

25 years of SPC protection for medicinal products in Europe: Insights and challenges

Malwina MEJER¹

May 2017

Abstract

This article documents increased use of SPCs protection in the EU since 1993. It attributes this trend to the establishment in 1995 of the centralized procedure for authorizing medicinal products and to the enlargement of the EU. SPCs for an innovative medicinal product are now being filed in 20 Member States on average. It further shows that the scope of protection is not uniform due to availability of the basic patent and differences in examination outcomes across national patent offices. While the geographical coverage of the basic patent is expected to increase in the future, efforts to harmonize the scope of SPC protection are needed as for one out of four products SPC applications results in different outcomes in different EU Member States.

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¹ Chief Economist Team, Directorate General for Internal Market, Industry, Entrepreneurship and SMEs, European Commission, 1049 Brussels, Belgium. email: malwina.mejer@ec.europa.eu

1. Introduction

The *effective patent life* is the period of time between a product's introduction to the market and the patent's expiration date. During this period the manufacturer of a product enjoys market exclusivity that may allow him to recover research and development costs. In industries that require regulatory approval to put the product on the market the effective patent life can be suboptimal to recover research and development costs. This is true for pharmaceutical and agrochemical industries where providing the evidence on the efficacy and safety of the product to protect human and animal health is both time consuming and costly.²

To compensate pharmaceutical companies for the time needed to comply with market authorization requirements the European Economic Community (EEA) enacted in 1992 the Supplementary Protection Certificate under Council Regulation No. 1768/92,³ hereafter "the SPC Regulation". The SPC Regulation aims at harmonizing the scope of SPC protection in the European Union (EU) by harmonizing substantive and, to less extent, procedural aspects of granting SPC rights with the ultimate goals to promote pharmaceutical research in the EU as well as to create a clear, transparent and simple (easy to apply) system.

This article documents the scope of SPC protection for medicinal products sought in the EU Member States under the SPC Regulation since its entry into force until 2016. Using detailed information on the SPC applications collected by Alice de Pastors, I show that since the entry into force of the SPC Regulation, the total number of SPC applications filed in the EU Member States has tripled – from about 500 applications filed in 1993 reaching its peak of 1,518 in 2013. Today, applications for SPC protection for an innovative medicinal product are filed on average in 20 EU Member States. I further show that establishment of the centralized procedure for authorizing medicinal products in 1995 that allows applicants to obtain marketing authorization valid throughout the EU, enlargements of the European Union as well as recent changes to pharmaceutical innovation contributed to this trend.

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 AB⁴ and Seattle Generics⁵ 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.

² In case of pharmaceutical industry the cost of discovery and development of new compound it to the market is exceptionally high and can vary between \$500 million to \$2 billion depending on the therapy or the developing firm. For the overview of the estimates of drug development process see DiMasi et al. (2014).

³ Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the *Creation of a supplementary protection certificate for medicinal products* subsequently codified as 469/2009.

⁴ The Court of Justice, 14 November 2013, C-617/12.

⁵ The Court of Justice, 6 October 2015, C-471/14.

Finally, using the example of vaccines I illustrate the multiplicity of SPC applications in the EU. The most outstanding example is the HPV vaccines - Gardasil and Silgard – for which more than 200 SPC applications have been filed in the EU with reference to one or both of these medicinal products. Such a situation results from fragmentation of the European patent system where SPCs are granted nationally combined with the possibility to file multiple SPCs with reference to a multi-component medicinal product and the plurality of basic patents holders.

This article is structured as follows. Section 2 introduces and discusses the provisions of the SPC Regulation. Section 3 describes the data used in this study. Section 4 analyse the trends in SPC applications and Section 5 the differences in the duration of SPC protection granted. In light of the results Section 6 concludes.

2. Supplementary protection in the EU

The SPC Regulation specifies the substantive conditions for obtaining supplementary protection and harmonizes application and, to a lesser extent, grant requirements. According to Article 3, the following conditions needs to be fulfilled in order to have supplementary protection granted:

- *the product* is protected by a *basic patent in force*
- a valid authorization to place the product on the market as a *medicinal product* was granted in accordance with EU rules
- the *product* has not already been a subject to the certificate
- the marketing authorization referred to is the *first authorization* to place the product on the market as medicinal product,

Article 1 of the SPC Regulation defines *product* as "the active ingredient or combination of active ingredients" and *medicinal product* as "any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals".

The duration of SPC protection is calculated on European Economic Area (EEA) - wide⁶ bases to assure equivalent expiry dates across its Members according to the following formula:

$$SPC\ term_{country\ i} = date\ of\ 1st\ MA\ in\ the\ EEA - date\ of\ patent\ filing_{country\ i} - 5$$

The duration of SPC protection is calculated as the period that elapses between grant of the first marketing authorization in the EEA and basic patent filing minus five years. The SPC term is subject to the maximum term of 5 years (Article 13) and an overall maximum of 15 years of exclusivity from the time the medicinal product in question obtains first marketing authorization (Recital 9).⁷

SPCs are national rights, therefore, in order to have SPC granted both marketing authorization and basic patent have to be valid in a given Member State. Marketing authorization to put a medicinal product on the market in a Member State can be granted either *directly* at national authority or in a *centralized authorization procedure*⁸ whereby the European Commission

⁶ The European Economic Area covers the Members of the European Union as well as Iceland, Liechtenstein and Norway.

⁷ In the US the patent restoration term under Hatch-Waxman Act provides 14 years of market exclusivity.

⁸ Regulation (EC) No 726/2004 *laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.*

grants marketing authorization based on the scientific assessment delivered by European Medicine Agency (EMA).⁹ Marketing authorization granted by the Commission is automatically valid in all EU conditional on the product being put on the market in one Member State only.¹⁰ The validity of national marketing authorization, however, is subject to putting the medicinal product on the market in that particular Member State.

For the basic patent, it can be applied for either at national or at the European Patent Office. In the period analysed, patents granted by the European Patent Office have to be nationally validated in order to be enforceable.

In what concerns application procedure, the SPC application has to be launched before the national patent office where the supplementary protection is sought. According to the rules laid out in Article 7, the application should be lodged within six months from the date of first marketing authorization in the EU to put the product on the market as medicinal product was granted; or in cases where the marketing authorization is granted before the patent, within six months from the date on which the basic patent is granted.

