.
US: But the United States Patent and Trademark Office publishes the name only.

(iv) Number of the basic patent
Yes: AT, AU, BE, CZ, DE, DK, EE, ES, FI, FR, GB, IE, IT JP, LV, NL, NO, PT, SE, US (20)

Remarks:
IT: Name and address of the representative, filing date and date of grant.

(v) Title of the invention
Yes: AT, BE, CZ, DE, DK, EE, ES, FI, FR, GB, IE, IT, LV, NL, NO, PT, SE, US (18)
No: AU, JP (2)

(vi) Number of any market authorization, including the product identified in the authorization
Yes: AT, BE, CZ, DE, DK, EE, ES, FI, FR, GB, IE, IT, JP, LV, NL, NO, PT, SE (18)
No: AU, US (2)

Remarks
AT: See explanations given under question 7(b)(vi).
DE: The German Patent Office publishes the date and number of the first authorization to market the product in Germany and, if different, the country, number and date of the first authorization to market the product in the EEC.
ES: The number of the first authorization to market the product in Spain and in the European Union.
GB: The number(s) and date(s) of the first authorization in the United Kingdom and the first authorization in the Community are quoted. The medicinal product is not identified.
IE: Irish market authorization, and where relevant, the number and date of the first authorization to market the product in the Community.
JP: No special registration number is given; the number of the basic patent is used.
NL: The number of the first relevant authorization in the Netherlands and, where different, the number of the first relevant authorization in the EC.

(vii) Date of the authorization
Yes: AT, BE, CZ, DE, EE, ES, FI, FR, GB, IE, IT, LV, NL, NO, PT, SE (16)
No: AU, JP, US (3)

Remarks:
DE: See explanation given under question (vi) above.

(viii) Duration of the SPC
Yes: AT, AU, CZ, BE, DE, DK, EE, ES, FI, FR, GB, IE, IT, JP, NL, NO, PT, US (18)
No: LV, SE (2)

Remarks
AT: The duration is identified by the expiry date of the maximum period.
ES: Expiry date of validity.
GB: The product name and product type (i.e. medicinal or plant protection).
IE: The duration is identified by the expiry date of the maximum period.
LV: The duration is identified by the expiry date of the SPC.

(ix) Other elements, e.g. patent classification, product name (please specify)

AT: See information given under question 7(a)(viii).
CZ: Product name.
DE: In addition to the minimum elements prescribed by the EEC Regulation, the German Patent Office publishes also the IPC main class symbol of the basic patent and the application number of the SPC.
EE: Identification data for the product specified in the authorization.
ES: Name of the product that has received the authorization.
FI: Number and date of the corresponding application, name and address of the representative.
FR: Filing date, application number and date of grant of the basic patent.
GB: Product name and product type (i.e. medicinal or plant protection).
IE: Where necessary, the fact that the application has been rejected is also published.
IT: Name and address of the representative, filing date and date of grant.
LV: Product name.
NL: Name and address of the agent, if any, and name of the product for which the SPC has been granted.
SE: Where relevant, the number and ate of the first authorization to market the product in the EEC.
US: Patent grant date, applicant, owner of record, patent classification, product trade name.

Question 10: In what form does your Office make or intend to make the publications referred to in questions 6 and 8?

(a) In the field of medicinal products

(i) As regards applications for SPCs

(a) As part of an Official Gazette?
Yes: AT, AU, BE, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, IE, IT, JP, KR, LU, LV, NL, NO, PT SE (23)
No: US (1)

Remarks:
LU: Publication of a notice in the Official Gazette.

(b) By publishing the application?
No: AT, AU, BE, CH, CZ, DE, DK, EE, ES, FI, FR, GB, IE, IT, JP, KR, LU, LV, NL, NO, PT, SE, US (23)

Remarks:
CH: The Office also publishes a notice of SPC applications that have been refused.
JP: Announcement is made in the Official Gazette.

