# Potential and Effective Exclusivity of New Drugs: A Comparison of Europe and the US

Margaret Kyle

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## 1 Introduction

Incentives for the development of new pharmaceutical treatments rely heavily on patent protection and other forms of exclusivity. Policymakers encounter several challenges in designing these incentives. First, these policies pull in socially desirable innovation only if firms expect higher profits from drugs that deliver more social benefits, which requires pharmaceutical markets to function efficiently. Second, the optimal length of protection is difficult to determine ex ante, and likely varies across products and over time. Too short a period of protection, and some disease markets will be neglected; too long, and consumers (or insurers or governments) will face high prices for many years. Because the market for most pharmaceuticals is global, policymakers may be tempted to free ride on incentives created by other countries, or be frustrated at free-riding by others.

This last point is central to the inclusion of intellectual property provisions in trade agreements and economic unions, which has resulted in significant harmonization of patent terms across countries. However, the availability of other forms of protection continues to vary across countries. In addition, the realized period of exclusivity may differ from the potential term defined by law. Firms may find it too costly to seek all forms of protection, or to enforce all their rights. Alternatively, other barriers or insufficient expected profits for competitors may result in actual exclusivity terms that exceed those defined by law.

This paper examines exclusivity terms in the European Union (EU). The EU's establishment led to the adoption of harmonized policies in its member states, and many other important changes to the internal market. These should affect both potential exclusivity through explicit pharmaceutical policy as well as incentives for entry and

competition. This research complements recent work by Hemphill and Sampat[1], who describe how the situation in the United States has evolved in the 40 years since the Hatch-Waxman Act, which included important changes to patent terms and exclusivity. Given concerns about free-riding on innovation incentives, it is useful to compare the policies and outcomes across regions. This is particularly relevant as the EU debates changes to its pharmaceutical policy.

## 2 Overview of drug approval

The US Food and Drug Administration (FDA) regulates the entry of pharmaceuticals for the US market. There are now three pathways to approval. The New Drug Application (NDA) is used for novel chemical entities, the Biologic License Application (BLA) is used for biologic products, and the Abbreviated NDA (ANDA) is used for generic products. The latter was created by the Hatch-Waxman Act in order to lower entry barriers and to encourage generic competition. While new drugs must provide clinical trials testing the safety and efficacy of their products, generic firms may rely on that data and show only evidence of bioequivalence. Regulations covering biosimilars are more recent, and the Hatch-Waxman framework does not apply.

Each European country has a comparable agency tasked with authorizing pharmaceuticals. The regulatory landscape in Europe has evolved significantly since the establishment of the the European Medicines Agency (EMA) in 1995, which introduced a centralized procedure for obtaining marketing authorization valid in any EU country. Alternatively, firms may elect to apply to a national agency under the decentralized procedure. Certain products are required to use the centralized procedure, including biologics, cancer treatments, and rare disease therapies. Because the regulatory standards have been harmonized across EU members, drugs approved in one country may also apply for mutual recognition in other member states. Despite the harmonization, not all drugs are launched in all EU countries[2].

Regulation (EC) No 726/2004 established a centralized procedure for generic/hybrid products as well as biosimilars. However, this procedure is intended for generic versions of originator products approved by the EMA, not via the decentralized or mutual

[1] C. Scott Hemphill and Bhaven N. Sampat. "Patents, Innovation, and Competition in Pharmaceuticals: The Hatch-Waxman Act After 40 Years". In: *Journal of Economic Perspectives* 39.2 (2025), pp. 27–52. DOI: 10.1257/jep.20241423. URL: https://doi.org/10.1257/jep.20241423.

[2] Margaret K. Kyle. "The Role of Firm Characteristics in Pharmaceutical Product Launches". In: *RAND Journal of Economics* 37.3 (2006), pp. 602–618; Margaret K. Kyle. "The Single Market in Pharmaceuticals". In: *Review of Industrial Organization* 55 (2019), pp. 111–135.

recognition procedures.[3] The EMA approved its first generic only in 2007, the same year as its first biosimilar. Generic versions of drugs that were not centrally approved must seek authorization at the national level, and a mutual recognition procedure exists for these as well. Consequently, the regulatory landscape remains somewhat fragmented.