Even though the SPC Regulation provides conditions for obtaining a certificate (Article 3), the procedural aspects are harmonized to a lesser extent. For example, there is no obligation for the national patent office to ex-officio examine whether conditions put forward in Article 3 are satisfied. In what concerns the appeal procedures for the SPC applications the same rules as for national patent files should apply (Article 18)..

The SPC Regulation entered into force on January 1993 and in countries joining the EU in 2004, 2007 and 2013 on the accession date. Country specific transitional agreements were negotiated in relation to both the date of entry into force. In particular, in that Member States who did not allow for the patentability of pharmaceutical products before 01 January 1990 – i.e. Greece, Portugal and Spain – the SPC Regulation entered five years later, in 1998. It was further agreed that products covered by the basic patent for which first marketing authorization in the EU was granted before the entry into force of the Regulation but after the 1st January 1985 were eligible for the certificate but here as well Member States individually negotiated derogations from this rule. Table 1 summarizes the scope of those agreements for all current EU Member States.

Finally, some countries had national SPC provisions in place before the SPC Regulation entered into force. Among there were: Cyprus, Czech Republic, Estonia, France, Italy, Lithuania, Latvia, Malta, Sweden, Slovakia and Slovenia. The SPC Regulation in those countries supplemented or replaced national provisions.¹¹

⁹ All human medicines derived from biotechnology and other high-tech processes must be evaluated by the EMA via the centralised procedure. The same applies to all advanced therapy medicines and medicinal products containing new active substances intended for the treatment of HIV/AIDS, cancer, diabetes, neurodegenerative diseases, auto-immune and other immune dysfunctions, and viral diseases, as well as to all designated orphan medicines intended for the treatment of rare diseases.

¹⁰ The so-called "sunset clause" is regulated under Article 14(4-6) of Regulation (EC) No 726/2004. This provision leads to the cessation of the validity of the marketing authorisation if the medicinal product is not placed on the EU market within three years of the authorisation being granted or where a medicinal product previously placed on the market is no longer actually present on the market for three consecutive years.

¹¹ For example, Italy introduced the supplementary protection certificate for medicinal products with Law No 349 of 19 October 1991 extending the patent term up to 18 years after legal expiry. The law No. 112 of 15 June 2002 shortened the term to a maximum of five years – for the certificates issued under the national law - bringing the standard in line with the EU SPC Regulation. The same law provided a process of progressive reduction of extension equal to six months per calendar year which effect from 1 January 2004 until full alignment (c.f. Scuffi, 2015)

Table 1: SPC provisions and transition

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

Note: The EC Regulation No. 1768/92 was published in the Official Journal on 18 June 1992 and effective six month later (Jan 1993). ^(a) 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.

3. Data

The data on SPC applications for medicinal products used in this article has been collected by Madame Alice de Pastors, European Patent Attorney, hereafter “AdP database”. It covers information on 20,030 SPCs published in Official Journals or available in National Patent Registers, from 1991 to April 2016 for the 28 EU Member States, Switzerland, Norway and Iceland. For each individual SPC application the following data is available: country and date of SPC application, the name of a product (i.e. the name of active ingredient(s)) and that of a medicinal product, the number of the basic patent and its application date, country and date of the first marketing authorisation in the EU.

Information provided in the AdP database is not harmonized and its scope differs from one Member State to the other. For example, while some national patent offices publish the trade name of the medicinal product next to the date of first marketing authorization others do not. Differences are also present regarding the reference to product and basic patent. In cases where the basic patent was applied and granted by the EPO some national patent offices publish the EPO publication number, others refer to national publication of the EPO grant.

For the purpose of statistical analysis presented in this article the data has been cleaned in the following way. First, product names have been harmonized to reflect the WHO substance name where possible.¹² Second, where information on trade name of the medicinal product is missing it has been inputted based on supplementary information available in the database.

With regard the first marketing authorization date the two following assumptions are made. I use the date of the grant of marketing authorization and not its publication date; and in cases where both EU and Swiss marketing authorization dates are cited with reference to the same medicinal product I refer to the marketing authorization in the EU as a reference.

Furthermore, I add information on biological origin of a medicinal product and match the patent numbers to the EPO's Worldwide Patent Statistical Database (Patstat) in order to identify equivalent patents across countries.¹³ This allows me to analyse the outcomes of examination process by looking at product-patent pair.¹⁴ The geographical coverage of patent analysis is, however, smaller as information on basic patent published by Estonian, Hungarian, Greek and Maltese patent offices do not correspond to information in Patstat.

Finally, I focus on those SPCs applications that were filed under the SPC Regulation,¹⁵ in the EU Member States that refer to the first marketing authorizations granted between 1993 and 2014. This leaves me with the final sample of 15,119 SPC applications referring to 909 products and 891 medicinal products.

In the analysis that follows, I use the date of the granting of the marketing authorization as a reference date. This is to better recover the trends and avoid double counting of medicinal products or products in cases where SPC applications covering the same product were filed in two different years.

¹² For example, in case of product *abacavir* two names are reported: *abacavir sulfate* and *abacavir*. I use the latter name as it appears in the WHO INN list.

¹³ Equivalent patents are defined as patents that belong to the same family defined as group of patents that share exactly the same set of priorities.

¹⁴ Information available in Patstat database, however, does not allow to distinguish patent pairs where multiple SPCs have been filed for the same product based on more than one basic patent, all of which cite the same prior art. This is for example the case the two basic patents - EP0595935 and EP1298211 filed on 20/07/1992 – covering the product titled HPV (TYPES 6, 11, 16, 18) L1 PROTEINS.

¹⁵ Information in the AdP Database allows distinguishing between SPCs granted under national and European law. As mentioned in former section, few countries had national SPC laws in place before the entry into force of the SPC Regulation. There are 1,290 SPC granted under national law, 85% of them before 1996.

