Economic Analysis of Supplementary Protection Certificates in Europe

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Executive Summary

This report provides a description of the use of supplementary protection certificates (SPCs) in Europe, focusing primarily on those for pharmaceuticals. The key findings include:

- Development times of pharmaceuticals developed from 1990-2015 have increased by more than 2 years on average, while the lag between the first global launch and the first EU launch has fallen by 1.4 years.
- The average period of protection provided by basic patents and SPCs, where applicable, is over 12 years.
- The use of SPCs has increased: a higher share of products (now 86%) is covered, and in more countries (now more than 18).
- In 80% of cases, SPC applications are tied to a single patent. However, in the remaining cases, firms have requested SPCs on additional patents. SPCs are less likely to be granted in such cases. The most common type of patent associated with an SPC is a product patent.
- There is no clear geographic bias in the use of SPCs by the location of patent holders. Almost 44% of SPC applicants are US-based, while the EU has close to 30%, followed by Japan and Switzerland at roughly 7% and 6%, respectively. These figures track those of the geography of R&D activity overall.
- SPCs and secondary patents, as well as the use of the centralized approval pathway, are associated with faster generic entry. This is likely because more valuable products are more likely to be protected with SPCs and secondary patents as well as to attract generic entry.
- Due to limited data availability, far less is known about the use of SPCs for plant patents.
- There is substantial heterogeneity across member states in the number of SPC applications and in the probability of SPC grants.
- Since SPC applications sometimes have different outcomes in different countries, efforts to harmonize SPCs across member states, either through the use of a unitary SPC or through improved information sharing, would reduce the variation in the intellectual property landscape and the uncertainty for generic entrants.
- A more complete analysis of the effects of SPCs on entry and prices, as well as on R&D incentives, is important for understanding whether SPCs are a valuable policy instrument.

1 Introduction

This report provides a description of the use of supplementary protection certificates (SPCs) in Europe, focusing primarily on those for pharmaceuticals. After describing the industrial organization and regulation of the pharmaceutical sector, the report details the role of intellectual property rights and supplementary certificates. A quantitative analysis of how the use of SPCs has evolved over time, by type of firm, and across countries is provided in Section 4. Section 5 discusses the implications for policy.

2 Background

2.1 Industry structure and regulation

Drug development generally is characterized by large fixed and sunk costs, particularly large-scale clinical trials. Estimates of these out-of-pocket costs are on the order of $1.395B (approximately €1.05B), with an average of 10 years in development (DiMasi et al. (2014)). Once a safe and effective treatment has been identified, the marginal costs of production are relatively low, particularly in the case of small molecule drugs.

Historically, firms in the pharmaceutical sector have pursued one of three business models. The first is that of a large multinational firm that invests significantly in research and development (R&D) to bring novel treatments to market. They also spend substantial sums to market their products, through detailing visits to prescribers or advertisements in medical journals, for instance. Pfizer, GlaxoSmithKline, Sanofi, and Roche are prominent examples. The second business model is that of a smaller firm, usually focused on biotechnology or large molecule drugs, that often partners with multinationals in the later stages of development of product launch. Finally, the generic sector is composed of firms that invest little in the development of new compounds or on marketing, but instead focus on producing older drugs at lower costs.

The boundaries between these business models are increasingly blurred. Many large multinationals own generic subsidiaries, and develop biological products in addition to small molecules. Some biotech firms, such as Amgen and Gilead, have the capacity to market their products globally, and invest in small molecules as well as biological products. There are now examples of traditionally generic firms that have initiated their own efforts to development novel compounds, including Teva and Dr. Reddy's. Nevertheless, the distinct business models are important for understanding the role of patent protection and other forms of intellectual property. For simplicity, I will refer to the large multinationals and the smaller biotech firms as the "innovators" for the purposes of regulation, in contrast to the generic sector.

To obtain marketing authorization in Europe, innovators must provide the clinical data establishing the safety and efficacy of a new product. Two regulatory pathways exist. Since 1995 and

the creation of the European Medicines Agency (EMA), firms have had the option of the centralized procedure, which provides authorization for a product in all member states. This procedure is required for certain products, including cancer treatments and biologicals. Alternatively, firms may use the decentralized or mutual recognition procedure, in which they apply in a single member state. Once a marketing authorization is obtained there, other national regulators refer to the decision in the first member state. Due to harmonization of regulatory standards, the ultimate decision to grant a marketing authorization should not vary. However, the mutual recognition procedure allows for more scope in differentiation across countries in packaging or brand names, and may be preferred if a firm intends to market a product in only a subset of EU countries.

Generic firms need only establish that their products are substantially similar to an innovator product. In effect, this means that generic firms rely on the information provided by the innovator on the safety and efficacy of the drug in question, which is much less costly. Fixed costs for generic firms are lower than those for innovator firms, so generics are able to realize profits even when selling their products at low prices. The EMA began approving generic products only recently, and also handles all biosimilar applications. From a regulatory standpoint, a generic drug is substantially similar to an existing product with a marketing authorization in chemical composition, dosage form, and strength. In addition, a generic drug is usually marketed using its international nonproprietary name (INN), rather than under a brand name. Generic status can be important in pricing and dispensing decisions, which vary by country. However, some "generic" (i.e., chemically similar) products are sold under brand names.

The tables below provide an overview of the industry in 2016. Aggregate data on R&D spending and sales is presented in Table 1 for the top 20 firms based on 2015 global sales. This information is not disaggregated by brand or generic status, nor by the geographic origin of sales. Alternative summaries of R&D activities, based on data sources that I describe in greater detail in Section 6, are included in Tables 2 and 3. I focus on first on upstream activities, i.e. R&D. Table 2 lists the top 20 organizations as measured by the number of drug development projects (since roughly 1990) for which they were the lead developers. The set of projects includes ongoing R&D projects and successful efforts that are currently marketed, as well as failures. Large multinationals dominate this list. Mergers and acquisitions have added significantly to the number of projects overseen by many of these firms. Organizations based in the United States account for 9 of the top 20 R&D organizations, and nearly half (45%) of all projects were led by organizations headquartered in the United States (Table 3). European-based firms lead about 29% of these projects, and British, French, and German firms are responsible for most of these.[1] However, the US has a greater share of projects in earlier stages of research (close to half), and some EU countries have declined. For example, while Italian firms have nearly 15% of projects ultimately marketed by 2016, they have

[1]Note, however, that the location of research activities may not be the same as the location of a company's headquarters. In addition, multiple firms can be involved in a single drug development project, and often a different firm (or firms) may ultimately market it.

only about 6% of the EU total of projects in the pipeline; Spain shows a similar pattern.

Table 1: Pharmaceutical firms ranked by 2015 global sales

Corporation (headquarters)	Mean R&D spending	Sales
1 JOHNSON & JOHNSON (US)	8,309.00	64,364.86
2 BAYER (Germany)	4,436.00	47,271.00
3 NOVARTIS (Switzerland)	9,001.57	46,281.82
4 PFIZER (US)	7,046.02	44,870.96
5 ROCHE (Switzerland)	8,639.95	44,574.62
6 MERCK US (US)	6,438.87	36,279.98
7 SANOFI (France)	5,246.00	34,542.00
8 GLAXOSMITHKLINE (UK)	4,214.17	32,563.17
9 GILEAD SCIENCES (US)	2,768.44	29,979.80
10 ASTRAZENECA (UK)	5,217.23	22,694.97
11 ABBVIE (US)	3,906.50	20,996.61
12 AMGEN (US)	3,619.92	19,897.13
13 ABBOTT LABORATORIES (US)	1,259.30	18,742.54
14 ELI LILLY (US)	3,663.36	18,332.61
15 TEVA PHARMACEUTICAL INDUSTRIES (Israel)	1,400.75	18,050.89
16 SUZUKEN (Japan)	43.49	16,985.75
17 BRISTOL-MYERS SQUIBB (US)	5,290.72	15,210.81
18 SHANGHAI PHARMACEUTICALS (China)	87.40	14,930.27
19 BOEHRINGER SOHN (Germany)	3,004.00	14,798.00
20 NOVO NORDISK (Denmark)	1,739.69	14,514.47
Total	4,266.62	28,794.11

Source: European Commission IRI Scoreboard 2016. Figures are in millions of 2015 €.