# 3 Overview of legal protections

## 3.1 Patents and patent extensions

Patents, and especially the choice of patent length, require policymakers to balance the dynamic benefits of innovation incentives with the static costs of limited competition. In almost all countries, patent protection runs 20 years from the date the application is filed. This term applies to all technologies, despite huge differences in the product life cycle across sectors. Specifically, for products that require little time to develop, a patent provides for nearly 20 years of protection on the market. In the case of pharmaceuticals, development times for drugs introduced since 2010 average around years 8-10 years[4], with many taking much longer. The hope is that on average, the expected profits realized during the expected period of exclusivity are large enough to attract investment – and that competition will quickly erode these profits once the patent expires.

In some sectors, overlapping patent claims or patent thickets create uncertainty and potentially raise costs for competitors, who need to invent around more patents. This is generally less of a concern in pharmaceuticals, where the mapping between patented invention (e.g., a chemical structure) and product (a combination of that chemical with other materials, and information on its uses and effects) is relatively straightforward. However, most drugs brought to market do have multiple patents. These can include "primary" patents that claim a drug substance or product, as well as "secondary" patents covering different aspects of the invention or method-of-use, for example.

Secondary patents raise several concerns. Because they are filed after the primary patent, sometimes many years later, their terms expire after the primary patent. Assuming they are not invalidated and run to their full terms, they may extend exclusivity beyond the period policymakers had in mind when balancing dynamic incentives and

[3] Under some conditions, the EMA will assess applications for generic versions of products approved via the non-centralized procedures.

[4] Dean G Brown et al. "Clinical development times for innovative drugs." eng. In: *Nat Rev Drug Discov* 21.11 (2022), pp. 793–794. ISSN: 1474-1784 (Electronic); 1474-1776 (Print); 1474-1776 (Linking). DOI: 10.1038/d41573-021-00190-9.

static costs, particularly because they are often filed many years after the initial invention occurs. Secondary patents may be weaker from a legal perspective, and thus vulnerable to invalidation. However, invalidating a patent can be a costly endeavor with benefits that spill over to many other parties. For example, a generic manufacturer that invalidates a patent on a branded product clears a barrier to entry not only for itself, but for all other generic firms. As a result, there may be socially insufficient effort to invalidate "bad" patents.

The Hatch-Waxman Act[5] in the US created an incentive for such patent challenges. The Act mandated the creation of a list of Approved Drug Products with Therapeutic Equivalence Evaluations or "Orange Book," which includes patents that branded (originator) firms designate as protecting their products. The Food and Drug Administration (FDA) awards the first generic firm that successfully challenges Orange Book patents on a branded drug 180 days of being the only generic with marketing approval. As Hemphill and Sampat[6] show, these "Paragraph IV" filings have increased substantially over time, and trimmed the realized exclusivity by several years relative to the nominal exclusivity implied by a drug's patents.

In contrast, there is no "prize" from European Medicines Agency, the EU equivalent of the FDA, awarded to generic firms that challenge patents. There also is no equivalent of the Orange Book. In practice, this makes the identification of relevant patents more challenging. While the Orange Book listings may have been subject to gaming, prompting an announcement of increased scrutiny from the US Federal Trade Commission in 2023, at least they provide a patent linkage for competitors (and researchers).

Determining patent status in Europe is further complicated by the fact that, while the European Patent Office (EPO) evaluates patents for EU members and others, patent protection and enforcement are at the national level. Thus, not all patents are in force in all countries at all times. The recent establishment of a Unified Patent Court and a Unitary Patent may well change this landscape going forward. However, for drugs currently on the market, patent status can vary significantly across EU member states.