4. SPC applications in the EU

Since the entry into force of SPC regulation in 1993, the total number of SPC applications filed in the EU Member States has tripled – from nearly 507 in 1994 reaching its peak of 1,518 in 2013. The detailed annual changes are presented in Figure 1 (bold blue line). Until 2004 the number of SPC application was stable at the level around 500. After year 2004 we see two trends: the overall increase in the total number of applications and greater fluctuations from one year to another.

There are different factors explaining this trend: frequent use of centralized procedure for innovative products, enlargements of the European Union, development of medicinal products consisting of multiple active ingredients (i.e. multi-component products) and the possibility to designate multiple patents with reference to the same medicinal product for the purpose of SPC grant. In what follows I will analyse each factor separately.

4.1. Geographical scope of protection

Figure 2 illustrates the average number of countries where the SPCs covering the same product were lodged. A clear increasing trend is depicted. By the end of 1990s the average number of EU Member States reached ten and then over the next fifteen years it then nearly doubled, reaching its maximum of 20 Member States in 2014.

One of the factors behind overall increase in the number of SPC applications has been the geographical expansion of the EU in 2004 and 2007 as the number of EU Member States where the SPC could be applied for has increased. The number of SPC application in countries that joined after 2004 is shown by thin red line on Figure 1. From 2004 to 2014 the number of SPC applications in those countries increased from 144 to 428 at the end of the period.

Establishment of the EMA in 1995 also contributed to this trend as indicated by the increased reference to centralized marketing authorizations in the SPC applications. In 1996 only 6% of products were covered in medicinal products authorized centrally by the Commission. In 2000 it was 40% and by 2010 the share reached almost 90%. The geographical scope of the SPC protection for the products covered in centrally approved medicines is on average about 70% larger than that for medicines approved nationally.

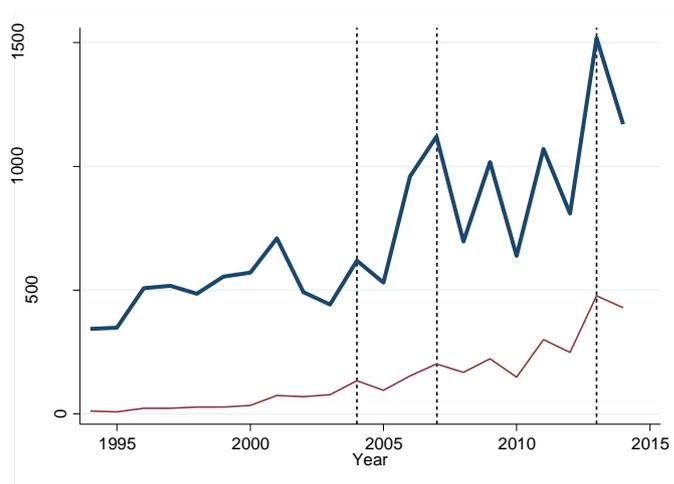
It is important to note that the geographical scope plotted in Figure 2 reflects the scope of product not a basic patent protection. The necessary condition for the SPC to be applied for is the availability of basic patent in force covering the product. Analysis of patent data in the AdP database shows that the average geographical scope protection of the basic patent increased from six Member States, for patents filed in 1984, to almost 13 for patents filed in 2004.¹⁶ In the future the geographical scope of the basic patent is expected to increase due to EU enlargements and possibility of having the EPO granted patents validated in the accession states.¹⁷

The analysis presented here shows only the geographical scope of product and basic patent protection at the moment of filing SPC. What it does not show is the number of Member States in which those patents are maintained until the end of patent life and during the SPC period.

¹⁶ This is lower bound as patents granted or validated at Estonian, Hungarian, Greek and Maltese patent offices are not taken into account – see Section 3 for details.

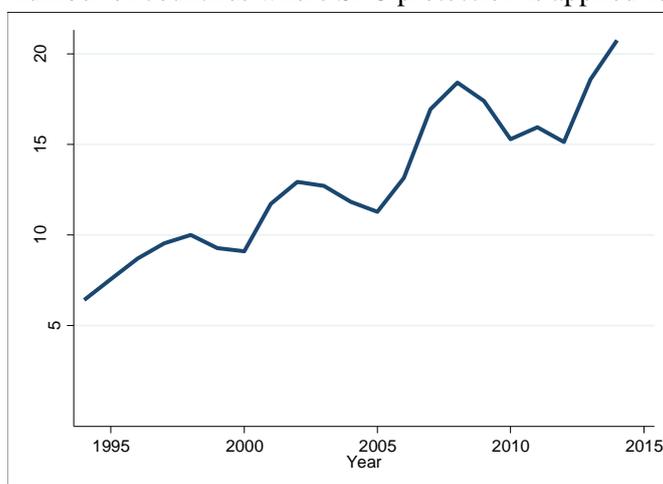
¹⁷ Estimates provided by Kyle (2017) shows that the average effective patent life is over 12 years. So the SPCs filed today are filed for basic patents granted by the EPO prior to the Central European enlargement.

Figure 1: Number of SPC applications in the EU, by first marketing authorization year



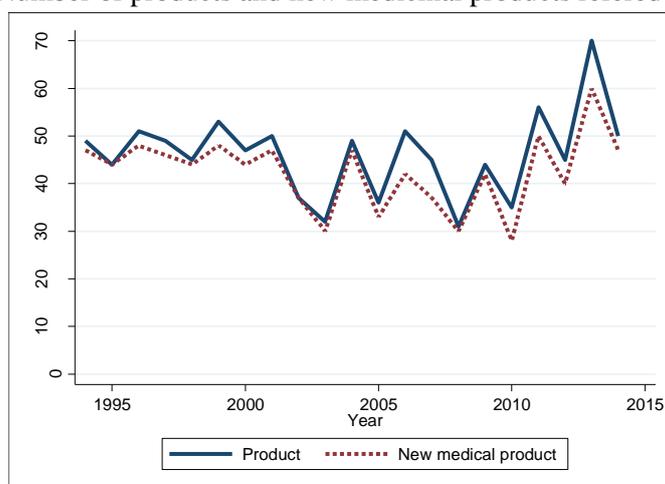
Notes: The bold blue line present the number of SPC applications in the EU28 and the thin red line the number of SPC applications in all 13 Member States that joined in 2004 and after. A vertical dashed line indicates subsequent enlargements in 2007 and 2013. Source: Based on AdP SPC Database.