(c) By laying the application open to public inspection?
Yes: BE, CH, CZ, DK, EE, FI, FR, GB, IE, IT, LU, NL, NO, PT, US (15)
No: AT, DE, ES, JP, KR, LV, SE (7)

Remarks:
AU: The announcement in the Official Gazette states that the application is open to public inspection.
CH: Only after notice of the application has been published.
LU: The file may be consulted as from the date of grant (=publication date) of the SPC.
NL: The application filed and correspondence between the Netherlands Industrial Property Office and the applicant are laid open to public inspection.

(d) Through online databases (or the Office's website)?
Yes: AT, BE, CZ, DE, DK, ES, FI, FR, GB, IE, IT, NL (12)
No: CH, EE, JP, LV, NO, PT, SE, US (8)

Remarks:
AU The internal database of the Office (PATADMIN) shows that an application has been made.
CH: All data on SPCs are contained in the internal BAGIS database. Possible third-party access is being studied.
BE: Registry.
DE: Bibliographic data and legal status information are obtainable from the Patent Registry and the PATDPA database.
FI: The Patent Gazette is available on the FIPO website.
IE: Certain details are entered in the PTOLEMY database under the register entry for the corresponding basic patent—the Register entry is viewable on the public search system of the Office.

(e) By delivery of the copy application on request?
Yes: CH, CZ, DK, EE, FI, FR, GB, IE, IT, KR, LU, NL, PT (13)
No: AT, AU, BE, DE, ES, JP, LV, NO, SE, US (10)

Remarks:
CH: Reference is made to the comment under Question 10(a)(i)(c).
DE: Copies of SPC applications are available in the course of a file inspection.

(ii) As regards granted SPCs

(a) As part of an Official Gazette?
Yes: AT, AU, BE, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, IE, IT, JP, KR, LU, LV, NL, MX, NO, PT, SE, US (25)

Remarks:
LU: Publication of a notice in the Official Gazette.

(b) By publishing the SPC?
Yes: BE (1)
No: AT, AU, CH, CZ, DE, DK, EE, ES, FI, FR, GB, IE, IT, JP, KR, LU, LV, NL, NO, PT, SE, US (22)

Remarks:
JP: Announcement is made in the Official Gazette.

(c) By laying the SPC open to public inspection?
Yes: CH, CZ, DK, EE, FI, GB, IE, IT, LU, NL, NO, PT, US (13)
No: AT, AU, BE, DE, ES, FR, JP, KR, LV, SE (10)

Remarks:
LU: The file may be consulted as from the date of grant (= publication date) of the SPC.
NL: The application as filed, correspondence exchanged between the Netherlands Industrial Property Office and the applicant, and the granted SPC are laid open to public inspection.

(d) Through online databases (or the Office's website)?
Yes: AT, CZ, BE, DE, DK, ES, FI, FR, GB, IE, IT, LV, NL, US (14)
No: AU, CH, JP, NO, PT, SE (6)

Remarks:
AU: The internal database of the Office (PATADMIN) shows that an extension of the term of protection has been granted.
BE: Registry.
DE: Bibliographic data and legal status information are obtainable from the Patent Registry and the PATDPA database.
FI: The Patent Gazette is available on the FIPO website.
IE: Certain details are entered in the PTOLEMY database under the Register entry for the corresponding basic patent—the Register entry is viewable on the public search system of the Office.
US: Patent number, approved product, extension period, and Official Gazette notice date, and full patent text for patents issued January, 1, 1976, to most recent, are available online.

(e) By delivery of a copy of the SPC on request?
Yes: AT, CH, CZ, DK, EE, FI, FR, GB, IE, IT, LU, NL, PT, US (14)
No: AU, BE, DE, ES, JP, LV, NO, SE (8)

Remarks:
AT: Copy delivery is possible for certain parts of the file that are available to the public.
DE: Copies of SPC files are available in the course of a file inspection.