### 3.1.1 Patent extensions

The Hatch-Waxman Act established patent term extensions, available for one patent per new chemical entity, as a concession to innovator firms who argued that the remaining

[5] John R. Thomas. *The Hatch-Waxman Act: A Primer*. CRS Report R44643. Congressional Research Service, 2016.

[6] Hemphill and Sampat, "Patents, Innovation, and Competition in Pharmaceuticals: The Hatch-Waxman Act After 40 Years".

patent term after lengthy development was often too short to allow them to recoup their investments. These extensions can be a maximum of 5 years, and provide for no more than 14 years of total exclusivity. The Orange Book includes information on which patents firms have selected for extension and the expiration date.

The counterpart in Europe is the Supplementary Protection Certificate (SPC), an instrument created in 1992.[7] The owner of a "basic" (intended to be the primary patent on a drug substance) must apply within 6 months of receiving approval to market in any member state. Its duration is a function of time spent in clinical trials (more precisely, the difference between the application date for the basic patent and the first marketing authorization), for a maximum of 5 years and no more than 15 years of total protection. However, despite being an EU policy, SPCs are granted at the national level (again, because patents are national).

## 3.2 Data and market exclusivity

Not all drugs qualify for patents. For example, the existence of the chemical may have been known for many years, so it is not considered novel for patenting purposes. Some drugs can take many years to develop, leaving little time remaining on their patent clock once they reach the market. With patents alone, the incentives to invest in such products may be insufficient.

As a complement to patents, governments can also grant periods of regulatory exclusivity to products. In contrast to patents, these periods begin from the date of a drug's marketing authorization. These exclusivity periods and their durations are not imposed by the TRIPS Agreement,[8] so countries have considerable flexibility in their design.

In both the US and Europe, generic firms are not required to provide the same data as the originator on safety and efficacy; instead, they can submit an abbreviated application to show that their product is bioequivalent to the originator, and otherwise rely on the clinical data provided by the originator. However, the use of the originator's data is possible only after the data exclusivity term has expired. The regulator may also provide a period of market exclusivity, during which no competitor can be approved, even if the competitor submits its own data.

[7] European Commission. *Supplementary protection certificates for pharmaceutical and plant protection products*. https://single-market-economy.ec.europa.eu/industry/strategy/intellectual-property/patent-protection-eu/supplementary-protection-certificates-pharmaceutical-and-plant-protection-products_en. Accessed: 2025-09-30.

[8] Exclusivity periods may be included in trade agreements, however. For example, the US-Korea Free Trade Agreement specifies a minimum of five years of market exclusivity for new pharmaceuticals.

| | US | EU |
|---|---|---|
| Patent linkage | Yes (Orange Book) | No |
| Patent extensions | Yes | SPCs |
| Patent challenges | PIV | No incentive |
| Pediatric extensions | 6 mos | 6 mos |
| Data exclusivity | 5 years | 8 years |
| Market exclusivity | No | 2 years |
| Additional use | 3 years (new use only) | 1 year (all uses) |
| Orphan drugs | 7 years | 10(+2) |

Table 1: Protection of non-biologics

Exclusivity policy, summarized in Table 1, is one area of important divergence between the US and the EU. Since the 1984 Hatch-Waxman Act, the US has granted 5 years of data exclusivity to new chemical entities (NCEs), with an additional 3 years for new uses of approved drugs. Following the passage of the Patient Protection and Affordable Care Act (PPACA) in 2010, new biologics receive 12 years of data protection.[9] In 2005, Europe adopted a uniform policy of 8 years of data exclusivity plus 2 additional years of market exclusivity for all new drugs.[10] This represented an increase over the 6 years of exclusivity that all but 8 member states provided before that. The EU also gives additional exclusivity for a new use, but only 1 year.