Figure 2: Average number of countries where SPC protection is applied for the same product



Note: The line presents average number of EU Member States where SPC related to the same product was applied for. Source: Based on AdP SPC Database.

Figure 3: Number of products and new medicinal products referred to in SPCs



Note: The figure plots the number of new medicinal products (red dotted line) and the number of products (bold blue line) referred to in SPC applications. Source: Based on AdP SPC Database.

4.2. Products and medicinal products referred in SPCs

Supplementary protection combines two systems: patent protection and marketing authorization which have very different aims and approaches (e.g. Katzka, 2008; Papadopoulou, 2016). According to the Article 3 of the SPC Regulation supplementary protection can be granted to the owner of *basic patent* in force covering the *product* with a valid authorization to place the *product* on the EU market as *medicinal product*. The product is considered as an active ingredient or combination of active ingredients of a medicinal product. The Regulation further specifies in Article 4 that the SPC shall be granted only to "*the product covered by marketing authorization [...] and for any use of the product as medicinal product*". The *product* term is therefore neither equivalent to term 'invention' or 'medicinal product' thus making the relationship between patent scope and that of SPC a complex one. The AdP data shows that about 5% of products refer to more than one medicinal product.¹⁸ The interpretation of *product* has been frequently challenged in the national disputes resulting in additional interpretation provided by the EU Court of Justice.

Figure 3 plots the number of products and medicinal products covered in SPC applications filed under the SPC Regulation since its entry into force in 1993. The number of medicinal products has been stable at the beginning of the period, reaching lower levels after 2000 and eventually increasing during the last four years. This pattern is consistent with an observation that discovery of small molecule drugs follows a Poisson distribution in which approvals fluctuate around a constant, low level (Munos, 2010). There are expectations that recent experiments to rejuvenate the R&D model could improve the rate at which new medicines are discovered and brought to the market. The recent increase in the number of new drug introductions suggests that this could be the case.¹⁹ Furthermore, using the IMS Health data Kyle (2017) documents that the share of new drug introduction which has an SPC in at least one country increased from 75% in the early 1990s to 86% more recently.

4.3. Multi-component products

In principle, the *one medicinal product - one product - one SPC rule* should apply. However, such a rule does not always hold as illustrated in Figure 3. At the beginning of 1990s the number of products closely follows that of medicinal products. However, larger gaps occur early in years (1999, 2006 and 2007) and then systematically after 2010. These gaps reflect developments in oncology, anti-asthmatic and hypertensive treatments where therapies are developed as combinations of active ingredients administrated with just one preparation – i.e. multi-component products.²⁰ In such cases, SPCs can be filed for different combinations of active ingredients thus contributing to the increased volume of SPC filings beyond of what would be predicted by the number of marketing approvals.

Multi-component products²¹ account for about 5% of all innovative medical products. Figure 4 shows the share of multi-component medicinal products with a distinction between medicines manufactured in chemical synthesis (i.e. chemical medicines) and those semisynthesized from biological sources (i.e. biological medicines). The share of medicines covering multiple components is higher for biological, in particular vaccines, when compared to traditional medicines.

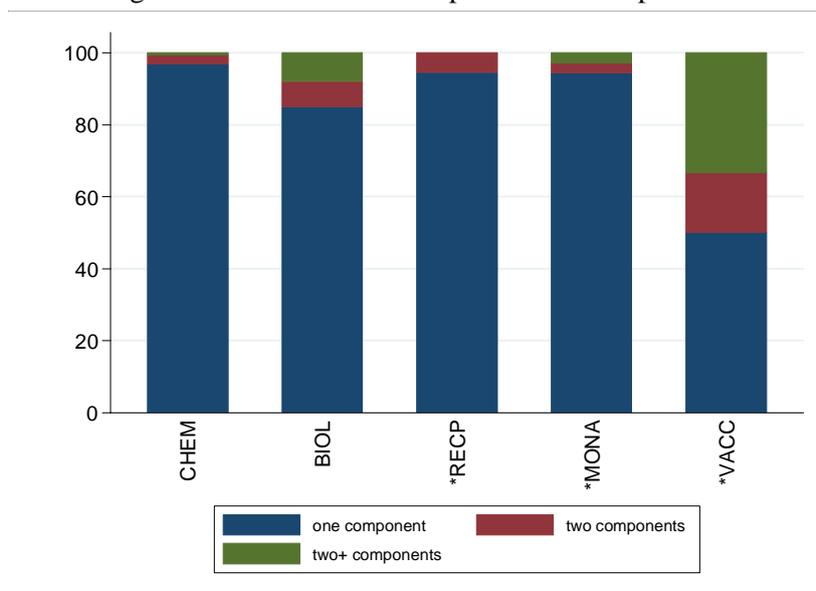
¹⁸ Among them there are: *dabigatran etexilate* (simple chemical entity), *dabigatran etexilate (Pradaxa)* or *pasiretite (Signifor)* (biological products) or HPV (vaccines).

¹⁹ See also Graul et al. (2010, 2015) for statistics on the number of first drug and biological approval since 1999.

²⁰ An example is *Vectibix* a cancer therapy developed by Amgen.

²¹ I consider multi-component medicines as those for which an SPC has been filed with reference to more than one component.

Figure 4: Share of multi-component medical product



Note: Medicinal products are classified into two main groups: medicines manufactured in chemical synthesis (CHEM) and medicines semisynthesized from biological sources (BIOL). Out of 891 medicinal products in the data, 125 are biological medicines. The Figure further distinguishes between different kinds of biological medicines: recombinant proteins (*RECP), monoclonal antibodies (*MONA) and vaccines (*VACC) which represents 42%, 28% and 19% of biological medicines.

4.4. Products protected by multiple patents

The SPC Regulation states that for the SPC to be granted the product has to be protected by the *basic patent* in force. In practice, however, where the product is protected by a number of basic patents in force, any of those patents may be designated for the purpose of the procedure for the grant of a certificate (c.f. *Medeva*,²² *Gorgetown*²³ or *Queensland*²⁴ cases). Furthermore, when there is a plurality of holders of patents related to the same product, each patent holder might get an SPC disregarding whether any of the other holders has been granted an SPC or their application is pending (c.f. *Biogen*²⁵ and in *AHP Manufacturing*²⁶).

