25 años de CCPs

11 Marzo 2019
Toni Santamaria
Head of IP, Europe

accord
The Evolution of Generics

- The legislation covering the SPC was enacted in 1993 and adopted immediately in nine countries.

- Since then, several countries have joined, and the agreement is now in force in all EU member states and the EEA countries Norway and Iceland.

- Since the enactment in 1993 an up until 2015, applications had been made for 20,900 SPCs for medicinal products in the participating countries.

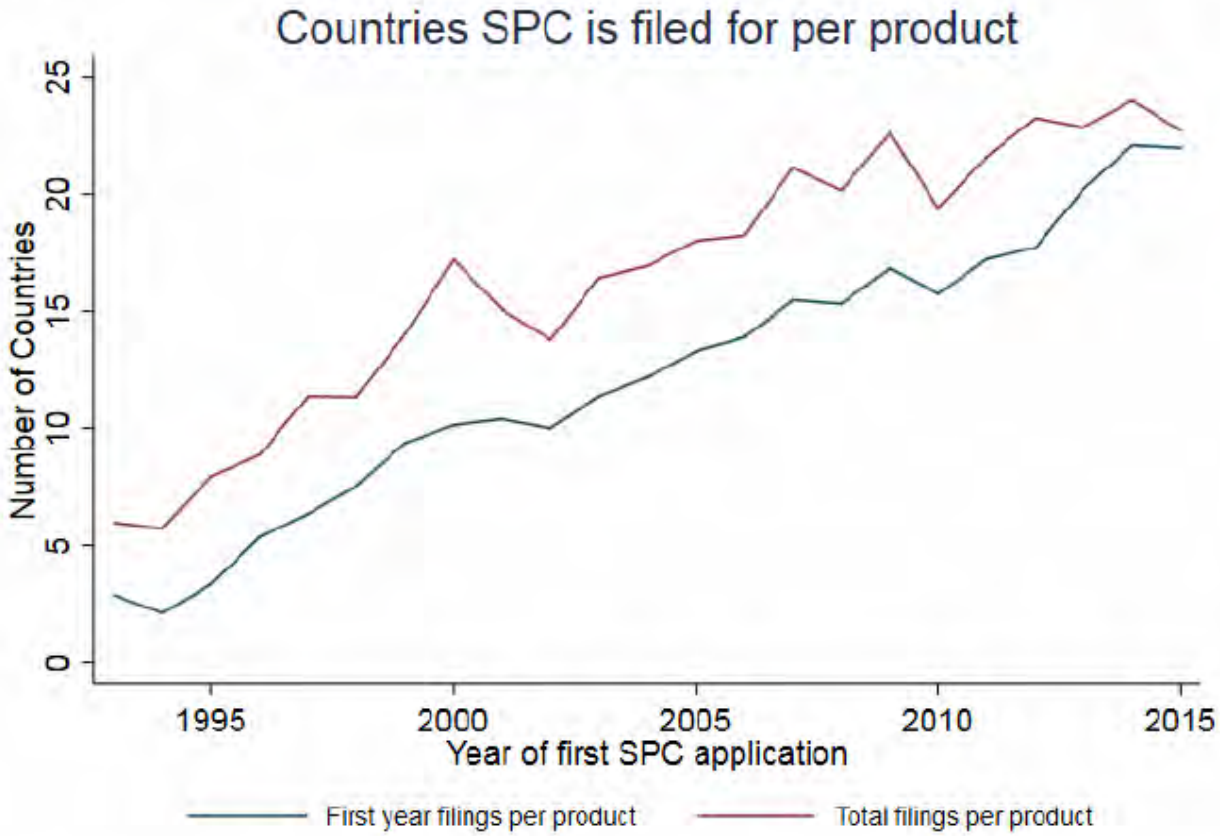
- SPCs are applied for in the individual member states, independently of each other. In many cases, this practice leads to contradictory decisions on the granting of rights. In Finland, Italy and the Czech Republic, less than 5% of applications are refused, while in Germany, Sweden and Spain, more than 15% of applications are refused.

- Twenty separate entities filed 57% of all SPC applications in 2015. The three companies having filed the most SPC applications in the past 10 years are Novartis, MSD and GSK.

- Market size seems to influence decisions to seek an SPC. In smaller markets, fewer SPCs are applied for than in larger markets. As such, less than 40 SPCs where applied for in Croatia, Malta and Norway in 2015, while more than 80 were applied for in Spain, Italy, Germany, the UK and France.

From:
European Commission.- Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe . Final Report. May 2018

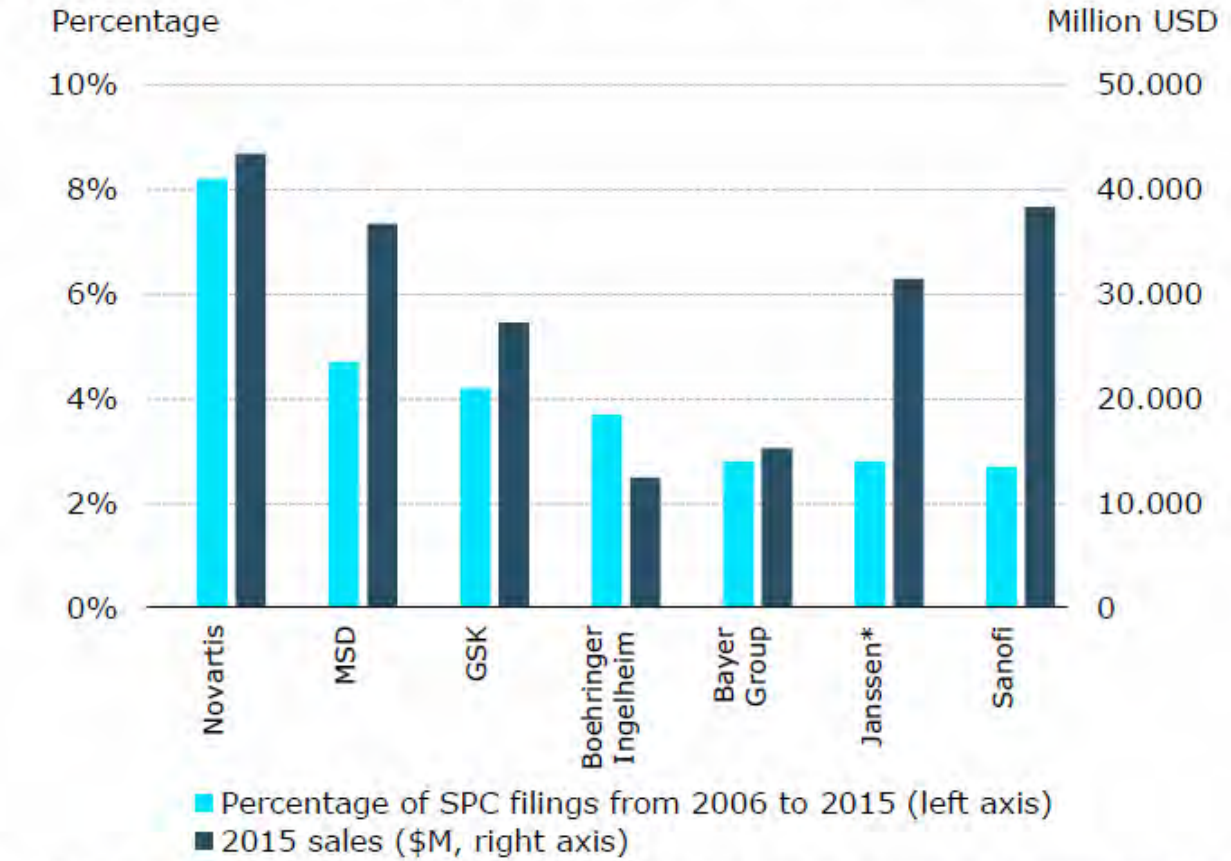
Number of countries where applications for SPCs are filed and the degree to which this is done in the same year or subsequently, 1993-2015



Note: Graph showing the number of countries SPCs are applied for and to what degree the applications are submitted in the same year or subsequently.
Source: Alice de Pastors database on SPCs collected from published data from National Patent Offices.

From:
European Commission.- Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe . Final Report. May 2018

Companies filing the most SPCs between 2006 and 2015 and their 2015 sales



*Note: The left axis depicts how a large a percentage of all SPC filings between 2006 and 2015 the filings for each company constitutes. The right axis depicts total sales for each firm in 2015 in million USD. * Sales for Janssen is taken from the below source as Johnson & Johnson, as Janssen is the pharmaceutical part of the company.*
Source: Percentage of SPC filings from Alice de Pastors, SPC-news 30 (2016 issue) available from http://thespcblog.blogspot.dk/2016/11/the-spc-blog-once-again-thanks-alice-de.html and 2015 sales from https://scrip.pharmaintelligence.informa.com/-/media/marketing/scrip-100/pdf/Scrip100_LeagueTables.pdf?la=en

From:
European Commission.- Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe . Final Report. May 2018

Creation of SPCs

- Proposal for council regulation concerning the creation of a supplementary protection certificate for medicinal product. - Explanatory memorandum. April 1990.

- A simple, transparent system

16. The proposal for a Regulation provides for a simple, transparent system which can easily be applied by the parties concerned.

It therefore does not lead to excessive bureaucracy. There is no need for any new administrative body and the patents offices should be able to implement the procedure for granting the certificate without an excessive burden being placed on their administrations.

The adoption of a standard system to calculate the duration of the protection given by the certificate without abstraction of certain information specific to the case (date of granting the authorization, date of filing the patent application, date of expiry of the patent) means that the calculation is easy to make.

17. The procedure envisaged lastly guarantees the transparency of the system since the decision to grant the certificate and the application are both published, the latter having been filed sufficiently early after marketing authorization was given to enable third parties to be swiftly informed.

A 'sui generis' proposal

B. Details and characteristics of the proposed system

(a) Details

9. The proposal for a Regulation provides for the creation of a protection certificate sui generis in the form of a supplementary protection certificate.

Proposal for council regulation concerning the creation of a supplementary protection certificate for medicinal product. - Explanatory memorandum. April 1990.