Within Europe, many of the same top R&D firms are also among the top 20 sellers of branded products listed in Table 4, including Novartis, Sanofi, Pfizer, and GlaxoSmithKline. Some of these firms also appear in the list of top sellers of unbranded products provided in Table 5, due to their ownership of generic subsidiaries. These tables are based on the number of product launches (of a unique chemical combination) per firm observed in the 2016 set of EU member states, not on revenues or market shares.[2] Not all branded products are novel or on-patent. For example, Stada and Krka, based in Germany and Slovenia respectively, are major sellers of branded products although their R&D presence is limited; they are also among the top unbranded firms. The set of top 20 branded sellers is relatively European: no Japanese firm appears on this list, and only 5 US-headquartered firms. The set of top 20 unbranded sellers includes a number of Indian firms (Aurobindo, Intas, and Sun Pharma).

[2]Revenue and market share data is considerably more expensive to obtain. Withdrawals or discontinued products are included in the numbers listed.

Table 2: Top developers, by number of projects (1990-2015)

Corporation (headquarters)	Stage				
	Early %	Clinical %	Marketed %	Failed %	Total %
AbbVie (USA)	3.19	4.55	4.28	3.06	3.56
Allergan (USA)	2.48	2.56	5.27	1.39	2.61
Amgen (USA)	3.47	3.36	1.34	1.83	2.63
Astellas (Japan)	2.57	2.33	4.54	4.04	3.27
AstraZeneca (UK)	5.86	4.66	4.23	8.06	6.05
Bayer (Germany)	4.42	4.55	4.97	2.67	4.01
Bristol-Myers Squibb (USA)	5.07	5.77	3.84	6.63	5.46
Daiichi Sankyo (Japan)	1.86	2.52	3.46	2.76	2.50
GlaxoSmithKline (UK)	7.55	11.93	9.07	7.75	8.62
Johnson & Johnson (USA)	5.07	5.58	5.66	3.34	4.74
Ligand (USA)	2.19	1.49	0.35	1.87	1.68
Lilly (USA)	4.89	4.43	2.20	3.54	3.99
Merck & Co (USA)	8.54	8.87	8.25	7.17	8.15
Novartis (Switzerland)	4.65	6.65	8.47	6.74	6.22
Pfizer (USA)	12.72	11.35	11.02	13.32	12.39
Roche (Switzerland)	5.69	6.23	6.05	8.32	6.62
Sanofi (France)	7.06	7.99	11.49	13.11	9.71
Takeda (Japan)	4.07	3.10	5.49	3.93	4.08
US Department of Health and Human Services (USA)	8.63	2.06	0.04	0.46	3.71
Total	100.00	100.00	100.00	100.00	100.00

Table 3: Geography of lead R&D role, by stage of development in 2016

	Stage				
	Early	Clinical	Marketed	Failed	Total
	%	%	%	%	%
Country of headquarters					
EU	26.80	24.99	31.66	34.87	28.87
USA	50.44	48.13	30.64	39.05	45.10
Japan	6.81	9.36	18.61	12.09	9.86
Switzerland	3.90	5.47	7.64	6.43	5.20
Other	12.05	12.06	11.45	7.56	10.97
Total	100.00	100.00	100.00	100.00	100.00
Within EU					
Austria	1.58	1.37	0.76	0.39	1.12
Belgium	3.10	3.04	4.03	3.60	3.35
Bulgaria	0.01	0.04	0.00	0.00	0.01
Croatia	0.01	0.00	0.00	0.00	0.01
Cyprus	0.06	0.00	0.00	0.00	0.03
Denmark	4.94	5.61	4.18	5.36	5.06
Estonia	0.03	0.00	0.00	0.00	0.01
Finland	0.97	1.20	1.46	1.19	1.13
France	17.78	18.98	20.69	23.01	19.77
Germany	18.37	15.85	15.86	17.68	17.47
Greece	0.12	0.04	0.25	0.02	0.10
Hungary	0.21	0.17	0.86	0.39	0.34
Iceland	0.01	0.00	0.00	0.00	0.01
Ireland	0.87	1.71	1.56	0.73	1.05
Italy	5.21	6.34	14.55	4.97	6.54
Latvia	0.01	0.00	0.15	0.00	0.03
Luxembourg	0.00	0.00	0.05	0.00	0.01
Netherlands	3.76	2.14	0.91	0.85	2.35
Norway	1.22	1.41	0.15	0.54	0.93
Poland	0.55	0.13	0.05	0.05	0.28
Portugal	0.73	0.39	0.35	0.22	0.49
Romania	0.00	0.00	0.05	0.00	0.01
Spain	3.01	3.13	6.95	4.33	3.91
Sweden	3.53	4.50	4.68	4.19	4.01
UK	33.90	33.93	22.46	32.48	32.02
Total	100.00	100.00	100.00	100.00	100.00

Table 4: Top sellers of branded products in Europe

Corporation	No.	%
Novartis	4349	13.92
Sanofi	4281	13.71
Pfizer	3588	11.49
Glaxosmithkline	2906	9.30
Teva	1987	6.36
Merck & Co	1977	6.33
Bayer	1578	5.05
Johnson & Johnson	1220	3.91
Astrazeneca	1177	3.77
Boehringer Ingelheim	927	2.97
Bristol-Myers Squibb	911	2.92
Roche	865	2.77
Stada	841	2.69
Krka	837	2.68
Lilly	821	2.63
Allergan	795	2.55
Novo Nordisk	782	2.50
Menarini	712	2.28
Merck Kgaa	682	2.18
Total	31236	100.00

Table 5: Top sellers of unbranded products in Europe

Corporation	No.	%
Teva	5050	24.41
Novartis	3649	17.64
Stada	2127	10.28
Mylan	1289	6.23
Aurobindo	980	4.74
Sanofi	947	4.58
Allergan	840	4.06
Pfizer	836	4.04
Intas	826	3.99
Merck Kgaa	766	3.70
Fresenius	627	3.03
Sun Pharma	606	2.93
Krka	411	1.99
Orion	331	1.60
Bluefish	314	1.52
Apotex	305	1.47
Alter	286	1.38
Servier	271	1.31
Esteve	228	1.10
Total	20689	100.00

2.1.1 Other sectors

Due to the limited availability of detailed data, particularly specific to Europe, I will only briefly summarize the market structure of the animal health and seed sectors. Animal health is generally more concentrated than the pharma sector. Many of the leaders in animal health are subsidiaries of the largest pharmaceutical firms (e.g., Bayer, Merck, and Novartis). While market exclusivity for animal health products is much shorter than for human (3-5 years vs. 10-12), generic competition has been much weaker (PriceWaterhouseCoopers (2015)). The seed sector is also very concentrated. According to Moschini (2010), DuPont and Monsanto own about 80% of US patents on corn and more than 60% on soybeans.