The data shows 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.²⁷

4.5. Case study: Vaccines

Table 2 illustrates the multiplicity of SPC applications in the sample of vaccines. The most outstanding examples are human papillomavirus vaccines: Gardasil, Silgard and Cervarix. Overall there were more than 250 SPC applications filed in the EU with reference to Gardasil, Silgard or both and 162 for Cervarix. Unfortunately, information provided in the data does not allow for clear distinction between SPC applications referring to Gardasil or Silgard.²⁸

²² Court of Justice, 24 November 2011, C-322/10.

²³ Court of Justice, 24 November 2011, C-422/10

²⁴ Court of Justice, 25 November 2011, C-630/10.

²⁵ Court of Justice, 27 January 1997, C-181/95.

²⁶ Court of Justice, 3 September 2009, C-482/07.

²⁷ For example in case of *aliskiren* (medicinal product *Rasilez*) in Denmark two SPC was filed for two patents: EP0678503 filed on 7/4/1995 by Novartis and EP1303478 filed on 26/6/2001 by Speedel Pharma.

²⁸ The marketing authorization date is the same for both products so are the names of active ingredients and the number of basic patents. This combined with the incomplete information on trade name makes it very difficult to precisely assign products and patents to a given medicinal product.

Therefore, numbers should be interpreted as an upper bound when referenced to single vaccine.

Table 2: Number of products, patents and SPC applications filed with reference to a single vaccine

Therapy	Medicinal Product	MA date	Number of distinct:			
			Products	EPs	Country	SPCs
Ankara	IMVANEX	31/07/2013	1	1	17	17
Diphtheria, tetanus & pertussis	INFANRIX HEPB	30/07/1997	3	1	9	9
	INFANRIX HEXA	23/10/2000	1	3	14	36
	INFANRIX PENTA	23/10/2000	2	3	14	30
Hepatitis B	HEPACARE	04/08/2000	1	1	11	11
Human papillomavirus	GARDASIL & SILGARD	20/09/2006	10	10	20	252
	CERVARIX	20/09/2007	5	7	18	162
Influenza	DARONRIX	21/03/2007	1	3	16	32
	FOCETRIA	02/05/2007	1	3	15	31
	OPTAFLU	01/06/2007	1	2	15	21
	PREPANDRIX	14/05/2008	2	5	17	88
	INTANZA	24/02/2009	1	1	5	5
	CELVAPAN	04/03/2009	3	2	14	17
	FLUENZ	27/01/2011	2	3	5	13
JP Encephalitis	IXIARO	31/03/2009	1	1	8	8
Meningococcal	MENVEO	15/03/2010	7	5	19	88
	NIMENRIX	20/04/2012	4	4	26	42
Neisseria meningitides	BEXSERO	14/01/2013	7	9	26	114
Pneumococcal	PREVENAR	02/02/2001	2	1	12	23
	SYNFLORIX	30/03/2009	1	4	19	60
Rotavirus	ROTASHIELD	07/05/1999	5	1	9	11
	ROTARIX	21/02/2006	1	1	23	23
	ROTATEQ	27/06/2006	1	1	7	7
Herpes zoster	ZOSTAVAX	19/05/2006	1	1	14	14

SPCs for medicinal products Gardasil and Silgard has been filed in 20 EU Member States, with reference to a total of 10 distinct products and 10 distinct basic (European) patents on which lists 8 different applicants.²⁹ Multiplying the number of products by number of patents and number of countries, however, would indicate that about 400 applications should be filed that is higher than 252 indicated. A closer look into the data shows that the variety of products is higher in EU15 (e.g. 10 in UK) than in EU10 (e.g. only one in PL) which could be partly explained with availability of the basic (European) patent in force in a given Member State. This example illustrates the complexity of the scope of protection across Member States.

5. Duration of SPC protection

As outlined in the Section 2, the duration of protection is dependent upon date of first authorisation in any EU Member State and the expiry of the basic patent in the country in which the application is made. SPCs are national rights and separate applications must be

²⁹ Among them: Chicago Loyola, Georgetown, Queensland, Rochester, GlaxoSmithKline, Merck, Medimmune, US Health Secretary.

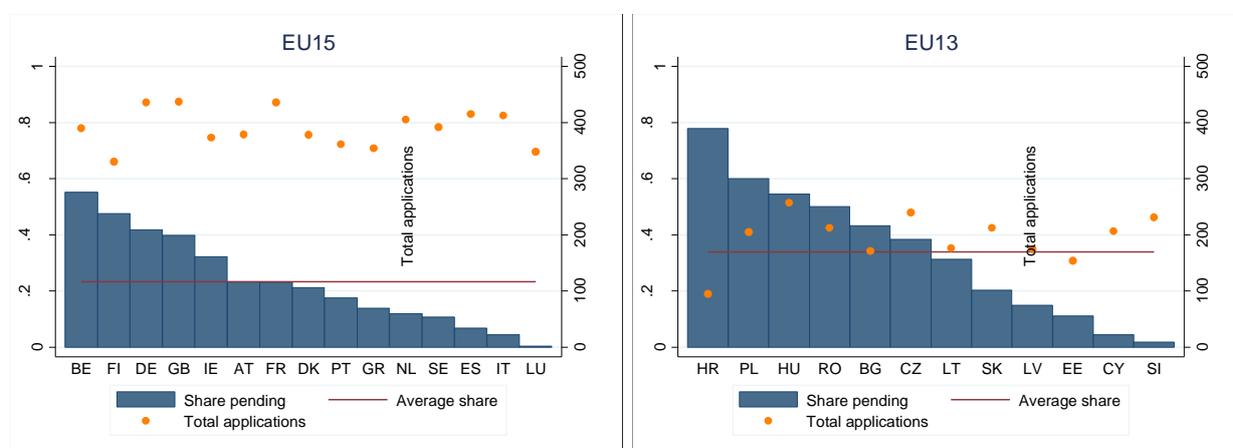
lodged in each EU Member State. To have an SPC granted both marketing authorization and basic patent has to be valid in a given Member State.