Creation of SPCs

•Whereas **pharmaceutical research** plays a decisive role in the continuing improvement in public health;

•Whereas medicinal products, especially those that are the result of long, costly research will not continue to be developed in the Community and in Europe unless they are covered by **favourable rules that provide for sufficient protection top encourage such research**;

•Whereas at the moment the period that elapses between the filing of an application for a patent for a new medicinal product and authorization to place the medicinal product on the market makes **the period of effective protection under the patent insufficient to cover the investment put into the research**;

•Whereas the current situation is creating the **risk of research centres situated in the Member States relocating** to countries that already offer greater protection;

•Incentivise research in pharmaceutical products.

•Insufficient protection to recover investment.

•Avoid relocation of research centres.

3. This situation, which has come about as a result of interference between two types of administrative procedure, imposes heavy penalties on pharmaceutical research, which is therefore discriminated against as compared with other technological sectors.

It is true that this interference also takes place in other industrial sectors, in particular the agro-chemical sector, the food sector, etc., but it is undisputed that the pharmaceutical sector is clearly the most affected. It is furthermore the only one which, for many years, has been asking the public authorities to find a solution.

Creation of SPCs

- Whereas a **uniform solution at Community** level should be provided for, thereby **preventing the heterogeneous development of national laws leading to further disparities which would be likely to create obstacles to the free movement of medicinal products within the Community** and thus directly affect the establishment and the functioning of the internal market;

- Avoid heterogeneous developments of national laws.
- Avoid obstacles to free movements of products.
- Uniform solution.
- Grant under same conditions

- Whereas, therefore, the creation of a supplementary protection certificate **granted, under the same conditions**, by each of the Member States at the request of the holder of a national or European patent relating to a medicinal product for which marketing authorization has been granted is necessary; whereas a Regulation is therefore the most appropriate legal instrument;

But, there is no such uniformity….

•Grant procedures at National patent offices

•Contradictory decisions by National Courts / Patent offices

Analysis of protection expiry dates unveils significant differences in the scope of SPC protection in the EU. For 80% of medicinal products approved between 2004 and 2014 protection expiry dates are not homogenous across Member States. In 26% of cases the existing discrepancy can be attributed to divergent decisions on the SPC applications. In 58% the discrepancy is due to differences in the first marketing authorization date reported in the applications. While, discrepancies in expiry dates caused by differences in the first marketing authorization dates are likely to disappear due to the increasing reference to marketing authorization granted in a centralized procedure and clarity brought on the definition of the first marketing authorization date brought by the EUCJ in AstraZeneca AB[4] and Seattle Generics[5] cases, the differences in examination outcomes will remain unless further harmonization efforts are made.

Furthermore, I find that for 20% of the products the SPC was applied for with reference to more than one basic patent in at least one EU Member State. The probability increases over time and is higher for biological medicines than for those derived in chemical synthesis.

Diverging decisions….

Thursday, 14 September 2017

Tenofovir - High Court Decision in France

Those following the tenofovir SPC litigation in Europe will be pleased to hear that the High Court of Paris has recently handed down a decision in relation to Gilead's SPC based on EP0915894. Denis Schertenleib, who acted for Mylan in these proceedings, has kindly provided a short summary of the case, along with a copy of the decision and an English translation.

"Recently, the High Court of Paris had to opine on the validity of the Gilead SPC on Truvada covering tenofovir and emtricitabine. The SPC was based on the basic patent for tenofovir. One of its claims covered a combination of tenofovir with another optional therapeutic ingredient.

In the context of preliminary injunction proceedings, the Presiding Judge of the Paris High Court had to decide whether this SPC was likely to be held invalid on the merits. The Court held in a ruling dated 5 September 2017, that the SPC was likely to be invalid.

The reasoning of the Court was based on the finding that the reference to another "therapeutic ingredient" could not be deemed to constitute a functional definition of any compound under the Eli Lilly v HGS doctrine of CJEU case C-493/12. In addition, the Court held that nothing in the description or the prior art could be held to point to Emtricitabine as being this optional therapeutic ingredient. Finally, the Court noted that the combination of tenofovir and emtricitabine could not constitute the core invention of the basic patent under the Actavis v Sanofi doctrine of CJEU case C-443/12. The Court thus held that the SPC was likely to be invalid and that no preliminary injunction could be granted.

Search ILO

Author

Preliminary injunctions revoked due to *prima facie* invalidity of Truvada SPC

January 08 2018 | Contributed by Grau & Angulo

Intellectual Property | Spain

- Background
- Facts
- Decision

TaylorWessing

News and Events | Topical Issues

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Another round of SPC references

January 2017

As we have **previously reported**, there is a lack of clarity about the requirements for the grant of a supplementary protection certificate ("**SPC**") and interpretation of aspects of Regulation 469/2009/EC ("**SPC Regulation**"). It is in this context, that Mr Justice Arnold has in three cases before the English Patents Court considered the correct interpretation of articles 3(a), (b) and (d) of the SPC Regulation. Incomplete reasoning in previous cases decided by the Court of Justice of the European Union ("**CJEU**") and diverging approaches across Europe has led in each case to the referral of further questions to the CJEU for a preliminary ruling.

Article 3(a)

Teva UK Limited and three other claimants challenged the validity of an SPC held by Gilead Sciences Inc ("**Gilead**") that covers its anti-retroviral treatment Truvada. The claimants argued that

THE SPC BLOG

A niche blog dedicated to the issues that arise when supplementary protection certificates (SPCs) extend patents beyond their normal life -- and to the respective positions of patent owners, investors, competitors and consumers. The blog also addresses wider issues that may be of interest or use to those involved in the extension of patent rights. You can email The SPC Blog here

Thursday, 29 March 2018

Denmark - Gilead successfully enforces its SPC for Truvada

Last year, the SPC Blog reported (here) the decision of the Danish Maritime and Commercial High Court not to grant a preliminary injunction against Accord Healthcare Limited on the basis of Gilead's SPC for the combination of tenofovir disoproxil (as fumarate) and emtricitabine.

On 7 March 2018, the Eastern High Court in Denmark overturned this decision and granted the preliminary injunction against Accord.

Mikkel Vittrup an

The East
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mentione

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Gilead's Truvada SPC: Preliminary Injunctions rejected in German Infringement Proceedings

Published on September 18, 2017

Dr. Ulrike Herr + Follow

Partner, Patent Attorney and European Patent Attorney at ISENBRUCK BÖSL ...

lünchen) recently rejected Gilead's motion for
PC of the anti-HIV drug Truvada in first
anies. The Court's judgement relied on the
nt Court concerning the validity of the SPC in

n/2017/09/hiv-medikament-zahlreiche-
-truvada).

Wednesday, 6 February 2019

Darunavir in Swedish Preliminary Injunction Proceedings

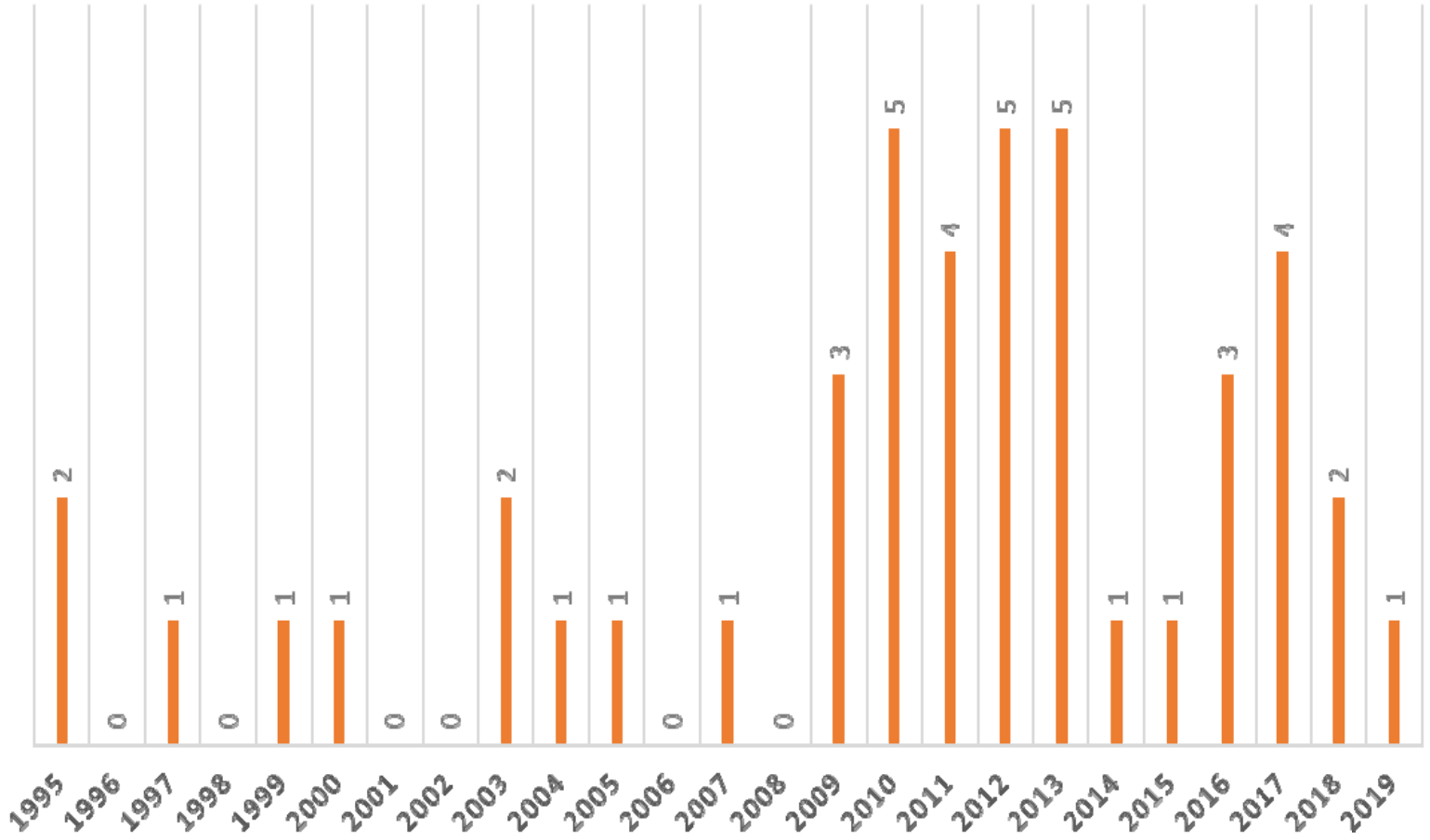
Recently, the Paris High Court decided for a preliminary injunction against the commercialisation of Darunavir by Sandoz, the SPC Blog report can be found here. In parallel proceedings, the Swedish Patent and Market Appeal Court has come to the opposite conclusion, and found that that the contested SPC would most likely be found invalid and thus denied a request for a preliminary injunction. Hampus Rystedt from Zacco has kindly provided the following summary of the case.