(b) In the field of phytopharmaceutical products

(i) As regards applications for SPCs

(a) As part of an Official Gazette?
Yes: AT, AU, BE, CZ, DE, DK, EE, ES, FI, FR, GB, IE, IT, JP, LV, NL, NO, PT, SE (19)
No: US (1)

(b) By publishing the application?
Yes: JP (1)
No: AT, AU, CZ, DE, DK, EE, ES, FI, FR, GB, IE, IT, LV, NL, NO, PT, SE, US (18)

Remarks:
JP: Announcement is made in the Official Gazette.

(c) By laying the application open to public inspection?
Yes: CZ, DK, EE, FI, FR, GB, IE, IT, NL, NO, PT, US (12)
No: AT, AU, BE, DE, ES, JP, LV, SE (8)

Remarks:
AU: The announcement in the Official Gazette states that the application is open to public inspection.
NL: The application as filed, correspondence exchanged between the Netherlands Industrial Property Office and the applicant, and the granted SPC are laid open to public inspection.

(d) Through online databases (or the Office's website)?
Yes: AT, BE, CZ, DE, DK, ES, FI, FR, GB, IE, IT, NL (12)
No: AU, EE, JP, LV, NO, PT, SE, US (8)

Remarks:
AU; The internal database of the Office (PATADMIN) shows that an extension of the term of protection has been granted.
DE: Bibliographic data and legal status information are obtainable from the Patent Registry and the PATDPA database.
FI: The Patent Gazette is available on the FIPOI website.
IE: Certain details are entered in the PTOLEMY database under the Register entry for the corresponding basic patent—The Register entry is viewable on the public search system of the Office.

(e) By delivery a copy of the application on request?
Yes: CZ, DK, EE, FI, FR, GB, IE, IT, NL, PT (10)
No: AT, AU, BE, DE, ES, JP, LV, NO, SE, US (10)

Remarks:
DE: Copies of SPC applications are available in the course of a file inspection.

(ii) As regards granted SPCs

(a) As part of an Official Gazette?
Yes: AT, AU, BE, CZ, DE, DK, EE, ES, FR, GB, IE, IT, JP, LV, NL, NO, PT, SE, US (20)
No: CZ (1)

(b) By publishing the SPC?
Yes: BE, JP (2)
No: AT, AU, CZ, DE, DK, EE, ES, FI, FR, GB, IE, IT, LV, NL, NO, PT, SE, US (18)

Remarks:
JP: Announcement is made in the Official Gazette.

(c) By laying the SPC open to public inspection?
Yes: CZ, DK, EE, FI, FR, GB, IE, IT, JP, NL, NO, PT, US (13)
No: AT, AU, BE, DE, ES, LV, SE (7)

Remarks:
NL: The application as filed, the correspondence between the Netherlands Industrial Property Office and the applicant, and the granted SPC are laid open to public inspection.

(d) Through online databases (or the Office's website)?
Yes: AT, BE, CZ, DE, DK, ES, FI, FR, GB, IT, NL, US (12)
No: AU, EE, JP, LV, NO, PT, SE (7)

Remarks:
AU: The internal database of the Office (PATADMIN) shows that an extension of the term of protection has been granted.
BE: Registry.
DE: Bibliographic data and legal status information are obtainable from the Patent Registry and the PATDPA database.
FI: The Patent Gazette is available on the FIPO website.
IE: Certain details are entered in the PTOLEMY database under the Register entry for the corresponding basic patent—the Register entry is viewable on the public search system of the Office.

US: Patent number, approved product, extension period, and Official Gazette notice date, and full patent text for patents issued January, 1, 1976, to most recent, are available online.

(e) By delivery of a copy of the SPC on request?
Yes: AT, CZ, DK, EE, FI, FR, GB, IE, IT, NL, PT, US (12)
No: AU, BE, DE, ES, JP, LV, NO, SE (8)

Remarks:
DE: Copies of SPC files are available in the course of a file inspection.