By making the reference to the first marketing authorization in the EU, the legislator aimed to assure homogenous expiry dates across Member States. In reality, however, the scope of harmonization remains limited. For SPCs covering the medicinal products approved between 2004 and 2014, the expiry date for as much as 80% of products making the reference to the same basic patent is not homogenous across Member States.³⁰ This significant level of divergence is driven by the differences in national examination and interpretation of marketing authorization date.³¹

5.1. Status of SPC applications

For the medicinal products approved between 2004 and 2014, Figure 5 shows the ratio of pending applications and Figure 6 the ratios for granted, rejected and withdrawn applications. Both figures display total number of applications received (right scale) and group countries depending whether they joined the EU before May 2004 (EU15) or after (EU13).

Figure 5: Share of pending SPC applications in total applications filed (2004-2014)



Note: EU Member States are grouped according whether they were Members of the EU before 2004 (left panel) and after (right panel). The figure shows the share of pending applications in the total number of SPC applications for medicinal products approved between 2004 and 2014 (left scale) and the total number of applications received (right scale).

The share of pending applications – also refer to in the literature as backlogs³² - differs across Member States. The average share is slightly higher for EU13 (34%) than for EU15 (23%). This is partly due to Croatia that joined EU only in 2013 but received high number of SPC applications referring to marketing authorizations dating back to 2003 (c.f. Table 1).

³⁰ Only the extension due to SPC is taken into account. The difference is calculated as difference between the earliest SPC expiry date and the latest expiry date for the same product-patent pair. Date of expiry of the SPC in the AdP database is calculated from the dates of the patent and marketing authorisation (anniversary of patent or MA date or date less one day). For granted SPCs, the expiry dates are the dates shown in gazettes or official documents. When the SPC has been rejected or withdrawn the expiry date is the patent expiry date. When the basic patent or the SPC has ceased to have effect, the SPC expiry date is the date of the loss of the corresponding right.

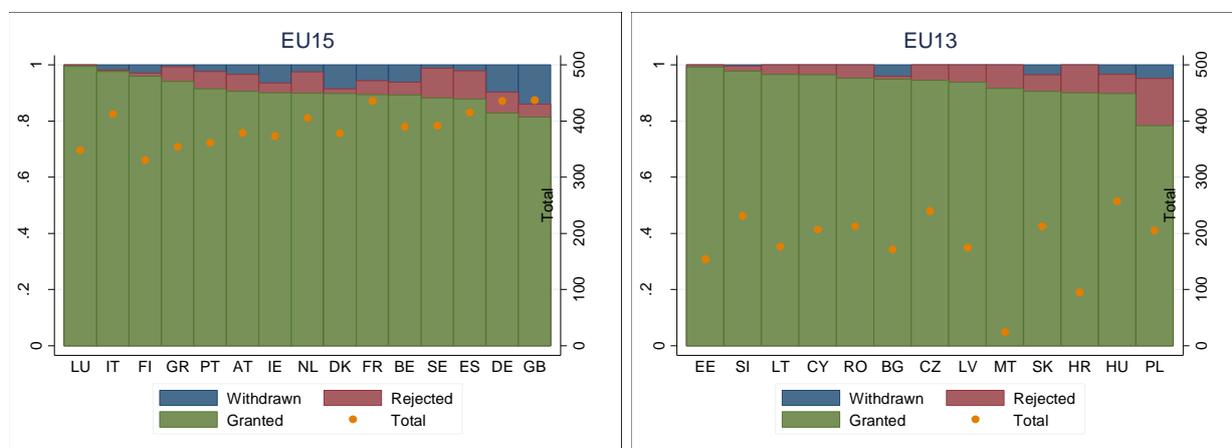
³¹ Another potential source of divergence could be the date of the basic patent application as it is application and not the priority date that is taken into account. However, the vast majority of SPC applications today are based on the patents granted by the EPO thus in principle refers to the same application date that is the date of application at the EPO.

³² Mitra-Kahn et al. (2013) discusses different drives behind the patent application backlogs and pendency at patent offices in the United Kingdom and the United States.

The backlog is not related to the volume of applications received. While Germany, United Kingdom, France and Italy receive very similar number of applications the share of pending applications is four times lower in France and Italy (less than 10%) when compared to Germany or UK (about 40%). These differences in backlog size could be explained by differences across national offices in the examiner capacity, examination proceedings³³ and the differences in the interpretation of substantive patent law by national offices. Unfortunately, the lack of information on how these procedural aspects differ across Member States does not allow me to analyse the issue in more detail.

Figure 6 shows the outcome of the SPC examination process – the share of SPCs granted, rejected in the patent office final decision or withdrawn by the applicant during the examination process. In general, for more than 80% of SPC applications for which the decision was taken had been granted. Among countries with the lowest grant rate there are: the United Kingdom, Germany, Sweden and Ireland as well as Hungary, Poland. Lowest rejection and withdrawn rates are being observed in the smallest Member States e.g. Luxembourg, Finland or Estonia. There is some evidence, at least for the EU15 that higher volume of SPC applications examined results in lower grant rate.

Figure 6: Share of SPC applications granted, rejected and withdrawn (2004-2014)



Note: EU Member States are grouped according whether they were Members of the EU before 2004 (left panel) and after (right panel). The figure shows the share of granted, rejected or withdrawn applications with respect to the number SPC applications referring to medicinal products approved between 2004 and 2014 for which decision was taken (left scale) and the total number of applications received.

The difference in grant rates across Member States suggests that there is a scope for divergent decisions concerning the outcomes of SPC applications for the same product-patent pair lodged in two or more Member States thus contributing to differences in SPC expiry dates. The data shows among 740 products approved between 2004 and 2014 and referring to the same basic patent no decision has been taken with respect to 34. Out of remaining 706 applications, 26% (182) were granted in one Member State but rejected or withdrawn in the other. This is a bit higher than withdrawal/rejection rate of 20% in Germany and in the United Kingdom.