The first instance Patent and Market Court, which is quite experienced in SPC appeals originating from the examination at the Swedish Patent Office, granted a preliminary injunction. The Patent and Market Appeal Court however reversed the decision. The PMAC specifically referenced the Teva case from the CJEU (C-121/17; EU:C:2018:585) and found that the criteria set out in Teva should be applied when assessing the plausibility that an SPC will be considered valid. The PMAC finds that darunavir is not specifically identified in the claims, and indeed appears to have been first synthesized only after the priority date. The PMAC therefore finds that it is likely that the SPC will be considered invalid in the main proceedings and that a preliminary injunction cannot be granted.

Of interest to note is that the decision in PMAC was split 3 to 2, with the chairwoman and the only chemical expert dissenting. The two dissenting judges found that the case law is not clear on how Art 3(a) of 469/2009 should be applied when the basic patent defines the invention by means of a Markush-formula. These judges were thus of the opinion that it had not been sufficiently shown that the SPC would likely be held invalid, and that the preliminary injunction granted by the lower court should be upheld.

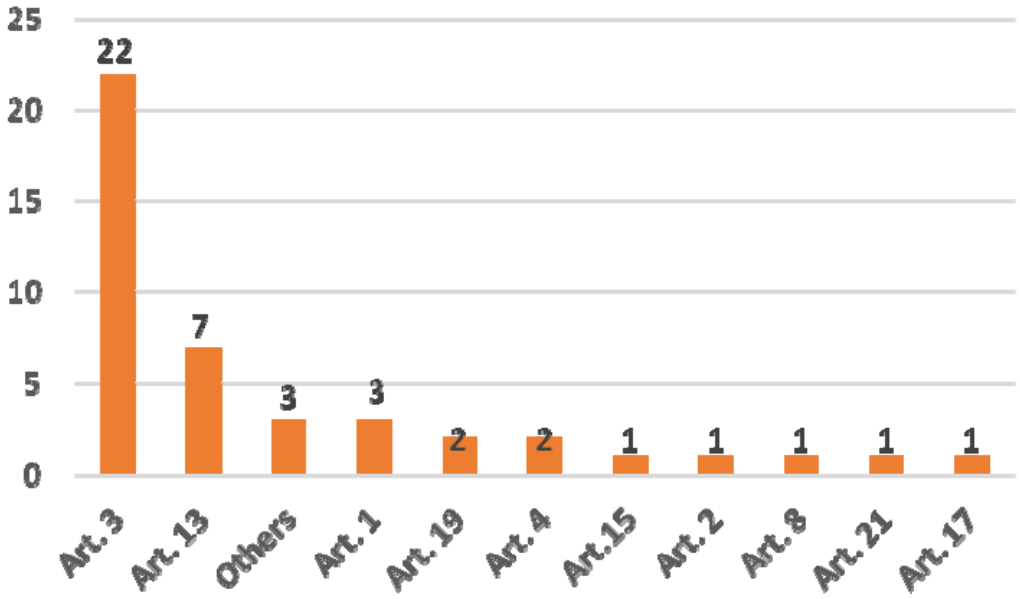
The main proceedings will now continue in the first instance court.

SPC CJEU REFERRALS by year



Total: 44. Search at curia.europa.eu

ARTICLES SUBJECT TO REFERRAL



Art. 1	Definitions
Art. 2	Scope
Art. 3	**Conditions for obtaining a certificate**
Art. 4	Subject matter of protection
Art. 5	Effects of the certificate
Art. 6	Entitlement to the certificate
Art. 7	Application for a certificate
Art. 8	Content of the application for a certificate
Art. 9	Lodging of an application for a certificate
Art. 10	Grant of the certificate or rejection of the application for a certificate
Art. 11	Publication
Art. 12	Annual fees
Art. 13	**Duration of the certificate**
Art. 14	Expiry of the certificate
Art. 15	Invalidity of the certificate
Art. 16	Revocation of an extension of the duration
Art. 17	Notification of lapse or invalidity
Art. 18	Notification of lapse or invalidity
Art. 19	Procedure
Art. 20	Additional provisions relating to the enlargement of the Community
Art. 21	Transitional provisions
Art. 22	Repeal
Art. 23	Entry into force

Creation of SPCs

- **1986** – European Commission – Protection to innovating firms. Directive 87/21/EEC (6-10 years of Data exclusivity).

- **1988** – EFPIA: "Memorandum on the Necessity to restore the effective duration of patents for pharmaceutical products".

    - 1984 – US Waxman-Hatch.
    - 1988 – JP.

- **1990** - Proposal for council regulation concerning the creation of a supplementary protection certificate for medicinal product.

- **1991** – National regulations on SPCs
    - FR – 7 years.
    - IT – 18 years.

1992

12 - EU member states (1992):
Germany, France, Italy, the Netherlands, Belgium, Luxembourg, Denmark, Ireland, United Kingdom, Greece, Spain and Portugal

Austria, Finland and Sweden joined in 1995.

EPC Contracting States (1992):
Austria, Belgium, Switzerland, Germany, Denmark, Spain, France, United Kingdom, Greece, Ireland, Italy, Liechtenstein, Luxembourg, Monaco, Netherlands, Portugal, Sweden.

Ley Patentes 11/1986 .
DISPOSICIONES TRANSITORIAS
Primera.
1. No serán patentables las invenciones de productos químicos y farmacéuticos antes del 7 de octubre de 1992.

Table 1: SPC provisions and transition

		National SPC regime	Entry into force the EU SPC Regulation (*)	Date of first EC/EEA authorization after which an SPC may be granted (*)
AT	Austria		Jul 1994	Jan 1982
BE	Belgium		Jan 1993	Jan 1982
BG	Bulgaria		Nov 2007	Jan 2000
CY	Cyprus	Jan 1998	May 2004	n/a
CZ	Czech Republic	May 2000	May 2004	Nov 1999
DE	Germany		Jan 1993	Jan 1988
DK	Denmark		Jan 1993	Jan 1988
EE	Estonia	Jan 2000	May 2004	n/a
ES	Spain		Jan 1998	n/a
FI	Finland		Jul 1994	Jan 1988
FR	France	Jun 1990	Jan 1993	Jan 1985
GB	Great Britain		Jan 1993	Jan 1985
GR	Greece		Jan 1998	Jan 1998
HK	Croatia		Jul 2013	Jan 2003
HU	Hungary		May 2004	Jan 2000
IE	Ireland		Jan 1993	Jan 1985
IS	Iceland		Jul 1994	Jan 1988
IT	Italy	Oct 1991	Jan 1993	Jan 1982
LT	Lithuania	Jan 2002	May 2004	(b)
LU	Luxembourg		Jan 1993	Jan 1985
LV	Latvia	1999	May 2004	n/a
MT	Malta	Jan 2003	May 2004	n/a
NL	Netherlands		Jan 1993	Jan 1985
NO	Norway		Jul 1994	Jan 1988
PL	Poland		May 2004	Jan 2000
PT	Portugal		Jan 1998	Jan 1998
RO	Romania		Jan 2007	Jan 2000
SE	Sweden	1993	Jul 1994	Jan 1985
SI	Slovenia	Jul 2003	May 2004	n/a
SK	Slovakia	Oct 2001	May 2004	Jan 2000

Note: The EC Regulation No. 1768/92 was published in the Official Journal on 18 June 1992 and effective six month later (Jan 1993). (*) For the transitional provisions c.f. Art. 19 of the EC Regulation No. 1768/92 and Article 20 of Regulation EC No. 469/2009 (b) for patents granted after 1 February 1994.

Source:
25 years of SPC protection for medicinal products in Europe: Insights and challenges
Malwina MEJER. May 2017

25 years of SPCs

- **Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products.**

C-350/92. 13 July 1995. Spain v Council

- [p34] -. Provisions concerning the creation of a supplementary protection certificate for medicinal products existed in two Member States and were at the draft stage in another State.
- [p35] Aimed to prevent heterogeneous development of national laws and to avoid obstacles to the free movement of medicinal products
- 5 years. Balance of all interests at stake.