2.2 The role of patents

In a competitive market, the incentives to invest in R&D are minimal: the firm that incurs the development costs creates a public good – namely the identification of a safe and effective drug – but competition from imitators drives prices down to marginal costs, leaving the investor unable to recoup the development costs. Patent protection is one solution to this incentive problem. With entry restricted for the duration of the patent, the investing firm has an opportunity to sell at prices that exceed production costs. Because a patent gives its owner some market power, there is usually a social loss. Patent policy must balance this loss against the benefits of incentives for innovation.

Patents pose problems beyond the social cost of monopoly. First, patents are very blunt policy tools. In all countries that are members of the World Trade Organization, the patent term is a minimum of 20 years. This fixed term allows no nuanced distinction between important and trivial inventions. In addition, the patent "clock" may begin ticking before a product reaches the market. As previously explained, drug development is a lengthy process, often requiring many years of clinical trials. Usually, firms apply for patents early in this process: a delay risks either preemption by competitors or invalidation due to the existence of prior art. Thus, upon reaching the market, drugs have less than the 20 year term of protection remaining on the initial patent. The fixed patent term can therefore distort incentives. Diseases for which drug development requires more time to demonstrate efficacy may see reduced investment, as firms have fewer years of effective patent protection remaining during which to recoup their R&D costs (Budish et al. (2015)).

A further complication is that a single product can be protected by many patents, each covering a distinct method of manufacturing, use, etc. These patents may have very different application dates, so that patent coverage changes over time. As well, some may be easier to invent around than others, so that the strength of the protection varies. This situation results in legal uncertainty for both the patent owner as well as potential competitors.[3] Even if little time on the initial patent

[3]If multiple patents read on the same product, but have different owners, the transaction costs associated with obtaining permission from all patentholders in order to manufacture can also be non-trivial, although this tends to

remains by the time a product reaches the market, these secondary patents may provide many years of additional protection (Hemphill & Sampat (2012), DG Competition (2009)).

Alternatives to patents exist, and are important in other sectors. For example, trade secrets can also shield an innovator from competition by imitators. However, the substitution of trade secrets for patents could be problematic in the context of pharmaceuticals. In particular, generic firms would have higher fixed costs if all the information provided by innovators to regulatory agencies was protected by trade secrets, rather than available for generics to reference following the expiration of data exclusivity. This, in turn, would probably reduce the number of generic firms able to compete, and prices would be higher.

A second alternative is the use of prizes or advance market commitments, in which funders (such as governments or foundations) award a pre-specified sum to the developer of a new drug, but allow competition among producers (Kremer & Glennerster (2004)). Though appealing, the costs of coordinating the interests of different funders and the potential for free-riding appear to limit their use in practice.

3 Legal protections for innovators

European pharmaceutical policy includes two instruments that aim to improve innovation incentives. Supplementary protection certificates (SPCs) add to patent protection, independently of exclusivity terms. This policy, adopted in 1992 by all EU members, works as follows. An innovator (patentholder) can apply for an SPC on a product's "basic" patent within 6 months of obtaining marketing authorization in any member state. The length of the SPC is "equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorization to place the product on the market in the Community reduced by a period of five years," but capped at 5 years.

In addition to patent-related protection, innovators benefit from exclusivity policies. In 2005, a uniform policy on market and data exclusivity was adopted for all member states. This policy allows for 8 years of data exclusivity, during which no other firm can rely on the regulatory dossier provided by the originator in an application for marketing authorization. In addition to the period of data exclusivity, the innovator receives 2 years of market exclusivity, during which no generic can be approved; additional terms are possible for orphan drugs, pediatric trials, or new indications. In contrast to a patent term, which begins at the time of patent application, the exclusivity clock begins when the product is first approved in any member state.

Legal protections available to innovators are summarized in Figure 1, in the simplest case for which a product has a single patent. Patent protection falls linearly over time, as illustrated by the blue line: each year in development implies one year less of protection post-launch. Data and market

be more of an issue in other industries than in pharma (notably in information and communications technology).

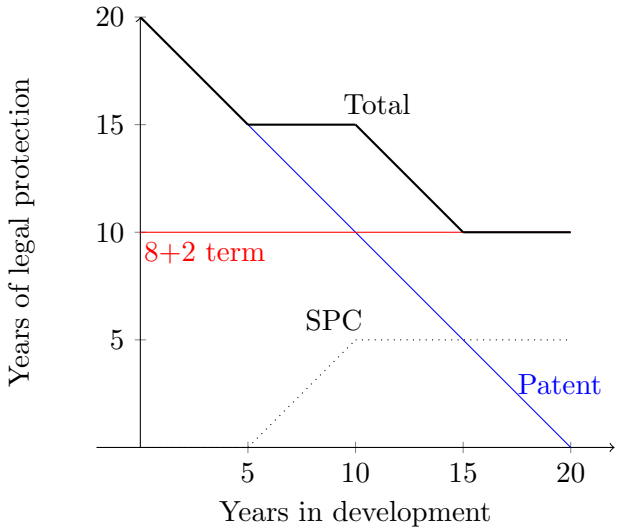

Figure 1: Legal protection provided by patents, SPCs and exclusivity

exclusivity terms are independent of development time, always guaranteeing the innovator 10 years. SPCs provide no additional protection for products that spend less than 5 years in development, and a maximum of 5 years for products that take more than 10 years to come to market. As a result, the total legal protection is the kinked black line, where SPCs increase protection beyond the standard patent and exclusivity terms for products with development times in the 5-10 year range.

The key point to realize is that SPCs should be irrelevant for products that are developed very quickly or very slowly, and the additional protection they provide (beyond both the standard patent term and exclusivity) should be capped at 5 years. In reality, the situation can be more complicated than illustrated here. As noted previously, secondary patents can extend an innovator's realized protection from competition. For older products, exclusivity terms vary between countries. Belgium, France, Germany, Italy, Luxembourg, the Netherlands, Sweden and the UK provided 10 years of exclusivity prior to the harmonization in 2005; other member states provided only 6. Therefore, there are cases where an SPC would not be valuable in some member states (because the exclusivity term would expire after the SPC) but would be in others. There are also cases, as discussed below, where SPCs based on secondary patents appear to extend protection beyond what would be the case if only the first patent were considered.

4 Quantitative analysis

4.1 Scope and term of regulation

As previously noted, drug development is a long and expensive process. Many factors affect development times. One is the nature of the disease itself. For example, diseases that progress slowly, or for which the clinical endpoint is measured after 5 years, require longer clinical trials than acute conditions for which the performance of a treatment is rapidly assessed. A second is that demonstrating safety and efficacy compared to existing products requires larger and lengthier clinical trials. Countervailing forces that might reduce development time include improved screening and drug design, as well as the use of surrogate endpoints (such as tumor size rather than 5-year survival, in the case of some cancers). While not the focus of this report, the consequence of an increase is that with fixed patent terms, an innovating firm expects fewer years of remaining patent protection during which to recover R&D costs, and SPCs can partly offset the reduction in R&D incentives that might result. Conversely, SPCs are less important if innovations in the process of drug development reduce the duration of the development period.