³³ Registration, renewal and invalidation of SPCs are not harmonized under the SPC Regulation. For example, national patent offices may conduct *ex-officio* examination or examine on formalities only. The former requires more resources and is more time consuming than the latter thus higher backlog. Furthermore, in cases where there is a pending case in front of national court concerning the patent for which SPC is applied for, some patent offices will wait with their grant or rejection decision until the court issue a judgement (e.g. UK), others would not. For those that do, the backlog is expected to be higher.

5.2. First marketing authorization

For the calculation of the SPC term the Regulation specifies that the date of the *first marketing authorization* to put the product on the market as medicinal product in the EEA should be used as a reference and that marketing authorization should be granted according to the EU rules.

Figure 7 shows the scope of differences between the first marketing authorization date in the EU and the one reported in the SPC applications filed in different Member States for the same product-patent pair. The existing ambiguity on the first marketing authorization date comes from two sources: ambiguity on the use Swiss marketing authorization date and ambiguity on interpretation on the grant date. Following de Pastors (2015) a two-week difference threshold have been chosen as it captures the cases related to different interpretation of the grant date.

In what concerns the reference to Swiss marketing authorization, 10% of products has been filed with reference to both marketing authorization dates: one in Switzerland and one in the EU. In two thirds of those cases the difference exceeds two weeks. The actual difference, however, can be much longer as illustrated in *AstraZeneca AB v Comptroller-General of Patents* case³⁴ where AstraZeneca referred to marketing authorization by Swiss authority granted in 2004 and to the Commission granted in 2009 when filing for SPC application in Member States. The EUCJ clarified in this case that AstraZeneca's 2004 Swiss marketing authorisation, and not its 2009 EU authorisation, is the “first authorisation” for the purpose of calculating the duration of the SPC.³⁵

Figure 8 looks at the marketing authorization granted through national route and Figure 9 concerns those cases where marketing authorization was granted by EMA. The pattern for national authorization is different than the one for EMA (centralized) authorizations. The share of patent-products for which the same first marketing authorization date is cited across Member States is higher for national marketing authorizations than for those granted by the Commission; so is the share of cases where the difference exceeds two weeks. The latter might be due to the possible discrepancy in referring to subsequent national marketing authorization date due to the lack of transparency and coordination across Member States.

In what concerns the cases where the first marketing authorization cited is that of the Commission, the difference in marketing authorization dates is smaller than two weeks. The reason behind this is that there are two dates associated with the grant of marketing authorisation: the date of the decision to issue an authorisation and the date of notification of that decision to the marketing authorization applicant. The notification date is frequently cited in Belgium and United Kingdom and to lesser extent in Portugal, Estonia and Italy.

In 2015, in its ruling in *Seattle Generics* case,³⁶ the EUCJ provided clarification the definition of marketing authorization date. The court ruled that the “date of the first authorisation to place the product on the market in the [European Union]’ within the meaning of that provision is the date on which notification of the decision granting marketing authorisation was given to the addressee of the decision.” For SPCs granted after October 6, 2015 the duration date will be calculated using the notification date so the identified discrepancies should remove (as noted in de Pastors, 2015).

³⁴ The Court of Justice, 14 November 2013, C-617/12.

³⁵ Switzerland is not a member of European Community. However, the ECJ argued that since the marketing authorizations granted in Switzerland are automatically valid in Liechtenstein and Liechtenstein is a member of the EEA, the Swiss marketing authorization should be considered and the first marketing authorization for the purpose of calculating the duration of SPC.

³⁶ The Court of Justice, 6 October 2015, C-471/14.

Figure 7: Differences in the first MA date for the same product-patent pair

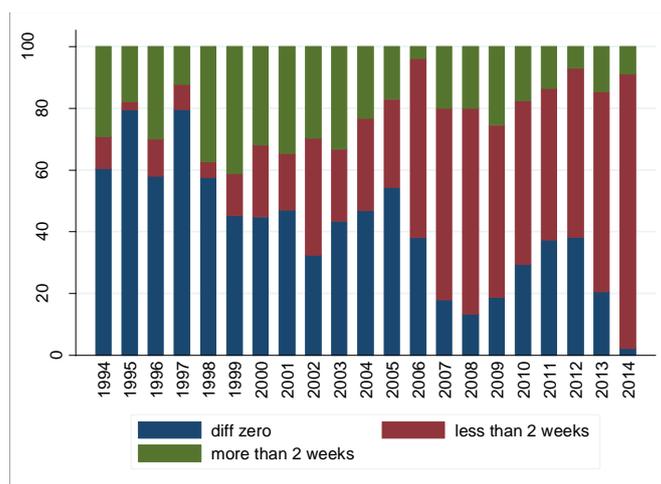


Figure 8: Differences in the first MA where national MA is referred to

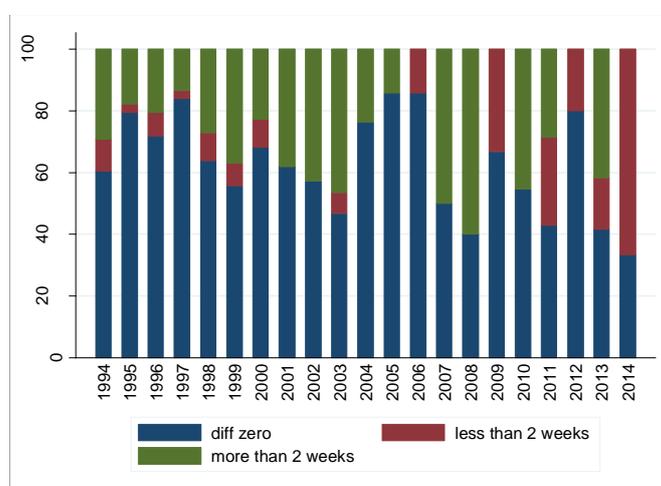
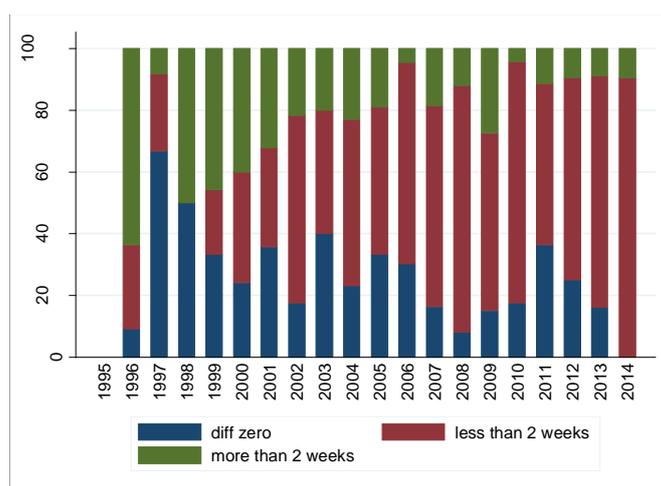


Figure 9: Differences the first MA date for centralized MA is referred to



Note: For each year the figures shows the share of products for which marketing authorization date differ across countries by zero (was exactly the same), less than 2 week and more than two weeks. The differences are calculated as the maximum difference between the first marketing authorization date in the EU and the one reported on the SPC applications filed for the same product in different Member States.