Question 11: If your Office enters or intends to enter data from the documents relating to SPCs in online databases (internal or commercial), please give the name(s) of the database(s) and specify the bibliographic data elements:

(a) In the field of medicinal products

(i) Name(s) of database(s)
AT: The Office's SPC Register ("Schutzzertifikatsregister") contains all data elements specified under question 9.
AU: PATADMIN (internal database).
CH: BAGIS (internal database only). See also comment under question 11.1(d).
CY: Not yet available.
DE: (i) Patent Register, (ii) PATDPA (via STN International).
DK: INPADOC.
ES: SIDATEX.
FR: (i) FPAT, (ii) EPAT.
GB: RSPC, this is the internal database for SPCs which has been made available on the Patent Office website: http://webdb2.patents.gov.uk/rspc/.
IE: (I) PTOLEMY (internal database), (ii) PTOLEMY Public Search System.
IT: The Office has only an internal line, with the bibliographic data elements mentioned in paragraph (ii) below.
JP: Data are included in an internal database (no name given).
NL: Computerized Register (in Dutch:"Het Octrooiregister") to be found on the website of the Dutch Industrial Property Office.
US: (i) Patent Term Extension, (ii) USPTO Web Patent Database.

(ii) Bibliographic data elements
AT: The Office's SPC Register ("Schutzzertifatsregister") contains all data elements specified under question 9.
AU: Application number, serial number, extension status, date of lodgment of extension application, market authorization date, extended expiry date, date of acceptance of extension, date of grant of extension, date of refusal of extension, date of withdrawal of extension, dates of advertisement of lodgment, acceptance, grant, withdrawal and refusal of the application for extension, date of filing of opposition, service address.
DE: Application number of SPC, application, number of basic patent, title of invention, name and address of SPC holder, number/date of authorization and name of product, IPC main class symbol, duration of the SPC.
ES: See information given under questions 7 and 9.
FR: Same data as those published in the Official Gazette.
GB: See Appendix 11, pages 1 and 2, photocopied from the Patents and Designs Journal.
IE:
- Application number- identical to the grant publication number,
- Whether application is for medicinal or plant protection patent,
- Date of application,

- Date of publication of application,
- Name and address of applicant,
- Basic patent,
- Date of expiry of patent,
- Title of patent,
- Irish market authorization number, date of grant, identity of product authorized, legal provision of authorization,
- Community market authorization, country, date of grant, identity of product authorized, legal provision of the authorization,
- Product identity,
- Address for service,
- Application status,
- Date of grant,
- Date of publication of grant,
- Renewal fees.

IT:

- Application number-identical to the grant publication number:
- Filing date,
- Owner,
- Representative,
- Date of grant,
- Product (name),
- References of the basic patent:
  - Title,
  - Application date,
  - Grant date,
  - Publication number,
  - Italian AMM (marketing authorization): number, date of grant,
  - Community AMM: country, number, date of grant,
  - Status (active, idle, withdrawn),
  - Dates
    - of entry into force,
    - of protection period.

JP: Date of application, number of application, date of registration, term of extension, further data as specified replies to questions 7 and 9 above.

NL: Same elements as specified in replies to questions 7 and 9 respectively. In addition,
the date on which the SPC was granted or on which the application was rejected or withdrawn is mentioned.

US: See elements specified in reply to question 10 above.

(b) In the field of phytopharmaceutical products

(i) Name(s) of database(s)

AT: The Office's SPC Register ("Schutzzertifikat") contains all data elements specified under question 9.

AU: PATADMIN (internal database).

DE: (i) Patent Register, (ii) PATDPA (via STN International).

DK: INPADOC.

ES: SIDATEX.

FR: (i) FPAT, (ii) EPAT.

GB: RSPC, this is the internal database for SPCs which has been made available on the Patent Office website: http://webdb2.patents.gov.uk/rspc/.

IE: PTOLEMY (internal database) and PTOLEMY Public Search System.

IT: See answer to Question 11(a)(i).

JP: Data are included in an internal database (no name given).