Table 6 illustrates how development times, EU launch lags, and the remaining term of protection have evolved over time for the 708 new chemical entities first introduced globally since 1990 that were launched in at least one EU market.[4]. The first column shows the average number of years between the first patent application (where applicable)[5] and the first global launch, or the average development time, for which there has been a clear increase. The second column presents the average number of years between a drug's first introduction somewhere in the world and its initial EU launch. This lag has fallen markedly, from 1.81 years in the early 1990s to just a few months in more recent years.[6] The reduction in launch lags should generally mean higher profits for firms.[7] The increase in development times is slightly greater than the reduction in launch lags, so that the remaining patent term at launch is almost a year less for products introduced since 2010 compared to those introduced in the early 1990s. Offsetting this is the term of protection with SPCs, which is calculated as the difference between the expiration date of a granted SPC and its first EU launch. This fell to just under 12 years from 2005-2009, but more recently has rebounded to slightly more than 13. Although SPCs should provide a maximum of 5 years of additional protection, the difference between SPC expiration dates and the expiration date of the first patent application is

[4]Further details about the sample used for this analysis are provided in the appendix.

[5]A small number of products (18) could not be matched to any patent data. In most cases, these products were based on plant extracts that could not be patented or on chemicals for which patents had already expired. In a few cases, the first patent application appeared after a product launch, and were process patents rather than product patents.

[6]The EU may not be the initial launch market for a number of reasons. If the EMA or national regulatory is slower to process a new drug application than regulators in other countries, or is more risk-averse, launch may be delayed. Firms may launch in their home markets or nearby markets first (Kyle (2006)), so that products from non-EU firms may arrive later.

[7]This assumes that regulators are converging to a faster review process.

sometimes more than 5 years, a point discussed further in the next section.

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 presents the distribution of development times, defined as the time elapsed between the initial patent on a drug and its first launch. SPCs are relevant for drugs that take between 5-15 to come to market, which comprise more than half of all drugs overall. This share has been increasing over time, while the percentages of drugs that are developed very quickly (in fewer than 5 years) or very slowly (more than 15) have both fallen since the early 1990s. To summarize, the average development time has increased over the last 20 years, but the distribution of development times is more concentrated. Investigating the reasons for this shift is beyond the scope of this report.

Table 7: Development times

Year of first global launch	Development time				
	0-5 years	5-10 years	10-15 years	15+ years	Total
	Row %	Row %	Row %	Row %	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

Tables 8 and 9 provide the same information by Anatomical Therapeutic Code (ATC) and regulatory status (orphan drug status or centralized approval). Parasitic products (class P) are a clear outlier: few products have been developed, and development times are relatively short. As the market for these products in Europe is generally small, SPCs are unlikely to play an important role. The category with the highest number of new products is class L, which includes cancer treatments. Perhaps due to the acceptance of secondary clinical endpoints, development times and years of protection with and without SPCs are roughly the average across all products. The two classes that seem to benefit most from SPCs, in terms of the years of additional protection provided, are class S (Sensory Organs) and class H (Systemic Hormonal Preparations).

In summary, the change in drug development has increased the relevance of SPCs over time.

Table 8: SPCs by ATC

ATC	Count		Mean			
	N	Sales	Development	EU lag	Patent only	With SPC
A	63	19,364	10.87	0.97	8.55	12.25
B	43	10,800	11.25	0.99	7.89	12.31
C	58	21,111	10.50	1.09	8.87	11.65
D	25		8.74	1.67	9.70	16.00
G	31	5,582	10.67	0.38	8.86	14.00
H	13	3,653	8.13	1.88	10.33	15.72
J	95	12,425	9.03	1.20	9.83	13.02
L	153		9.98	0.88	9.29	12.56
M	30	6,387	12.13	0.18	7.72	11.63
N	81	24,454	11.35	0.79	8.01	12.16
P	7		7.15	2.00	9.68	14.45
R	33	11,164	10.16	0.49	9.39	14.14
S	17		11.99	2.22	5.77	11.50
V	24		11.67	1.64	8.01	11.52
Total	673	14,702	10.33	0.99	8.86	12.68

Sales in millions of US$ as reported in OECD Health Statistics for EU OECD members in 2014, excluding the UK, for which data was not available. Sales are provided for only a subset of ATCs by this data source.

Table 9: SPCs by type of drug

	Count	Mean			
	N	Development	EU lag	Patent only	With SPC
Orphan					
No	648	10.34	1.05	8.77	12.61
Yes	60	10.20	0.60	9.16	13.64
Total	708	10.33	1.01	8.81	12.68
Centralized approval					
No	316	10.27	1.30	8.46	13.19
Yes	392	10.37	0.79	9.02	12.43
Total	708	10.33	1.01	8.81	12.68

While the EU has achieved faster access to new drugs, the reduction in launch lags has not offset the overall increase in time elapsed between patenting and first global launch and the corresponding decrease in remaining patent term once the product arrives in the EU. Overall, innovators could expect about 12.68 years of legal protection before facing the threat of generic entry, though slightly less (12.46) in more recent years. Orphan drugs arrive more quickly in the EU than non-orphans, and realize almost one additional year of SPC protection as well.

A shortcoming of this analysis, and indeed patent and SPC policies, is that there is no link to therapeutic value. Innovation incentives should favor the development of therapeutically important products. At the time a patent is granted, usually very little is known about the therapeutic effects of a new drug; this information results from the years of clinical trials that follow. At the time of product launch, when SPC applications are filed, much more is known. However, SPCs address a distortion in research incentives caused by differences in development times across products, but development times are not necessarily related to therapeutic value. An important question for future research is whether SPCs in practice benefit relatively more therapeutically important drugs, even if the policy is not explicitly designed to do so.[8]

4.2 Companies' strategies and SPCs

The previous section explained that SPCs are increasingly important, as an increasing share of drug development projects fall into the range of development times for which they are relevant. I now turn to an examination of how firms have availed themselves of SPCs.

Table 10 confirms that the use of SPCs has generally expanded. In the early 1990s, 75% of new drug introductions had an SPC in at least one country, and on average, an SPC in 6-7 countries. In more recent years, the share is 86% with at least one and 18-19 countries on average. The latter reflects both the expansion of the EU as well as an increased tendency to apply for SPCs in smaller markets, in addition to the fact that more products fall into the range of development times for which SPCs are relevant.

An overview of SPC application strategies is presented in Table 11. On average, a single drug is associated with more than 20 SPC applications, is granted about 15 SPCs, and is denied an average of 2.58.[9]. Most of applications represent a single firm applying in many countries. However, it can also include multiple SPCs on the same drug owned by different firms (see Table 12). When the patent to which an SPC is tied has multiple assignees, each can elect to pursue a separate SPC, which partially explains how a single drug can receive more than 100 SPCs: if there are 4 owners and each applies in most eligible countries, the total quickly mounts. It is also possible to apply

[8] If therapeutically important drugs are rewarded through higher prices or market shares, extra years of protection may not be necessary in order to provide innovation incentives. Because governments may have difficulty committing to such rewards, however, patents and exclusivity could play a role.

[9] Some SPC applications appear as neither granted nor rejected or withdrawn, presumably because they are still under review or because some withdrawals are unreported.