Article 8

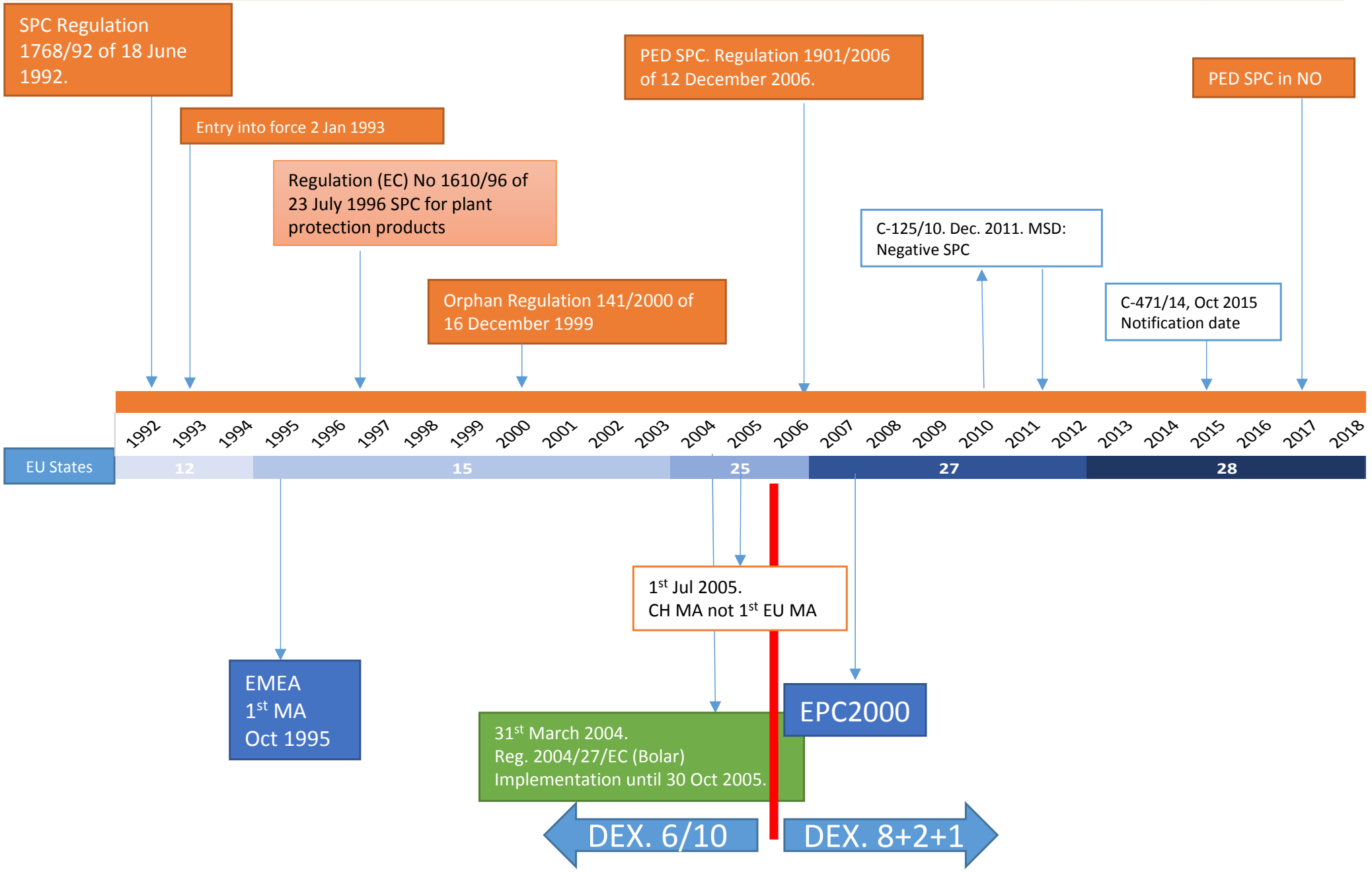
Duration of the certificate

1. The certificate shall take effect on the day following 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, as referred to in Article 6 (3) (c), reduced by a period of four years.

2. Notwithstanding paragraph 1, the duration of the certificate may not exceed 10 years from the date on which it takes effect.

Proposal for council regulation concerning the creation of a supplementary protection certificate for medicinal product. - Explanatory memorandum. April 1990.

The History of SPC



DEVELOPMENT TIME – R&D PHARMACEUTICALS

Table 6: Expected years of protection at launch

Year of first global launch	Count	Mean			
	N	Development	EU lag	Patent only	With SPC
1990-1994	149	9.90	1.81	8.28	13.75
1995-1999	172	8.94	1.06	10.24	13.56
2000-2004	128	9.84	0.79	9.49	12.19
2005-2009	116	10.43	0.92	8.63	11.73
2010-present	143	12.18	0.41	7.40	12.46
Total	708	10.33	1.01	8.81	12.68

Table 7: Development times

Year of first global launch	Development time				
	0-5 years Row %	5-10 years Row %	10-15 years Row %	15+ years Row %	Total Row %
1990-1994	6.7	23.5	16.8	53.0	100.0
1995-1999	14.5	33.7	16.3	35.5	100.0
2000-2004	9.4	31.2	25.8	33.6	100.0
2005-2009	14.7	28.4	24.1	32.8	100.0
2010-present	4.9	27.3	38.5	29.4	100.0
Total	10.0	29.0	23.9	37.1	100.0

Source: Economic Analysis of Supplementary Protection Certificates in Europe. Margaret Kyle. January 30, 2017

SPCs between regulatory and patent law

Duration of SPC

Article 13

Duration of the certificate

1.The certificate shall take 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 reduced by a period of five years.

2. Notwithstanding paragraph 1, the duration of the certificate may not exceed five years from the date on which it takes effect.

•SPC requires:

- Marketing authorization validly granted in a member state of EU.
- Basic Patent granted.

Duration of SPCs

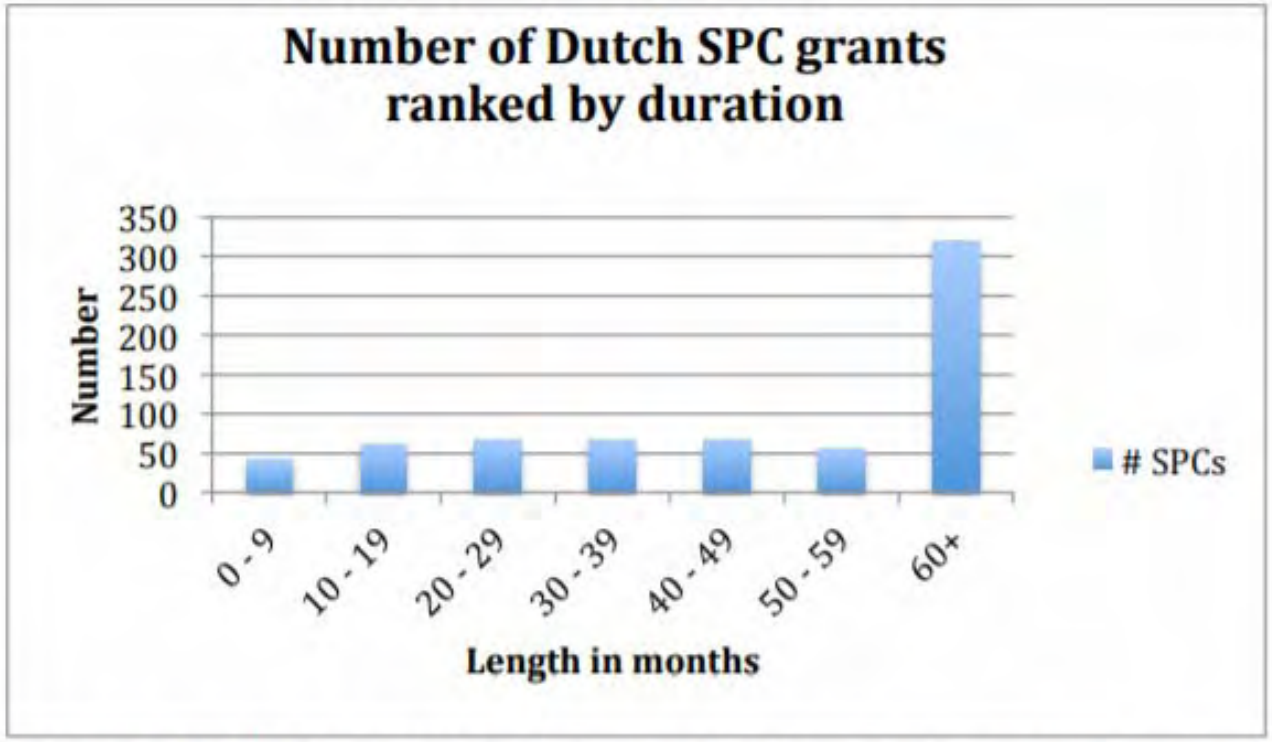


Figure 4 All SPCs, granted, expired and in force, between January 1993 and May 2014, on the 23rd of May, in the Netherlands. The length of these SPCs is ordered into 7 categories. One granted SPC had the duration of -4 months and is excluded from this analysis, 5 SPCs had the length of 66 months. Data retrieved from the RVO database. Corresponding data is public. Corresponding table can be found in appendix C.

The Netherlands' Ministry of Health: Supplementary Protection Certificate for medicinal products: An assessment of European regulation (2014)

SPCs between regulatory and patent law

Global Marketing authorization[1]:

Article 6(1) second subparagraph of Directive 2001/83/EC provides that when a medicinal product has been granted an initial marketing authorisation, **any additional strengths, pharmaceutical forms, administration routes, presentations** as well as any variations and extensions must also be granted an authorisation or be included in the initial marketing authorisation. **All these marketing authorisations are considered as belonging to the same global marketing authorisation**, in particular for the purpose of the application of Article 10 of the directive, which lays down rules on data exclusivity and market protection and on the so-called European Reference Product

Article 52.- Patentable inventions (EPC)

(1) European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application.

Article 123.- Amendments

(2) The European patent application or European patent may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed.

1 European Commission. Notice to applicants. VOLUME 2A Procedures for marketing authorisation. CHAPTER 1 MARKETING AUTHORISATION December 2016

What is a Product?

Art. 3a

(a)the **product** is protected by a basic patent in force;

(b)(d) the authorisation referred to in point (b) **is the first authorisation** to place the product on the market as a medicinal product.

Art. 1 . Definitions For the purposes of this Regulation:

(b) 'product' means the **active ingredient or combination of active ingredients** of a medicinal product;

•**C-130/11. 19 Jul 2012. Neurim**: New use for known medicinal product. (Deviating from previous decisions, i.e. C-202/05 Yissum)

•**C-631/13. 15 Jan 2015. Forsgren**: Active ingredient has to produce a pharmacological, immunological or metabolic action of its own.

•**C-443/17. Abraxane**. AG Opinion 13 Dec 2018. Decision expected 21 March 2019.

One SPC per Product.

The certificate confers the same protection as the basic patent, but only protects the product covered by the authorization, for all pharmaceutical uses authorized, until the expiry of the basic patent.

11. The proposal for a Regulation therefore concerns only new medicinal products. It does not involve granting a certificate for all medicinal products that are authorized to be placed on the market. Only one certificate may be granted for any one product, a product being understood to mean an active substance in the strict sense. Minor changes to the medicinal product such as a new dose, the use of a different salt or ester or a different pharmaceutical form will not lead to the issue of a new certificate.

Proposal for council regulation concerning the creation of a supplementary protection certificate for medicinal product. - Explanatory memorandum. April 1990.

Marketing authorization – Application types

Full dossier – Art.8(3)

Requirements:

• Stand alone application

•An application for marketing authorisation must be accompanied by the particulars and documents set out in Article 8(3) of Directive 2001/83/EC and therefore the following documentation must be included in the dossier:

- pharmaceutical (physico-chemical, biological or microbiological) tests,
- **preclinical (toxicological and pharmacological) tests,**
- **clinical trials.**

Incentives

•8+2 (+1) years of Market exclusivity.