NL: Computerized Register (in Dutch:"Het Octrooiregister") to be found on the website of the Dutch Industrial Property Office.

US: (i) Patent Term Extension, (ii) USPTO Web Patent Database.

(ii) Bibliographic data elements

AT: The Office's SPC Register ("Schutzzertikatsregister") contains all data elements specified under question 9.

AU: Application number, serial number, extension status, date of lodgment of extension application, market authorization date, extended expiry date, date of acceptance of extension, date of grant of extension, date of refusal of extension, date of withdrawal of extension, dates of advertisement of lodgment, acceptance, grant, withdrawal and refusal of the application for extension, date of filing of opposition, service address.

DE: Application number of SPC, application, number of basic patent, title of the invention, name and address of SPC holder, number/date of authorization and name of product, IPC main class symbol, duration of the SPC.

ES: See information given under questions 7 and 9.

FR: Same data as those published in the Official Gazette.

GB: See Appendix 11, pages 1 and 2, (photocopied from the Patents and Designs Journal.

IE: See answer to Question 11(a)(ii).

IT: See answer to Question 11(a)(ii).

JP: Date of application, number of application, date of registration, term of extension, further data as specified in the replies to questions 7 and 9 above.

NL: Same elements as specified in replies to questions 7 and 9 respectively. In addition, the date on which the SPC was granted or on which the application was rejected or withdrawn is mentioned.

US: See elements specified in reply to question 10 above.

<u>Question 12:</u> If your Office assigns or intends to assign specific application and/or registration numbers to SPCs, please give details.

(a) As regards medicinal products

(i) Concerning the numbering system for applications for SPCs

AT: The application number and the registration number are prefixed with "SZ" followed by a serial number, which restart at 1 every year, and the four-digit number of the year (SZ NNNN/YYYY).

AU: No specific numbering system is applied (see replies to questions 7 and 9).

CZ: An annual numbering system for SPC applications is applied. Example: SPC/CZ/YYYY/1.

BE: Before 2000: 09Y C XXXX, since 2000: 2XXX C/xxx.

CH: The Office uses the basic patent number with an addition ("CNNNNNN").

DE: A certain range of numbers within the series of patent application numbers is used for SPC applications.

DK: CA YYYY XXXXXX.

EE: C YYYY NNNN (where C denotes the SPC; YYYY the year and NNN the number of the SPC application of the year).

ES: CYYYYNNNNN.

FI: Annual number series in format: L CCYY NNNN, e.g. L 2000 0001.

FR: AACXXXX (where AA is the year of filing of the application, C is for an SPC (type of title) and XXXX the registration number). Example: 97C0019 means the 19th SPC filed in1997; no distinction is made between a medicinal and a phytopharmaceutical product).

GB: SPCs are identified SPC/GB/, followed by the two-digit year and the case number. The case numbers are ordered chronologically by the application date, beginning with 001 for the first application of the calendar year, e.g. SPC/GB/99/001 was the first application received in 1999.

IE: The Office uses the format SPC YYYYNNN, where YYYY represents the year in which the application is filed and NNN is the application number, commencing with 001 for the first application filed in a given year.

IT: The Office uses the following format for SPC application numbers: UBYYCCPN. The first two digits are the abbreviation of "Ufficio Brevetti," the next two (YY) denote the filing

year of the SPC application, the letters CCP the type of industrial property title, and N the serial number of the SPC application in ascending order, starting with 1.

JP: The Office uses an annual numbering series for SPC applications consisting of a numeral to identify the year of filing (by year of the reign of the Emperor) followed by a six digit number starting with 700 001.

LU: Upwards series; as SPCs are entered in the Patent Register, the numbering system for patents is used.

NL:

- From 1943 to 1999, the number system was YY0NNN, where YY are the last two digits of the year of filing, 0 is the numeral zero and NNN is a serial number from 001 onwards.
- Since 2000, a serial numbering system beginning with 300 001.