Table 10: Use of SPCs over time

Year of first launch	Count	Mean	
	N	% with any SPC	Countries
1990-1994	149	0.75	6.50
1995-1999	172	0.85	11.60
2000-2004	128	0.86	13.94
2005-2009	116	0.94	17.91
2010-present	143	0.86	18.81
Total	708	0.85	13.44

for SPCs on new uses of existing drugs, and to apply for SPCs for different drugs on the basis of a single patent.[10]

Table 11: Use of SPCs by drug

Variable	**Mean**	**Std. Dev.**	**Min.**	**Max.**	**N**
SPCs applied for	20.09	32.66	0	443	707
SPCs granted	15.23	23.7	0	299	707
SPCs refused or withdrawn	2.58	11.78	0	210	707

Table 12: Number of SPC owners

Number of SPC owners	Observations
0	11,016
1	8,353
2	937
3	147
4	28
5	17
6	34
Total	20,532

In addition, a single drug can have multiple SPC applications linked to different patents. The most extreme example of this is the HPV vaccine Gardasil, for which 10 different patents were the subject of SPC applications within 5 countries. In theory, this should not occur: SPCs are intended to extend the "basic" patent only. Some of these applications (or the patents on which they are based) were rejected or withdrawn, but nevertheless, Gardasil received 3 SPCs in France. In more than 80% of cases, only a single patent is concerned in the SPC application(s) for a drug, and nearly 80% of these applications result in a granted SPC (see Table 13). In the remaining cases, a single drug has multiple SPC applications associated with different patents in a single

[10]For example, the Danish patent DK0174317 was the basis of SPC applications associated with 9 different products in Denmark.

country. While a smaller share of these are granted than in the single patent case, this can result in the extension of several *patents* (rather than multiple SPCs granted to different owners of a single patent) protecting a drug within a country. When an SPC extends a patent that is not the first patent, the result can be an effective extension of protection beyond the maximum of 5 years intended by the policy, assuming that the first patent is the "basic" one. Table 14 provides a tabulation of the types of patents associated with SPC applications in all EU countries. Almost 3000 involved process patents rather than product or composition patents. These are more likely to be refused or withdrawn (sometimes after being granted); SPC applications tied to method-of-use patents are also granted at a much lower rate. However, it is clear that the definition of "basic" patent for the purposes of SPCs requires more clarification for SPC applications or implementation of the regulation by patent offices.

Table 13: Number of SPC patents per drug

	Count Cases	Fraction Granted
1	1,928	0.80
2	294	0.62
3	54	0.61
4	16	0.67
5	13	0.61
6	2	0.45
7	7	0.46
8	1	1.00
9	6	0.66
10	5	0.36
Total	2,326	0.72

The differences in SPCs across countries, which is related to differences in patenting as well as litigation, result in a complicated IP landscape in Europe. This complexity could have implications for generic firms or others adversely affected by patents, and disproportionately affect smaller firms. For example, Gaessler & Lefouili (2016) find that small plaintiffs in patent cases in Europe prefer courts that are local; litigation in different member states could be especially costly for them.

I can provide only limited evidence on this point, but next present an overview of the types of firms linked to SPCs. This is not entirely straightforward, for several reasons. An SPC is requested by the holder(s) of the patent to be extended. The owner of this patent is often different from the firm that owns the marketing authorization. SPC ownership can differ across countries, as well as the owners of marketing authorizations. In between, the process of drug development can involve several other firms through licensing and research partnerships. A further complication is the difficulty in matching on firm names across different data sources.

Based on the applicant names of the patents for which SPC applications were filed and the

Table 14: Types of patents associated with SPCs

	Total			
Patent type	Applications	Grants	Refusals	Withdrawn
Composition	1,517	946	171	126
Device	6	0	0	0
Drug delivery system	264	169	10	17
Equivalent to composition	8	4	0	1
Equivalent to drug delivery system	2	1	0	0
Equivalent to method of use	5	3	2	1
Equivalent to process	25	23	0	2
Equivalent to product	127	108	8	11
Intermediate	2	1	0	1
Method of use	1,572	821	79	71
Not claimed	16	7	4	6
Not claimed in combination	169	64	38	23
Only claimed in combination	162	58	54	18
Process	2,949	2,384	356	357
Process to composition	59	32	4	1
Product	8,155	6,629	358	335
Product by process	86	64	4	4
Total	15,124	11,314	1,088	974

locations listed for those applicants, Table 15 provides a breakdown of the geography of ownership. The number of observations is slightly higher than the total number of SPC applications because some SPCs involved jointly-owned patents, and I consider each of these owners separately. Almost 44% of SPC applicants are US-based, while the EU has close to 30%, followed by Japan and Switzerland at roughly 7% and 6%, respectively. These figures track those of the geography of R&D projects shown in Table 3. Thus, there is no clear geographic bias in the use of SPCs by the location of patent holders.

Table 15: SPC ownership by nationality

Country of headquarters	No.	%
EU	4894	29.73
USA	7233	43.95
Japan	1163	7.07
Switzerland	975	5.92
Other	2194	13.33
Total	16459	100.00

Top R&D firms are involved at some stage in the vast majority of products brought to market, even if they are not the original patent holder or the lead R&D firm. The use of SPCs based on

the participation of a leading R&D firm (one that is in the top 20 by number of drug development projects as the lead developer), for products for which a drug development history was available, is shown in Table 16. The share of products with at least one SPC was higher (89% vs. 72%), and SPCs were sought in roughly 4 additional countries, if a top R&D firm was involved in development. This pattern suggests that there is some advantage for large, experienced firms. However, it is also possible that the value of an SPC differs: if products developed by top firms have greater profit potential, an extra year of market exclusivity is worth more, and we would expect to see greater use of the added protection provided by SPCs.

Table 16: SPCs by size of R&D portfolio

Top R&D firm	Sum	Mean	
	Products	Any SPC	Countries
No	131	0.72	10.21
Yes	568	0.89	14.40
Total	699	0.86	13.61

Table 17 presents a similar breakdown based on the involvement of a top branded firm in at least one European market. These firms sell about 70% of the new products somewhere in Europe, and this set of products is more likely to have an SPC in at least one country as well as SPCs in more countries. As with top R&D firms, one might expect an advantage for large branded firms in availing themselves of SPCs, as they should have a superior understanding of the European market. However, they could also select more valuable products to include in their portfolios.

Table 17: SPCs by size of product market portfolio

Top branded firm	Sum	Mean	
	Products	Any SPC	Countries
No	212	0.75	10.90
Yes	496	0.89	14.53
Total	708	0.85	13.44

4.3 Use of SPCs

To examine the determinants of companies' use of SPCs, I estimate the following linear regression:

$$SPC_{ic} = X\beta + \gamma_c + \epsilon_{ic} \tag{1}$$

where the dependent variable SPC_{ic} is 1 if product i has an SPC in country c. Explanatory variables in X include the number of years in development for product i, the number of secondary patents related to i in c, whether the product was approved via the centralized procedure, and

the involvement of a leading R&D or branded firm, using the definitions previously described. A categorical variable for the period during which the product was first launched is included to allow for changes over time in the use of SPCs. Country fixed effects γ_c are also be included. Since the dependent variable is either 0 or 1, the regression can also be estimated as a logit or probit; results are similar, but a linear model is used here for simplicity.