To sum up, for SPCs covering the medicinal products approved between 2004 and 2014, out of 740 distinct product-patent pairs the expiry date for as much as 590 (80%) is not homogenous across Member States. For 182 cases the existing discrepancy in expiry dates

can be attributed to divergent decisions taken by the national IPO (or applicant in cases of withdrawal of the SPC application). In 431 cases the discrepancy can be attributed to differences in reporting or interpretation of marketing authorization date.

In the future the discrepancies in the first marketing authorization date will disappear. This is, on one hand, due to the increasing reference to the Commission authorizations that induces transparency, on the other, due to the judgements of the EUCJ on the first marketing authorization cases.

6. Conclusions

This article documents that in the EU the use of SPC protection has significantly increased since 1993. Establishment of the EMA in 1995 and later expansion of the EU contributed to this trend. Today SPC protection for a single medicinal product is filed on average in 20 EU Member States. Furthermore, developments of therapies based on multi-component medicinal products and the possibility to file SPC over multiple patents increased the scope of individual product protection as 20% of products that are tied to more than one basic patent.

It further shows that the scope of protection is not uniform across EU Member States due to availability of the basic patent(s) and differences in examination outcomes across national patent offices. While the geographical coverage of the basic patent is expected to increase in the future due to the past expansion of the EU and related to its possibility to validate the EPO granted patents in new Member States, further harmonization efforts should be made to assure coherent examination outcomes across national patent offices.

Greater coherence of examination outcomes could be achieved through increased clarity on the scope of medicinal product protection and harmonization of national SPC granting procedures. Coordination across national patent offices and exchange of information on SPC applications might facilitate this process further. More coherence and transparency is expected to reduce the divergence in the scope of protection for originators as well as may improve legal certainty for generic entrants.

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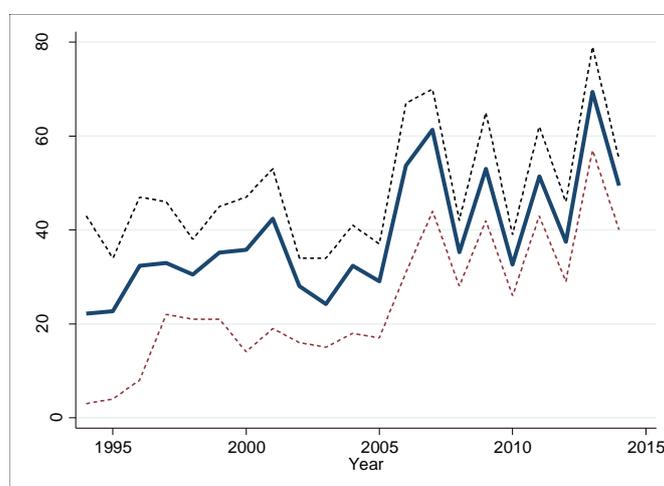
Appendix A

Country Statistics

These trends are also confirmed in Figures A.1 and A.2 that plot the average number of SPC applications in the group of EU15 Member States and that of EU13 respectively. Until 2004 the average numbers of SPC filings in the EU15 remain at the level of 30. It then shifted to about 50 applications annually. The highest number of SPC filings has been recorded in the biggest markets DE, FR, IT and UK – with the maximum level of 80 in 2013 – and the lowest in FI, GR, LU and PT. For EU13 the number of SPC applications increased from about 10 in 2004 to more than 30 in 2014. In this region among Member States with the highest level of SPC applications there are HU, CZ, SK and SI. The very small economies MT and Baltic States recorded the lowest levels.

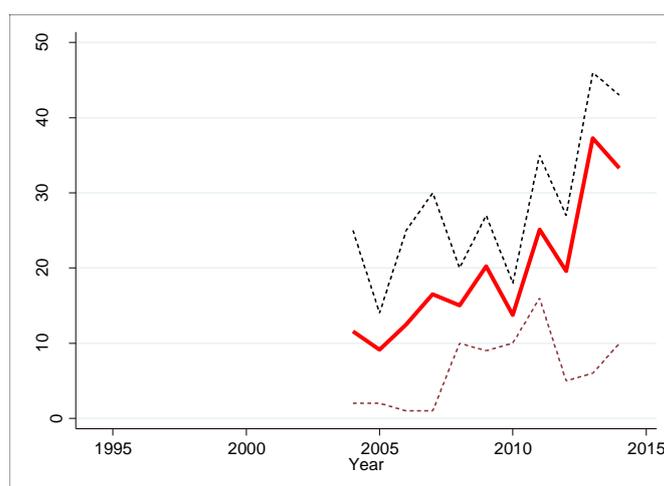
There is an increase at the country level, which suggests that the recent increase in filings, as shown in Figure 1, cannot be solely attributed to the EU enlargements. In the next section we will analyse trends in the number of products for which SPC was requested.

Figure A.1.: Average number of SPC applications in EU15



Note: The bold blue line shows the average number of SPC applications in the EU15 Member States. The dashed lines above and below show the maximum and minimum number of applications in the same sample of countries.

Figure A.2.: Average number of SPC applications in EU13



Note: The bold blue line shows the average number of SPC applications in the EU13 Member States. The dashed lines above and below show the maximum and minimum number of applications in the same sample of countries. Applications for marketing authorizations that were granted before 2004 are not taken into account.