NO: SPC/NO YYYY NNN, where YYYY is the year and NNN is a three digit number (e.g. SPC/NO 2000 001).

SE: A special number is given to an SPC consisting of seven digits and a check digit. First the two last digits of the year, the digit 9 indicating the SPC and then four digits for the number in chronological order. For example, 0090004-3 is the fourth SPC application in the year 2000, with 3 is the check digit.

US: Publication number of patent is used.

(ii) Concerning the numbering system for registrations or grants of SPCs (if different from (a)(i))

CH: The Office uses the basic patent number with an addition ("CNNNNNN").

CY: It is planned as follows: CY/year/001.

BE: The application number is used.

DE: The number of the granted SPC is identical to the number of the application for an SPC.

DK: CR YYYY XXXXXX.

FI: Serial number in grant order.

GB: There is no change to the application number to signify that the application has been granted.

IE: The granted SPC retains the application number given.

IT: The number of the granted SPC is identical to the number of the application for an SPC.

JP: No specific number is given. The granted SPC takes to the patent number.

(b) As regards phytopharmaceutical products

(i) Concerning the numbering system for applications for SPCs

AT: The application number and the registration number are prefixed with "SZ" followed by a serial number, which restart at 1 every year and the four digit number of the year (SZ NNNN/YYYY).

AU: No specific numbering system is applied (see replies to Questions 7 and 9).

CZ: An annual numbering system for SPC applications is applied. Example: SPC/CZ/YYYY/1.

BE: Before 2000: 09Y C XXXX, since 2000: 2XXX C/xxx.

DE: The same numbering system as for SPCs for medicinal products is used.

DK: CA YYYY XXXXXX.

EE: C YYYY NNNN (where C denotes the SPC, YYYY the year and NNN the number of the SPC application of the year).

ES: CYYYYNNNNN.

FI: Annual number series in format K CCYY NNNN, e.g. K 1998 0004.

FR: AACXXXX (where AA is the year of filing of the application, C is for an SPC (type of title) and XXXX the registration number). Example: 97C0019 means the 19th SPC filed 1997; no distinction is made between a medicinal and a phytopharmaceutical product).

GB: There is no change to the application number to signify that the application has been granted.

IE: The Office uses the format SPC YYYYNNN, where YYYY represents the year in which the application is filed and NNN is the application number, commencing with 001 for the first application filed in a given year.

IT: See answer given to question 12(a)(i).

JP: The Office uses an annual numbering series for SPC applications consisting of a numeral to identify the year of filing (by year of the reign of the Emperor) followed by a six-digit number starting with 700 001.

NL:

- From 1943 to 1999, the number system was YY1NNN, where YY are the last two digits of the year of filing, 1 is the numeral one and NNN is a serial number from 001 onwards.
- Since 2000, a serial numbering system beginning with 350 001.

NO: SPC/NO YYYY NNN, where YYYY id the year and NNN is a three-digit number (e.g. SPC/NO 2000 001).

SE: A special number is given to an SPC consisting of seven digits and a check digit. First the two last digits of the year, the digit 9 indicating the SPC and then four digits for the number in chronological order. For example, 0090004-3 is the fourth SPC grant in the year 2000, with 3 is the check digit.

US: Publication number of patent is used.

(ii) Concerning the numbering system for registrations or grants of SPCs (if different from (b)(i))

AU: No specific numbering system is applied (see replies to questions 7 and 9).

BE: The application number is used.

DE: The number of the granted SPC is identical to the number of the application for a SPC.

DK: CR YYYY XXXXXX.

FI: Serial number in grant order.

GB: Phytopharmaceuticals and medicinal products are not differentiated in the numbering scheme.

IE: The granted SPC retains the application number given.

IT: See answer given to Question 12(a)(ii).

Remarks:

EE: The numbering of SPC grants will be different from that of SPC applications (no SPC has been granted so far).

IE See Appendix 12.

JP: No specific number is given. The granted SPC takes the patent number.