•If PIP is completed can qualify for 6 months of SPC extension. (Subject to patent and SPC being granted)

Art. 10 (3) Hybrid applications

Where bioequivalence cannot be demonstrated through bioavailability studies, for example for locally applied and locally acting drugs, Article 10(3) requires that the results of appropriate pre-clinical tests or clinical trials shall be provided and this Article provides the correct legal basis for the application.

Examples:

•where the strict definition of a 'generic medicinal product' is not met;

•where bioavailability studies cannot be used to demonstrate bioequivalence (for example where the new product is supra-bioavailable);

•where there are changes in the active substance(s), therapeutic indications, strength, pharmaceutical form or route of administration of the generic product compared to the reference product.

DIRECTIVE 2004/27/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use

Abraxane

About the product:

Abraxane is a cremophor-free colloidal suspension of paclitaxel and human serum albumin. Abraxane is a **new formulation developed to overcome the water insolubility of the active component paclitaxel** and prevent hypersensitivity reactions associated with solvent-containing formulations. Abraxane is presented lyophilized and contains 800 mg albumin per 100 mg paclitaxel prior to reconstitution with 0.9% saline. The size of the paclitaxel nanoparticles is approx.130 nm.

The applicant has submitted an application for a full marketing authorization under Article 8(3) of Directive 2001/83/EC (as amended). The claimed indications and posologies were metastatic breast carcinoma (260 mg/m2 administered intravenously over 30 minutes every 3 weeks) and adjuvant treatment of node-positive breast carcinoma following anthracycline and cyclophosphamide therapy (260 mg/m2 administered intravenously over 30 minutes every 3 weeks for 4 courses). Clinical data to support the application for the first line therapy MBC was insufficient and the indication has been restricted to treatment of metastatic carcinoma of the breast in patients who have failed, or are not candidates for standard, anthracycline containing therapy. The applicant did not submit any clinical trials to establish the efficacy in breast cancer in the adjuvant setting and this indication has been withdrawn.

https://www.ema.europa.eu/en/documents/assessment-report/abraxane-epar-public-assessment-report_en.pdf

Conditional Marketing Authorisation

Regulation (EC) No 726/2004: a new provision was introduced in Article 14(7) – a renewable marketing authorisation that is valid for one year and is subject to specific obligations.

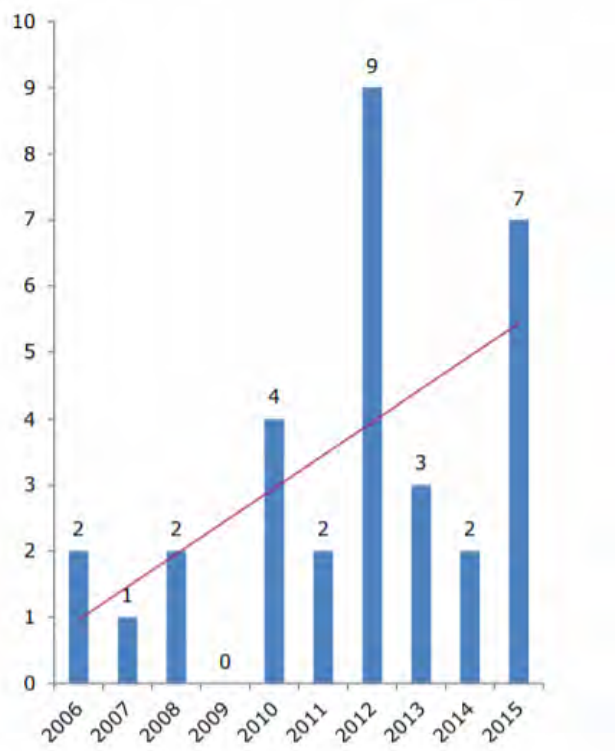
Eligible for a conditional marketing authorisation:

1.medicinal products which aim at the treatment, the prevention or the medical diagnosis of seriously debilitating diseases or life-threatening diseases;

2.medicinal products to be used in emergency situations, in response to public health threats duly recognised either by the World Health Organisation or by the Community in the framework of Decision No 2119/98/EC;

3.medicinal products designated as orphan medicinal products in accordance with Article 3 of Regulation (EC) No 141/2000.

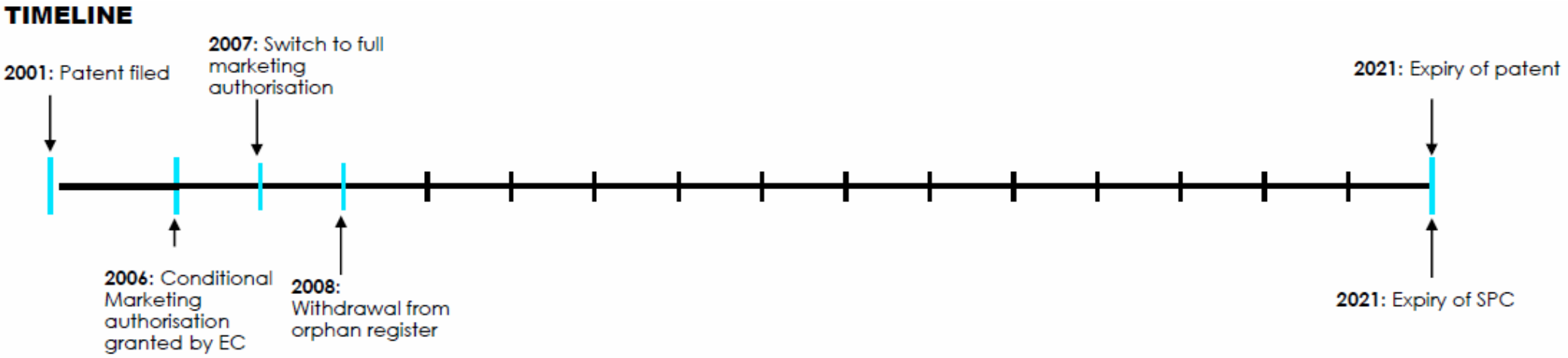
Votubia®- Novartis (Everolimus)
Prezista® - Janssen (Darunavir)
Tyverb®- Novartis (Lapatinib)



Note: Includes only applications for CMA submitted till 2015 and resulting before end of 2016 in a positive or negative opinion, or a withdrawal of the application after adoption of the list of questions by the CHMP

Conditional marketing authorisation Report on ten years of experience at the European Medicines Agency.
https://www.ema.europa.eu/en/documents/report/conditional-marketing-authorisation-report-ten-years-experience-european-medicines-agency_en.pdf

Conditional Marketing Authorisation – Sutent ® Pfizer (Sunitib)



Conditional marketing authorisation Report on ten years of experience at the European Medicines Agency.
https://www.ema.europa.eu/en/documents/report/conditional-marketing-authorisation-report-ten-years-experience-european-medicines-agency_en.pdf

Duration of SPC – First Marketing Authorisation

Article 13. Duration of the certificate 1. The certificate shall take 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 reduced by a period of five years.

- **C-207/03 and C-252/03. 21 Apr 2005. Novartis**: CH (LI) can be the first MA. Change July 2005.
- **C-125/10. 8 Dec. 2011. MSD:** Negative SPC. – Relevant since Paediatric Regulation.
- **C-555/14. 13 Feb 2014. Merck:** Maximum of 15 years from first MA. (PT -National patents with longer duration)
- **C-471/14. 6 Oct 2015. Seattle**: notification date vs grant date.
- **C-572/15. 6 Oct 2016. Roche:** Accessing states. First MA in EU.
- **C-492/16. 20 Dec 2017. Incyte**: No ex-officio correction. Appeal must be filed.

Expiration date of an SPC

- Same Patent and same MA, but…
- Different expiry dates depending on national law for calculation of patent expiry depending if filing date is considered.

Duration of SPC – PAEDIATRIC EXTENSIONS

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.

- Children are not "merely small adults", which would allow administering a smaller dosage of products tested, approved and authorised for the general population

TITLE V

REWARDS AND INCENTIVES

Article 36

1. Where an application under Article 7 or 8 includes the results of all studies conducted in compliance with an agreed paediatric investigation plan, the holder of the patent or supplementary protection certificate shall be entitled to a six-month extension of the period referred to in Articles 13(1) and 13(2) of Regulation (EEC) No 1768/92.