Table 18: Linear probability model for any SPC

	1	2	3
	b/se	b/se	b/se
5-10 years in development	0.50^{***}	0.42^{***}	0.43^{***}
	(0.01)	(0.01)	(0.01)
10-15 years in development	0.53^{***}	0.44^{***}	0.44^{***}
	(0.01)	(0.01)	(0.01)
15+ years in development	0.30^{***}	0.25^{***}	0.26^{***}
	(0.02)	(0.01)	(0.01)
Number of granted patents	0.03^{***}	0.02^{***}	0.02^{***}
	(0.00)	(0.00)	(0.00)
Centralized approval	-0.02^{**}	-0.02^{**}	-0.02^{**}
	(0.01)	(0.01)	(0.01)
Top branded firm	0.03^{***}	0.05^{***}	0.04^{***}
	(0.01)	(0.01)	(0.01)
Top R&D firm	0.11^{***}	0.12^{***}	0.11^{***}
	(0.01)	(0.01)	(0.01)
Launched 1995-1999	0.18^{***}	0.19^{***}	0.19^{***}
	(0.01)	(0.01)	(0.01)
Launched 2000-2004	0.26^{***}	0.27^{***}	0.27^{***}
	(0.01)	(0.01)	(0.01)
Launched 2005-2009	0.38^{***}	0.40^{***}	0.40^{***}
	(0.02)	(0.01)	(0.01)
Launched 2010-present	0.37^{***}	0.37^{***}	0.36^{***}
	(0.02)	(0.02)	(0.02)
N	9777	9777	9626
Adj. R^2	.266	.337	.343
Fixed effects		Country	Country ATC

* p<0.10, ** p<0.05, *** p< .01.

Table 18 presents the estimation results, which confirm the relationships described in the tables above. SPCs are valuable for products in development for at least 5 years, and the positive coefficients on the categorical variables confirm that these products are more likely to have SPCs. This is true even for those in development for more than 15 years, for which data exclusivity is probably the longer than patents or SPCs. However, this could reflect either the use of SPCs in countries that provided only 6 years of data exclusivity or the attempt to use SPCs for later patents or new uses. SPCs are more likely when there are also many secondary patents, suggesting that firms seek multiple means of protection.

Leading R&D firms, as well as top branded firms, are more likely to have SPCs. These firms are probably best positioned, both financially as well as in terms of understanding the regulatory

structure in Europe, to incur the costs of acquiring and maintaining patents as well as SPCs. It is difficult to determine whether these costs are an important barrier for small firms or non-profits. In general, such organizations can resort to licensing their intellectual property to larger firms with the necessary resources to do so. The terms of such licensing arrangements are often confidential, which makes analysis difficult.

4.4 European vs. national SPCs

The use of SPCs, as well as patents, varies widely across countries, as illustrated in Table 19. The definition of "refusals" includes both withdrawals of the SPC application by the petioning firm as well as rejections by the patent office. The more recent EU members have fewer total patents on all drugs included in the analysis here as well as fewer SPC applications; most small countries also have fewer, although the Benelux countries are have high counts of both. Interestingly, however, only 7 SPC applications were refused or withdrawn out of 658 in total, while Belgium and the Netherlands saw 91 and 134 denied, respectively. Thus, there appears to be substantial heterogeneity in the use of SPCs as well as the application of SPC regulations across member states.

Ideally, one would compare the outcome of SPC applications based on the *same* underlying patent across member states to identify how much of the difference in SPCs can be attributed to decisions at the country level versus the selection of different patents by SPC applicants. However, in practice this is complicated by the inconsistent use of national or EPO patent numbers across member states in the SPC data available. To illustrate the variation in outcomes that can result from the use of national applications, take the antiretroviral treatment TRUVADA©. This is a fixed combination of two drugs, tenofovir and emtricitabine. There are 4 different unique applicants for 3 patent families related to this product. The SPC application tied to one of these patent families was withdrawn in Greece and rejected in Spain and Sweden, though the same patent (EP0915894) was granted an SPC in 10 other countries. Fewer SPC applications were filed for the other patent families, and these also had mixed experiences across Europe.

Some of this heterogeneity, of course, reflects differences in the importance of a country to a pharmaceutical firm's revenues. Patent protection and SPCs are important only if the originator expects generic competition to occur quickly in the absence of these barriers. With a unitary patent or European SPC, the number of patents or SPCs might increase in some countries, but these could be countries where generic competition would be slow to take place anyway (see the following section for further discussion). However, there also appears to be important variation in the application of SPC regulations across countries. Eliminating this variation would reduce the uncertainty that generic producers have about the strength of intellectual property barriers in a country. A unitary patent and/or European SPC would also increase the returns to challenging the validity of the patent or SPC, because a successful invalidation would apply in all EU countries. Questionable patents or SPCs would be more likely to be eliminated than in the present system.

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

4.5 SPCs and generic entry

This section considers the relationship between SPCs and generic entry. SPCs, by design, extend patent protection in order to offset time lost in drug development. The extension provided by SPCs will depend on the distribution of development times. If a larger share of products require more than 15 years in development (or fewer than 5), SPCs are less relevant. As explained above, however, most drugs fall into the range of development times for which SPCs extend protection. Thus, the period of legal protection with an SPC is longer for these products than those without, and one might expect to see generic entry occur more slowly in the presence of this additional barrier.

However, the set of products that do not have an SPC, but that could benefit from one in theory, is not random. It is likely that firms apply for SPCs only when they perceive the threat of immediate generic entry to be relatively high. Products without SPCs may be less attractive to generics, so that entry could be slow even when no legal barrier exists. In addition, other barriers to generic entry may be important, including secondary patents or simply the fixed costs associated with obtaining a marketing authorization for a generic product in some countries.

Table 20 provides a summary of originator and generic entry by country. First, note that some countries have a higher number of new drug launches than others: smaller countries, and especially more recent EU members, generally have fewer launches by originators (column 2) and longer waits for those products (column 3). Because of SPCs and data protection, the average period of protection (excluding secondary patents) claimed innovators does not vary as much across countries (column 4). Markets that are unattractive to originators are usually unattractive to generics as well, as reflected in the number of generic launches in column 5. Note that many products are still covered by patents, SPCs or data exclusivity as of 2016, so not all are eligible for generic entry yet. The average lag between the expiration of legal protection and generic launch[11] is presented in column 6, and ranges from a few months to almost 3 years. The last column shows the average number of years between the first global launch of a new drug and the availability of a generic. This is a censored measure, since it is affected by future generic entry. On average, this is around 14 years, somewhat more than the period of legal protection.

To examine whether SPCs are systematically related to differences in the speed of generic entry, I estimate a Cox proportional hazard model. This model accounts for the fact that generic entry is censored, i.e. some entry has not been observed but may occur in the future. In this model, a product is "at risk" for generic entry starting from the originator's launch date, and is a function of whether an SPC was granted for product i in country c, the total number of patents related to product i in country c, and whether product i was approved via the centralized procedure. Alternatively, the product can be considered at risk starting from the first EU launch, and the

[11] I do not have information on so-called authorized generics, i.e. those introduced under license from the patent owner. Authorized generics can be launched prior to patent expiration.