Summary

1. With regard to the grant of SPCs, in the field of medicinal products as well as phytopharmaceutical products, the replies show that:
   - 25 Offices (AT, AU, BE, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, IE, IT, JP, KR, LU, LV, MD, MX, NL, NO, SE, US) grant SPCs in the field of medicinal products and in the field of phytopharmaceutical products, whereas two Offices (UA, SI) provide, in a particular manner, a protection derived from some general national legislation;
   - 26 offices (BG, BY, CN, CY, EA, EP, HU, JO, KZ, LT, MA, MK, MX, MY, NZ, OM, OA, PA, PL, PT, QA, RU, SI, SK, TM, TR) do not yet grant SPCs, although four of them (BG, KZ, LT, SI) intend to grant SPCs in the field of medicinal products and seven (BG, CY, KZ, LT, NZ, SI, SK) intend to do the same in the field of phytopharmaceutical products;
   - 11 Offices (CN, EP, MK, MX, MY, NZ, OM, PA, PL, SK, QA) do not intend, at least in the near future, to grant SPCs in the field of medicinal products and eight of those (CN, MK, MX, MY, OM, PA, PL, QA), in the field of phytopharmaceutical products.

2. As to the publication of applications for SPCs,
   - 24 Offices (AT, AU, BE, CH, CY, CZ, DE, DK, EE, ES, FR, FI, GB, IE, IT, JP, KR, LU, LV, MX, NL, NO, PT, SE) in the field of medicinal products and 18 Offices (AT, AU, BE, CZ, DE, DK, EE, ES, FR, FI, GB, IE, IT, JP, LV, NL, NO, SE) in the field of phytopharmaceutical products publish or intend to publish in their Official Gazettes, whereas
   - Five Offices (CN, KZ, MY, OA, US) do not intend to do so either for the medicinal or for phytopharmaceutical products.

3. As regards the grant of SPCs,
   - 22 Offices (AT, AU,BE, CH, CZ, DE, DK, EE, ES, FI, FR, GB, IE, IT, JP,KR, LU, LV, NL, NO, PT, SE) publish or intend to publish grants in their Official Gazettes.

4. Several Offices enter bibliographic data of the documents relating to SPCs in internal or commercial databases (see replies to Question 11).

5. 19 Offices (AT, BE, CH, DE, DK, EE, ES, FI, FR, GB, IE, IT, JP, LU, LV, NL, NO, PT, SE) gave information on the numbering system that they used for SPC applications or grants in the field of medicinal products and phytopharmaceutical products. The following formats (or examples) were given by the Offices:

   (i) for applications for SPCs

   - SZ NNNN/YY (used by AT for applications and grants)

   - YYCNNNN (used by BE for applications and grants)[2]

   -CNNNNNN (used by CH for applications and grants)

   -SPC/CZ/YYYY/1 (used by CZ)

   - CA CCYY XXXXXX (used by DK)

   -CYYYYNNNN (used by EE)

   - YYCNNNN (used by FR for applications and grants)[2]

   - SPC/GBYY/NNN (used by GB for applications and grants)

[2] *Note regarding the format used by BE and FR. The letter "C" contained in the number series denotes the kind of industrial property right, namely, the SPC (CCP in French).*

- SPC YYYYNNN (used by IE)
- UBYYCCPN (used by IT for applications and grants)

- (Year of the reign of the Emperor) – 700 001 (used by JP)[3]

- YY0NNN (used by NL for applications and grants)

- YY9NNNN-D (used by SE for applications and grants)

(ii) for registrations or grants of SPCs

- CR CCYY NNNNN (used by DK).

6. Specimens of announcements concerning SPC applications and SPC grants published by several Offices (AT, AU, BE, CH, CZ, DE, DK, EE, ES, FR, GB, IE, IT, JP, LU, LV, NL, NO, PT, SE, US) are reproduced as Appendices 1 to 21 to this Survey.

[Appendices to be added]

3 *See reply to question 12.*