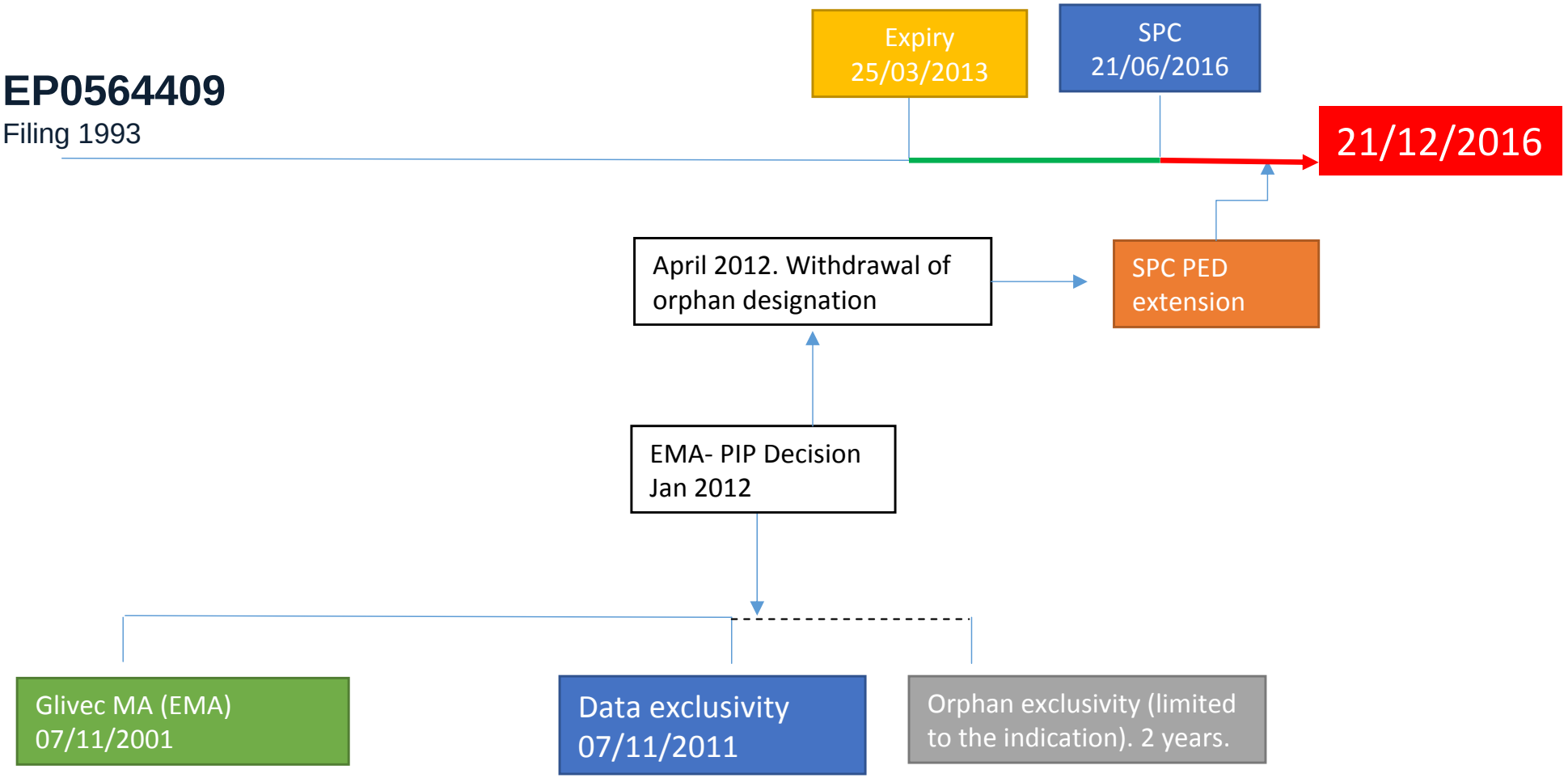
The first subparagraph shall also apply where completion of the agreed paediatric investigation plan fails to lead to the authorisation of a paediatric indication, but the results of the studies conducted are reflected in the summary of product characteristics and, if appropriate, in the package leaflet of the medicinal product concerned.

3. Where the procedures laid down in Directive 2001/83/EC have been used, the six-month extension of the period referred to in paragraph 1 shall be granted only if the product is authorised in all Member States.

4. Paragraphs 1, 2 and 3 shall apply to products that are protected by a supplementary protection certificate under Regulation (EEC) No 1768/92, or under a patent which qualifies for the granting of the supplementary protection certificate. They shall not apply to medicinal products designated as orphan medicinal products pursuant to Regulation (EC) No 141/2000.

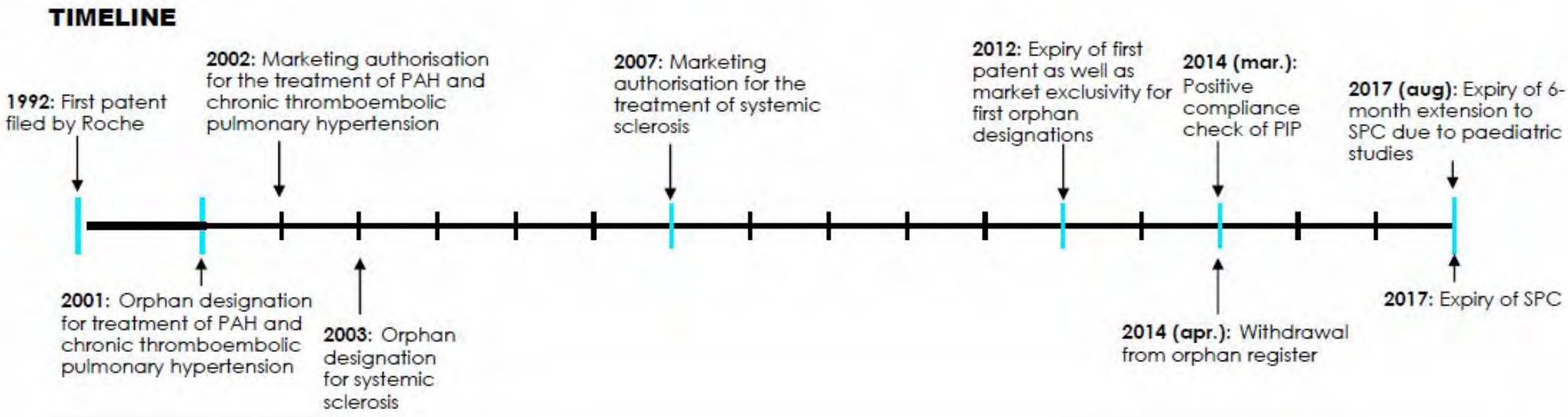
5. In the case of an application under Article 8 which leads to the authorisation of a new paediatric indication, paragraphs 1, 2 and 3 shall not apply if the applicant applies for, and obtains, a one-year extension of the period of marketing protection for the medicinal product concerned, on the grounds that this new paediatric indication brings a significant clinical benefit in comparison with existing therapies, in accordance with Article 14(11) of Regulation (EC) No 726/2004 or the fourth subparagraph of Article 10(1) of Directive 2001/83/EC.

Glivec® Novartis – Withdrawal of orphan designation



Orphan market exclusivity for "Treatment of chronic myeloid leukaemia" started on 12/11/2001. (exp. 2011)
Orphan market exclusivity for "Treatment of malignant gastrointestinal stromal tumours" started on 27/05/2002.
Orphan market exclusivity for "Treatment of acute lymphoblastic leukaemia" started on 18/09/2006
Orphan market exclusivity for "Treatment of dermatofibrosarcoma protuberans" started on 18/09/2006
Orphan market exclusivity for "Treatment of chronic eosinophilic leukaemia and the hypereosinophilic syndrome" started on 1/12/2006
Orphan market exclusivity for "Treatment of myelodysplastic / myeloproliferative diseases" started on 1/12/2006

Tracleer® Actelion – Withdrawal of orphan designation



- Potential extension of OEx. 2017- 2019 abandoned.
- 6M SPC PED extension granted.

- Is choosing between incentives in accordance with the spirit of the regulation?

From:
European Commission.- Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in
Europe . Final Report. May 2018

Products covered by SPC

- Council Regulation (EEC) No 469/2009 of 6 May 2009 concerning the supplementary protection certificate for **medicinal products** (human and animal).
  - (b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC, as appropriate;

- Council 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.**
  - (b) a valid authorization to place the product on the market as a plant protection product has been granted in accordance with Article 4 of Directive 91/414/EEC or an equivalent provision of national law;

- SPC's are not granted just because authority approval is required. In other areas approval before commercialization is also necessary.

- SPC are created to compensate the cost of the clinical trials and the time required to obtain regulatory approval.

- **C-527/17 (Boston).** No SPC available for medical devices[1].

- No SPCs available for animal feed additives [2]

[1] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance.)

[2] http://patentblog.kluweriplaw.com/2019/02/25/spcs-not-available-for-animal-feed-additives/

Products covered by SPC

Products covered under current regulation

- Medicinal products: for human use, for animals
- Plant protection products (agrochemicals): pesticides, insecticides, herbicides, fungicides, nematicides, fertilizers, growth agents & concentrations

Sectors which might face similar challenges to the pharmaceutical sector and might be candidates for SPC-type incentive schemes and areas within SPC-protected sectors that could need specific attention

- Medicinal devices & diagnostics
- Food sector
- Seeds
- Substances w/o therapeutic effect of their own (catalysers)
- Personalised medication
- Intelligent pills
- Chemicals
- Biopharmaceuticals
- New uses of patented products

From:
European Commission.- Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in
Europe . Final Report. May 2018

SPC Applications

- SPC are national rights.
- National Patent offices responsible for granting SPCs (Art. 9)
- (and national Courts for interpretation of scope of protection)

Different approach to SPC:

- Administrative filing.
- Substantive Examination.
- No opposition process. No intervention of third parties.

Correction of SPC duration:

- Not possible for third parties to request correction at PTO. i.e. SPC not based on CH MA (pre July 2005).
- **C-492/16**:"…**the holder** of a supplementary protection certificate may, under Article 18 of Regulation No 469/2009, **bring an appeal for rectification** of the duration stated in the certificate, provided that that certificate has not expired."

Table 19: SPCs by country

Country	Total Patents	SPC Applications	SPC Grants	SPC Refusals
Austria	2,636	774	618	78
Belgium	2,671	752	496	91
Bulgaria	863	181	105	20
Croatia	506	79	19	1
Czech Republic	1,146	272	165	33
Denmark	2,411	742	596	126
Estonia	628	145	121	6
Finland	1,853	571	385	19
France	2,845	775	582	135
Germany	2,923	942	560	219
Greece	2,308	531	455	23
Hungary	1,218	338	177	60
Iceland	363	101	66	8
Ireland	2,211	669	486	100
Italy	2,692	771	722	55
Latvia	967	211	155	15
Lithuania	911	201	119	11
Luxembourg	2,484	658	656	7
Netherlands	2,648	782	668	134
Norway	978	387	324	32
Poland	931	213	74	41
Portugal	2,137	542	421	68
Romania	1,167	234	126	15
Slovak Republic	1,020	203	147	21
Slovenia	1,120	282	254	26
Spain	2,709	643	535	165
Sweden	2,632	770	630	117
Switzerland	2,717	631	539	66
UK	2,797	807	566	134
Total	52,492	14,207	10,767	1,826

Source: Economic Analysis of Supplementary Protection Certificates in Europe. Margaret Kyle. January 30, 2017

Conditions for obtaining a certificate

Article 3

Conditions for obtaining a certificate

A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application:

(a) the **product** is protected by a **basic patent** in force;

(b) a **valid authorisation** to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC, as appropriate;

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

(d) the authorisation referred to in point (b) is the **first authorisation** to place the product on the market as a medicinal product.

Is the product protected?

Art. 3a

(a) the product is **protected by a basic patent** in force;

- **C-392/97. Farmitalia**. In absence of patent law harmonization in the EU, it is a question of national law whether a product is protected by a basic patent.

- Two approaches:
  - Infringement test
  - Disclosure test

- **C-322/10. Medeva.** Specified in the wording of the claims. (Disclosure test)
  - No clarity on what "specified" means.