Table 20: Drug launches by country

Country	Sum	Mean		Sum	Mean	
	Launches	Lag	Protection	Generics	Lag	Wait
Austria	554	2.09	13.31	108	0.31	14.06
Belgium	444	2.99	12.92	108	0.82	14.16
Bulgaria	371	5.58	12.27	103	2.87	14.58
Czech Republic	464	3.66	12.39	107	1.84	13.82
Denmark	510	1.83	13.16	105	0.42	14.01
Estonia	195	5.46	12.43	58	1.44	12.89
Finland	525	2.03	12.83	108	0.33	13.65
France	457	2.44	13.16	117	1.75	14.69
Germany	574	1.64	13.00	132	1.12	14.17
Greece	381	3.20	12.99	93	2.30	14.95
Hungary	429	3.62	12.21	97	1.82	13.56
Ireland	476	2.55	12.96	87	2.13	15.43
Italy	502	2.61	13.43	131	1.33	14.87
Latvia	390	5.25	12.62	94	1.45	13.62
Lithuania	298	5.16	12.40	75	0.62	12.31
Luxembourg	260	4.24	13.45	47	1.50	14.89
Netherlands	421	1.77	13.24	110	0.05	13.12
Norway	504	2.59	12.70	97	0.87	13.91
Poland	439	4.11	12.09	116	2.23	14.19
Portugal	250	3.79	12.94	91	1.03	13.31
Slovak Republic	467	4.02	12.50	104	1.98	13.60
Slovenia	418	4.30	12.70	98	2.49	14.67
Spain	504	2.76	13.08	125	1.26	13.68
Sweden	488	1.68	13.37	101	1.33	14.85
UK	537	1.65	13.05	125	1.69	15.06
Total	10,858	3.03	12.85	2,537	1.39	14.11

sample can be restricted to those countries that were EU members at the time the originator launch occured.

In Tables 21, 22 and 23, I present the results of Cox proportional hazard models under different assumptions regarding the time "at risk" and for different samples. All point to the same qualitative finding, which is that products with SPCs have somewhat faster generic entry than those without. It is important to emphasize that this is not a causal relationship: it likely reflects the non-random selection of products for SPC applications. For the same reason, products with more patents in a country see slightly faster generic entry as well. Protection is sought where it is needed; where additional protection is not pursued, generic entry is less attractive for other reasons. In other words, generic entry is less likely despite the absence of patent or SPC barriers because the product market has lower expected profits. Finally, products approved via the centralized procedure, which grants a marketing authorization throughout Europe, also see faster generic entry. This suggests that reducing the fixed costs associated with a generic application is likely to increase the availability of generics in all member states, and would be especially beneficial in smaller markets.

The difference between the speed of generic entry is easiest to see in Figure 2, which presents the Kaplan-Meier "failure" curve (where failure is the introduction of a generic version). There is very little difference between products with and without SPCs for the first 15 years following EU launch. The difference after that point probably reflects that products without SPCs are not sufficiently valuable to protect, or generic entry is perceived to be sufficiently low risk; these less valuable products are not targeted by generic firms for quick launch.

Table 21: Cox hazard model for time to generic entry (from originator launch), EU member st originator launch

	1	2	3
	b/se	b/se	b/se
Has SPC	0.38***	0.33***	0.65***
	(0.06)	(0.06)	(0.07)
Number of granted patents		0.03***	0.04***
		(0.01)	(0.01)
Centralized approval		0.31***	0.26***
		(0.06)	(0.06)
N	7185	7185	7185
Log L	-10645	-10612	-10380
Chi sq	43.6	111	574
Fixed effects			Country

* p<0.10, ** p<0.05, *** p< .01.

4.6 SPCs for other products

Moschini (2010) reports a large increase in the use of patents covering corn and soybeans in the United States since the early 1990s. A key difference between the pharmaceutical sector and agribusiness is the concentration of patent ownership. The importance of biotech crops is lower in

Table 22: Cox hazard model for time to generic entry (from 1st EU launch), EU member at originator launch

	1	2	3
	b/se	b/se	b/se
Has SPC	1.21***	1.06***	1.35***
	(0.06)	(0.06)	(0.07)
Number of granted patents		0.04***	0.04***
		(0.01)	(0.01)
Centralized approval		0.82***	0.77***
		(0.06)	(0.06)
N	11707	11707	11707
Log L	-11090	-10962	-10880
Chi sq	492	748	913
Fixed effects			Country

* p<0.10, ** p<0.05, *** p< .01.

Table 23: Cox hazard model for time to generic entry (from 1st EU launch), current EU members

	1	2	3
	b/se	b/se	b/se
Has SPC	0.73***	0.61***	1.00***
	(0.04)	(0.04)	(0.05)
Number of granted patents		0.03***	0.04***
		(0.00)	(0.00)
Centralized approval		0.86***	0.76***
		(0.05)	(0.05)
N	14553	14553	14553
Log L	-18191	-18000	-17850
Chi sq	308	689	989
Fixed effects			Country

* p<0.10, ** p<0.05, *** p< .01.

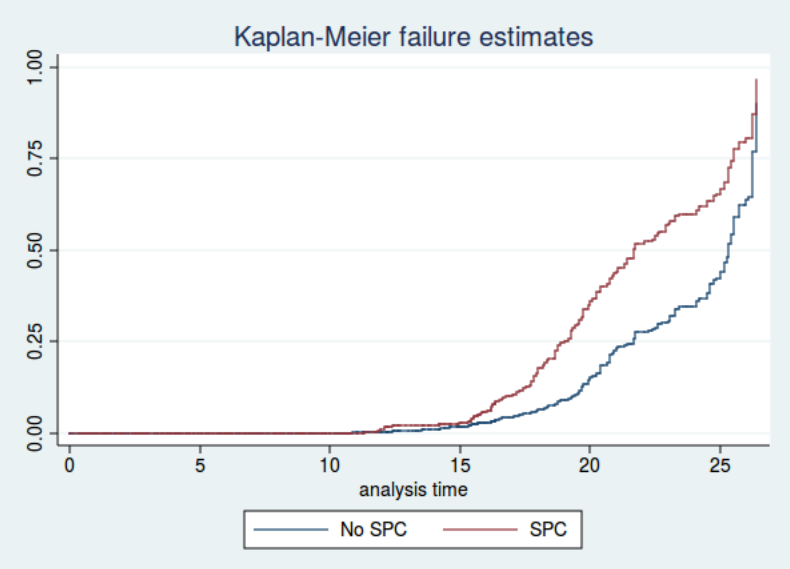

Figure 2: SPCs and speed of generic entry

Europe than in the US (James (2014)), and the legal protection available under patent law also differs. According to the PINTO database provided by the European Seed Association, which is derived from the voluntary disclosure of information by patent owners, there are more than 1000 species covered by patents in the European Economic Area.[12]

The data available for analyzing plant protection SPCs is considerably more limited than for medical products. In general, compiling information on SPCs at the country level is tedious. Not all countries provide data in a transparent and easily exported format, and they vary in the amount of information provided. For example, it is not always easy to determine whether a given SPC corresponds to a medical product or plant without linking it to other sources of information. Two countries that do provide information that is easily summarized are the UK and Germany. In the UK, 800 SPCs were granted for medicinal products, compared to 128 for plant protection products. In Germany, 197 plant protection SPC applications were lapsed, in force, or pending, compared to 1257 for medical products.

Presently, SPCs are not available for medical devices. The market for these products has a number of key differences with pharmaceuticals. It is somewhat less transparent: EUDAMED, the database that covers medical devices on the market in Europe, is not publicly accessible. Most medical device firms (95%) are SMEs,[13] and patents related to medical technology accounted for the highest volume of applications at the European Patent Office in 2015.[14] The regulatory framework, and in particular the design of clinical trials, is rather distinct from pharmaceuticals. In addition, the US and EU have different regulatory approaches, and medical devices generally reach the market earlier in Europe than in the US (Kramer et al. (2012)). There is no equivalent of the generic regulatory pathway for medical devices, and the patents on medical devices can be broader than a basic pharmaceutical product patent (Masterson (2014)). Survey evidence from the US, in a study sponsored by the medical device industry association, indicates that the cost of bringing a medical device to market is well below that of the average novel pharmaceutical product (Makower et al. (2010)). The argument for patent extensions in devices appears to be weaker than that for pharmaceuticals, given that devices are less expensive and faster to commercialize and do not face the same threat of competition from perfect substitutes (generics) as pharmaceuticals. However, this assertion is mainly speculative given the paucity of data available.