- **C493/12. Lilly**: "implicitly but necessarily and specifically". Interpretation left to National Courts.

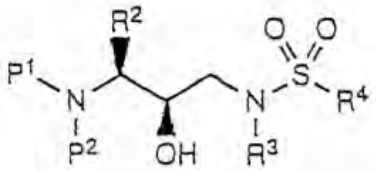
- **C-443/12. Actavis.** "Core inventive advance".

- **C-121/17- Gilead.** " a combination product is eligible for an SPC, if the claims in the underlying patent relate necessarily and specifically to that combination of active ingredients (even if the combination of active ingredients of which that product is composed is not expressly mentioned in the claims of the basic patent)"

- 2 referrals still pending:,
  - **C-114/18 Searle.** Darunavir
  - **C-650/17 QH.** Sitagliptin

EP0810209 - Darunavir

1. A compound represented by the formula:



(I)

P^1 and P^2 independently represent hydrogen, alkoxycarbonyl, aralkoxycarbonyl, alkylcarbonyl, cycloalkylcarbonyl, cycloalkylalkoxycarbonyl, cycloalkylalkanoyl, alkanoyl, aralkanoyl, aroyl, aryloxycarbonyl, aryloxycarbonylalkyl, aryloxyalkanoyl, heterocyclylcarbonyl, heterocyclyloxycarbonyl, heterocyclylalkanoyl, heterocyclylalkoxycarbonyl, heteroaralkanoyl, heteroaralkoxycarbonyl, heteroaryloxycarbonyl, heteroaroyl, alkyl, alkenyl, cycloalkyl, aryl, aralkyl, aryloxyalkyl, heteroaryloxyalkyl, hydroxyalkyl, aminocarbonyl, amino alkanoyl, and mono- and disubstituted aminocarbonyl and mono- and disubstituted aminoalkanoyl radicals wherein the substituents are selected from alkyl, aryl, aralkyl, cycloalkyl, cycloalkylalkyl, heteroaryl, heteroaralkyl, heterocycloalkyl, heterocycloalkylalkyl radicals, or where said aminoalkanoyl radical is disubstituted, said substituents along with the nitrogen atom to which they are attached form a heterocycloalkyl or heteroaryl radical;

R2 represents alkyl, aryl, cycloalkyl, cycloalkylalkyl and aralkyl radicals, which radicals are optionally substituted with a group selected from alkyl and halogen radicals, $-NO_2$, $-C\equiv N$, CF_3, $-OR^9$, $-SR^9$, wherein R^9 represents hydrogen and alkyl radicals;

R^3 represents hydrogen, alkyl, haloalkyl, alkenyl, alkynyl, hydroxyalkyl, alkoxyalkyl, cycloalkyl, cycloalkylalkyl, heterocycloalkyl, heteroaryl, heterocycloalkylalkyl, aryl, aralkyl, heteroaralkyl, aminoalkyl and mono- and disubstituted aminoalkyl radicals, wherein said substituents are selected from alkyl, aryl, aralkyl, cycloalkyl, cycloalkylalkyl, heteroaryl, heteroaralkyl, heterocycloalkyl, and heterocycloalkylalkyl radicals, or in the case of a disubstituted aminoalkyl radical, said substituents along with the nitrogen atom to which they are attached, form a heterocycloalkyl or a heteroaryl radical; and

R^4 represents radicals as defined by R^3 except for hydrogen;

wherein aryl wherever occuring may optionally carry one or more substituents selected from alkyl, alkoxy, halogen, hydroxy, amino, nitro, cyano, haloalkyl;
wherein heterocycle or heteroaryl may optionally be substituted on one or more carbon atoms by halogen, alkyl, alkoxy, oxo and/or on a secondary nitrogen atom by alkyl, aralkoxycrbonyl, alkanoyl, phenyl or phenylalkyl or on a tertiary nitrogen atom by oxido and which is attached via a carbon atom;
and the pharmaceutically acceptable salt, ester, or prodrug thereof.

EP1084705 - Sitagliptin B1

Claims

1. Activity-lowering effector of dipeptidylpeptidase IV (DP IV)-enzymatic activity for use in lowering the blood glucose level below the glucose concentration in the serum of a mammalian organism characteristic of hyperglycemia for alleviation of diabetes mellitus, wherein said effector results in the reduced degradation of the endogenous insulinotropic peptides GIP_{1-42} and $GLP\text{-}1_{7-36}$ by DP IV.

Is the product protected?

Article 69. Extent of protection
(1). The extent of the protection conferred by a European patent or a European patent application shall be determined by the claims. Nevertheless, the description and drawings shall be used to interpret the claims.
(2). For the period up to grant of the European patent, the extent of the protection conferred by the European patent application shall be determined by the claims contained in the application as published. However, the European patent as granted or as amended in opposition, limitation or revocation proceedings shall determine retroactively the protection conferred by the application, in so far as such protection is not thereby extended.

- Scope of protection determined by National Courts.

C-493/12. Lilly. Article 3(a) of 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 must be interpreted as meaning that, in order for an active ingredient to be regarded as 'protected by a basic patent in force' within the meaning of that provision, it is not necessary for the active ingredient to be identified in the claims of the patent by a structural formula. Where the active ingredient is covered by a functional formula in the claims of a patent issued by the European Patents Office, Article 3(a) of that regulation does not, in principle, preclude the grant of a supplementary protection certificate for that active ingredient, on condition that it is possible to reach the conclusion on the basis of those claims, interpreted inter alia in the light of the description of the invention, as required by Article 69 of the Convention on the Grant of European Patents and the Protocol on the interpretation of that provision, that the claims relate, implicitly but necessarily and specifically, to the active ingredient in question, **which is a matter to be determined by the referring court**.

How many SPC per product per patent?

Art. 3(c) the product has **not already been the subject of a certificate**;

(d) the authorisation referred to in point (b) **is the first authorisation** to place the product on the market as a medicinal product.

Multiple SPCs for same product protected by several basic patents belonging to different owners.

C-181/95 Biogen:
*"28 Consequently, where a product is protected by a number of basic patents in force, which may belong to a number of patent holders, **each of those patents** may be designated for the purpose of the procedure **for the grant of a certificate**. Under Article 3(c) of the Regulation, however, only one certificate may be granted for each basic patent."*

One SPC per patent

C-322/10. Medeva:

" Second, where a patent protects a product, in accordance with Article 3(c) of Regulation No 469/2009, **only one certificate may be granted for that basic patent** (see *Biogen*, paragraph 28)."

How many SPC per product per patent?

Art. 3(c) the product has **not already been the subject of a certificate**;

Art. 4 . Subject-matter of protection. Within the limits of the protection conferred by the basic patent, the protection conferred by a certificate **shall extend only to the product covered by the authorization to place the corresponding medicinal product on the market** and for any use of the product as a medicinal product that has been authorized before the expiry of the certificate.

Combination products:

C-443/12. **Actavis**. SPC for single active ingredient can oppose to commercialisation of a combination containing that active ingredient.

C-484/12. Georgetown. SPC for combination of active ingredients does not preclude the grant of SPC for active ingredients individually.

Who can obtain a SPC?

Article 6. Entitlement to the certificate. The certificate shall be granted to the holder of the basic patent or his successor in title.

- SPC were created to promote innovation.
- There is no link required between MA holder and Patent holder.
- **C-181/95, 23 Jan 1997. Biogen**. SPC can be based on MA granted to companies not holding the MA.
- **C-493/12. Lilly.** Para 43. "….that patent holder had not made any investment in research relating to that aspect of his original invention, that would undermine the objective of Regulation No 469/2009, as referred to in recital 4 in the preamble thereto."
- **1 March 2019-** CJEU Referral (UK). *Does the SPC Regulation preclude the grant of an SPC to the proprietor of a basic patent in respect of a product which is the subject of a marketing authorisation held by a third party without that party's consent?"*
    - Genentech SPC based on EP 1 641 822 based on Eli Lilly's MA for Taltz® (Ixekizumab).
- Other examples: Sovaldi® (Sofosbuvir), gliptins,

SPCs for Plant Protection Products

Regulation No 1610/96 "concerning the creation of a supplementary protection certificate for plant protection products".

The European Commission commonly defines plant protection products as containing "*at least one active substance and hav*[ing] *one of the following functions:*

- *Protect plants or plant products against pests/diseases, before or after harvest*
- *Influence the life processes of plants (such as substances influencing their growth, excluding nutrients)*
- *Preserve plant products*
- *Destroy or prevent growth of undesired plants or parts of plants*

They may also contain other components including safeners and synergists".

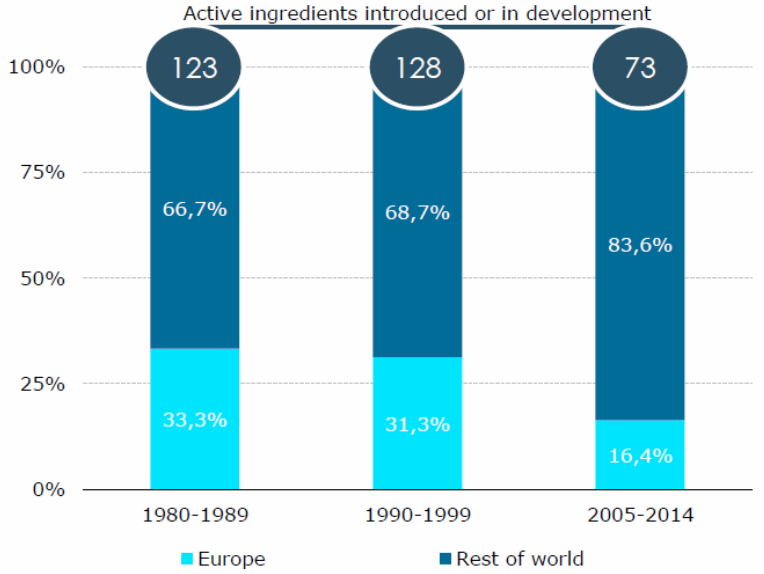
From:
European Commission.- Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe . Final Report. May 2018

SPCs for Plant Protection Products

- Significant difference between Agrochemicals and Pharmaceuticals
- From 1980 there's a decrease in innovation and an increase on R&D Costs: In 1995 the average cost was estimated to be USD 152m. In the years 2005- 2008, this estimate had increased to USD 256m.