5 Policy recommendations

In the years since SPCs were introduced, intellectual property rights on pharmaceuticals have been extended to other countries, including major emerging markets such as India and Brazil. As a result, products are more likely to be launched in these markets, and producers have realized an

[12]The PINTO database is available here.
[13]See DG Growth webpage on the medical device sector.
[14]See EPO Annual Report 2015.

increase in revenues (Kyle & Qian (2014)). In addition, as noted in this report, products are reaching the European market with shorter lags after their first global launch. The SPC term is calculated based on the first EU launch rather than the first global launch, which is important if European regulations add significantly to delays and if this unfairly penalizes firms. In practice, the difference between these two dates has been shrinking.[15] Finally, the EU has harmonized exclusivity terms, which are generous by international standards. These changes may have reduced the need for SPCs.

SPCs have few direct costs, in the sense that governments spend very little to implement and grant them. The intention of SPCs is to correct distortions in research efforts that result from lengthy development times with correspondingly shorter remaining terms of patent protection. This correction necessarily implies some costs in the form of delayed generic competition. Although the analysis above shows that SPCs are not extending an innovator's protection much beyond the average of products without SPCs, this does not mean that removing SPCs (or modifying their scope or term) would have no impact. Products valuable enough to seek SPCs for would probably see earlier generic entry without the additional protection that SPCs give. In order to provide sound econometric support for this hypothesis, however, a more sophisticated analysis is required than that undertaken here. Specifically, a larger study that incorporates market share and revenues in a structural model of demand would allow consideration of policy counterfactuals, such as the removal of SPCs or changes to the length of protection.

In addition, the effect of SPCs on incentives for research and development also needs to be estimated. It is very difficult to determine whether SPCs indeed correct the distortion of research incentives associated with fixed patent terms, for a number of reasons. First among these is that research investments reflect expectations of global profits. While the European market is large, the effect of (for example) one extra year of exclusivity in Europe may represent too small a change in global profits to shift R&D investment. If this is true, then there is little justification for incurring any shorter-run costs associated with delayed competition. If the European policy is coordinated with similar efforts in other important markets, however, then the effect on R&D incentives may be important. Integrating a model of R&D supply and investment decisions with the demand model described above is necessary to quantify these tradeoffs.

That said, there are several areas identified by the analysis in this report where the policy could be improved. As noted in the Commission's pharmaceutical sector inquiry, a unitary patent would likely reduce costs for both originator and generic firms (DG Competition (2009)). Similarly, a single SPC application that is valid in all member states would also simplify the complex terrain of intellectual property across Europe. Barring these changes, better information sharing across patent offices on SPC applications and outcomes would make it easier to identify cases where the rules are not evenly applied, for example. Clarification of the definition of a "basic" patent, so

[15]However, pricing and reimbursement negotiations could add to effective launch delays, even if a marketing authorization is granted with less of a lag.

that there is greater uniformity across member states, would also be useful. Finally, the speed of generic competition could be increased by reducing the fixed costs of preparing applications for marketing authorizations across many countries with varying IP barriers. Generics that can make use of the centralized procedure (i.e. for originator products approved using this pathway) seem to reach the market more quickly, for example. This suggestion is a bit speculative, as not all generic producers have the scale to market throughout Europe. Those with a narrower geographic focus would not necessarily benefit from this change, and indeed the main beneficiaries could be large generic producers that market globally, most of which are located outside of Europe.

Finally, there are presently two policies in Europe that attempt to correct the distortion of fixed patent terms: SPCs, and the 8+2 data and market exclusivity term. The latter does not vary across member states, and there may be less scope for different interpretations of how the regulation is implemented than is the case with SPCs. If harmonization of patents and SPCs across member states is very costly, an alternative is to adjust the exclusivity policy and eliminate SPCs. A key difference is that exclusivity is independent of the time spent in development. This may reduce the incentives for firms to move products quickly through trials and for rapid launch compared to a situation with a "ticking" patent clock. Studying the effects of such a change would also be worthwhile.

6 Data appendix

The pharmaceutical industry is highly regulated, which means that a great deal of information is available from national agencies as well as the EMA. Unfortunately, the ease of obtaining information varies greatly across countries. As a result, private firms sell competitive intelligence to industry participants based on regulatory and other sources. In this document, I rely heavily on data provided by IMS Health, specifically R&D Focus, Patent Focus, and New Product Focus. R&D Focus includes information on drug development projects, including the organizations involved in each project and their respective roles. Patent Focus provides data on patents linked to drugs that have reached late-stage clinical development or have been launched, as well as SPCs. New Product Focus covers the introduction of products, both branded and unbranded, in a large number of countries. A major challenge is to link information across these three sources, as product names and firm names are not always standardized. In addition, firm names change as a result of mergers and acquisitions.

In general, I rely on the ingredients or chemical composition of each product and/or its trade name to match across data sources. In the case of firms, I use the listed corporation (rather than subsidiary names). R&D Focus and Patent Focus update all records with the name of a merged firm or acquiring firm when a merger or acquisition takes place. New Product Focus records reflect the name of the corporation at the time of product launch.

I focus on new chemical or biological entities (NCEs) first introduced since 1990 and in at least

one European market. Due to the difficulties in classifying insulin-based products and in linking them to patent information, I exclude these from the analysis. I also drop products withdrawn from the European market, as notified by the European Medicines Agency. Product withdrawals that occurred at the national level are potentially overlooked.

For each of these 708 products, I identified its launch date in each EEA market based on IMS New Product Focus. This reported launch date can differ from the date of marketing authorization, because of pricing and reimbursement negotiations that take place after authorization but prior to launch. I also identified the first generic introduction in each of these countries using the same data source. Based on outlier observations, such as where generic entry precedes the originator launch or occurs more than 20 years after the originator, I verified launch dates using the websites of national medicines regulators where possible or other data sources. However, many errors no doubt remain.

I also linked these products to IMS Patent Focus, providing information on patent applications at the country level as well as SPC information. The linkage depends mainly on the generic or trade name listed in different IMS data sources; I rely on the accuracy of IMS in identifying and classifying the relevant patents. The SPC information was further cross-checked with data obtained by the Commission.

When presenting summary information at the firm level, I attempted to account for mergers and acquisitions that occurred between 1990 and 2016, and I aggregated subsidiaries to the corporate level where applicable. For example, what is now Sanofi includes any products listed in IMS New Product Focus under Aventis, Synthelabo, Hoechst, and Zentiva, among others. It is very likely that I neglected to include all mergers and acquisitions, particularly those involving smaller firms, but this should have little impact on the figures for the top 20 firms reported in the tables. IMS New Product Focus includes a large number of homeopathic products in some countries as well as parallel imports, and I excluded these from the data used to compile tables at the firm level.

The accuracy of the SPC information in IMS Patent Focus was verified using data on SPCs provided to DG GROW by Alice de Pastors. More than 90% of the observations could be matched. Not all countries included in the de Pastors data are covered by IMS Patent Focus (e.g., Malta and Cyprus), and as explained previously, the use of national patent numbers vs. EPO numbers complicates the merge. However, both sources yield the same qualitative conclusions regarding the heterogeneity of SPCs and patents across member states.

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