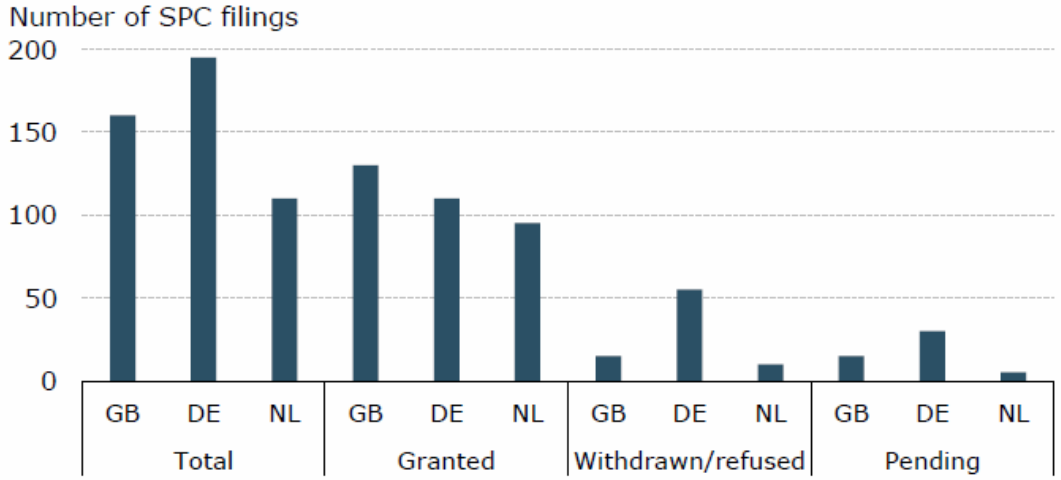
- No data protection (exclusivities, orphan, etc..)
- No Bolar provision

Number of active ingredients introduced or in development and distribution between Europe and the rest of the world, 1980-2014



Notes: The number of active ingredients introduced or in development within the agrochemical sector is depicted in the top three circles. The percentage distribution depicts the share of products which are focused on either the European market or the rest of the world.
Source: Arunasalam, V-C. & de Corte, F. (2016), Supplementary protection certificates for plant protection products: the story of 'The Ugly Duckling' and McDougall, P. (2013), R&D trends for chemical crop protection products and the position of the European Market.

Number of SPC filings within plant protection products for three patent offices between 1997 and 2015



Note: Graph showing the number of SPCs granted, withdrawn/refused and pending for plant protection products in the United Kingdom (GB), Germany (DE) and the Netherlands (NL).
Source: Reproduced from figure 1 in Arunasalam, V-C. & de Corte, F. (2016), Supplementary protection certificates for plant protection products: the story of 'The Ugly Duckling'.

From:
European Commission.- Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in
Europe . Final Report. May 2018

The Future of SPCs

Study on the Legal Aspects of Supplementary Protection Certificates in the EU. Final Report . Max Planck Institute for Innovation and Competition .

•33 recommendations

Recommendation No 7: Clarification of Art. 3(a) Reg. 469/2009 and Reg. 1610/96

We recommend clarifying the requirement under Art. 3(a) according to which the product must be protected by the basic patent.

The Study has identified three options:

- infringement test;
- an Art. 123(2) EPC standard-disclosure test; and
- (core-) inventive-advance test.

Recommendation No 14: Clarifying the status of the product description and its impact on the scope under Art. 4 Reg. 469/2009

We recommend clarifying whether a product description has to be included in the SPC application and what the legal effects on the scope of the certificate are.

Recommendation No 15: Biological products – soft law clarifying the scope

We recommend a clarification, according to which the scope of a biological SPC extends to all products having the same INN as the product covered by the MA submitted in support of the application, irrespective of differences in the manufacturing process between the biosimilar and the original product, provided that the basic patent protects the product as such, its use or the process for obtaining it.

Recommendation No 13: Entitlement to SPC and third-party MA issue

We recommend clarifying whether any patentee or only the patentee that has contributed directly or indirectly to the development of a marketable medicinal product and to the obtaining of an MA should be entitled to an SPC.

25.5 NATIONAL PRACTICE AND FURTHER HARMONISATION

Recommendation No 24: Guidelines for the examination

We consider it opportune to adopt guidelines providing the NPOs with common criteria for the examination. The issue of guidelines does not require amendment of the SPC Regulations. The Commission is already entitled under Art. 288 TFEU to adopt "recommendations and opinions" that may inform, without binding effect, the interpretation of Union law.

Recommendation No 27: Creation of a unitary SPC system

We recommend establishing a system for granting unitary SPCs.

The Future of SPCs

- **Unitary SPCs for Unitary Patents.**
  - SPC not included in UP
  - Unitary SPC favoured by large majority of respondents to Commission consultations.
  - Not clear who should grant U-SPC
  - Unitary SPCs with static or dynamic territorial coverage [1]

[1] **Study on the Legal Aspects of Supplementary Protection Certificates in the EU.** Final Report . Max Planck Institute for Innovation and Competition

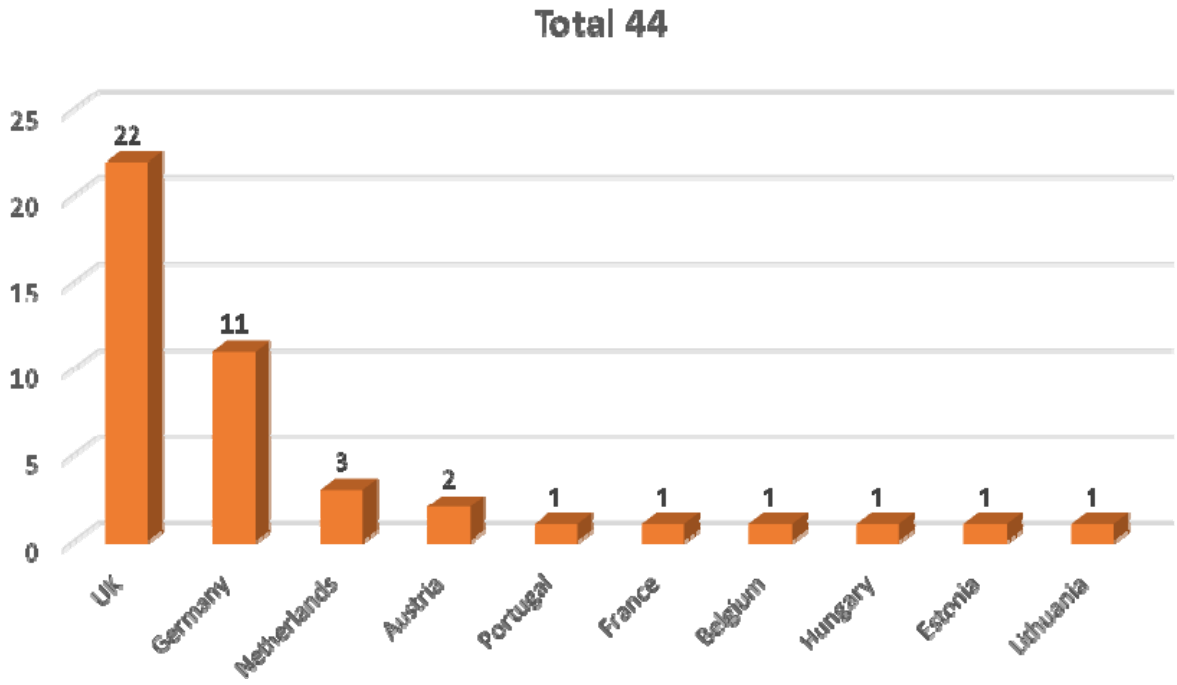
The Future of SPCs

- Manufacturing waiver. Proposal to be voted on April 3rd 2019.

- **Make**r
  - (-1) in Article 1, the following point is added: '(f) 'maker' means the person established in the Union on whose behalf the making of a product or a medicinal product containing that product, for the purpose of export to third countries or for the purpose of storing, is done;'
- **Effects:**
  - Making for export.
  - Making for day-1 launch.
- **Notification**
  - 3 Months before starting manufacturing.
  - To National Authority that will publish the information.
  - To SPC holder.
- **Entry into force**
  - July 2022 (or 3 years from approval).

The Future of SPCs

- 2019……Brexit (EU 27)
  - Current SPCs shall continue to apply in UK.
  - **UK MA for UK SPCs**. Different expiry dates UK vs. EU?
  - UK Courts may no longer refer cases to CJEU. Who will send questions?



The last referral from UK?

HP-2017-000044. Eli Lilly vs. Genentech. 1 March 2019.

The need for a reference

45. It can be seen from the Patent Judgment that I have concluded that all the claims of the Patent defended by Genentech are invalid. If that conclusion is correct, then it necessarily follows that the Application must fail. In those circumstances, it would at first blush appear that there is no need to refer the question identified above to the CJEU because the answer to the question would be academic.

47. `[…] As he pointed out, however, as matters currently stand, **there is a very real possibility that the courts of the UK will lose their jurisdiction to make references to the CJEU on 29 March 2019**. Since any judgment of the Court of Appeal would necessarily be given some time after that, it could well be the case that, whereas this Court currently has jurisdiction to make a reference, the Court of Appeal would not have jurisdiction to do so. In those exceptional circumstances, this Court should make a reference now. As he pointed out, it would be possible for the reference to be withdrawn later if circumstances changed.

48. [….] The reason for this was that the **dispute between Lilly and Genentech was not confined to the UK. Genentech had filed parallel applications for SPCs based on the Patent and the Taltz MA in other EU Member States. Accordingly, an EU-wide answer to the question was required, which only the CJEU could provide.**

49. Thirdly, he pointed out that **this issue had arisen in previous cases, as discussed above, but for varying reasons no question had been referred to the CJEU. Moreover, it was one which had been discussed by commentators. Accordingly, he submitted that it was an issue for the pharmaceutical industry generally which should be resolved sooner rather than later. Only the CJEU could provide a definitive resolution**.

50. I accept these arguments, and in particular the first one. Accordingly, I conclude that, in the current exceptional circumstances, it is necessary to refer the question to the Court of Justice even though I have concluded that the Patent is invalid.

https://www.bailii.org/ew/cases/EWHC/Patents/2019/388.html

Thank you!