Exclusivity terms are also used to steer innovative activities towards particular goals. For example, to overcome insufficient incentives to develop treatments for diseases with very small patient populations, the US grants 7 years of exclusivity to orphan drugs. The EU provides 10 years, with protection not only from generics or biosimilars but also drugs with a similar mechanism of action. The GAIN Act[11] in the US allows for an additional 5 years of exclusivity for certain new antibiotics, in response to worries about resistance to existing treatments. Both jurisdictions also reward firms for conducting trials in pediatric populations.

Patent and exclusivity periods run concurrently, with different expiration dates. The latter are more transparent, particularly in Europe. The effective term of patents also depends on uncertain development times and, if a patent is challenged, uncertain outcomes of legal proceedings. Exclusivity periods provide a clear floor on protection.

[9] US Food and Drug Administration. *Implementation of the Biologics Price Competition and Innovation Act of 2009*. https://www.fda.gov/drugs/guidance-compliance-regulatory-information/implementation-biologics-price-competition-and-innovation-act-2009. Accessed: 2025-09-30.

[10] European Union. *Regulation (EC) No 726/2004*. https://eur-lex.europa.eu/eli/reg/2004/726/oj/eng. Accessed: 2025-09-30.

[11] US Food and Drug Administration. *GENERATING ANTIBIOTIC INCENTIVES NOW*. https://www.fda.gov/media/110982/download. Accessed: 2025-09-30.

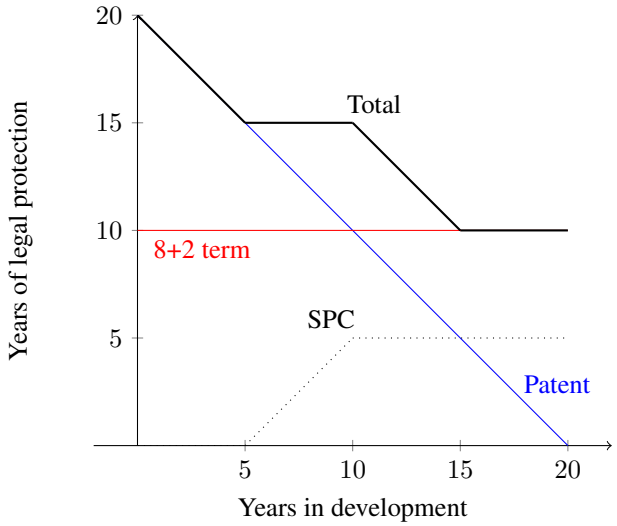


Figure 1: Legal protection in the EU provided by patents, SPCs and exclusivity

# 4 Data sources

## 4.1 European Medicines Agency

Ideally, I would study the potential and realized exclusivities of all new drugs introduced in Europe since the creation of the EMA in 1995. While most new drugs in Europe now apply to the EMA via the centralized procedure, it is not mandatory for all drugs, and some new drugs were approved using the decentralized or mutual recognition procedures. While I include non-EMA drugs in some of my analyses, regulatory data on these is more sparse and non-standardized.

The EMA maintains a list of centrally-approved drugs on its website, including the date of approval. Initially, the EMA's approvals were primarily new molecular entities, i.e. not generics or biosimilars, because approval for the latter would be sought at the national regulators who authorized the originator version. Over time, due to expiration of exclusivities on EMA-approved products, the EMA now also reviews generic and biosimilar applications.

Unfortunately, the EMA does not provide a list of exclusivity terms. As explained, all new drugs receive 8 years of data protection plus 2 years of market exclusivity as a minimum. To obtain information on the "+1" extensions, I search European Public Assessment Reports (EPARs) available on the EMA's website. Specifically, I record a drug as having the "+1" if a report mentions Article 14(11) of Regulation (EC) No

726/2004, and states that the Committee for Medicinal Products for Human Use considers that the new therapeutic indication "brings significant clinical benefit in comparison with existing therapies," meeting the criteria for the extension.

I also collect information from the EMA's annual reports to the European Commission on pediatric incentives. These reports specify which products benefit from a 6-month extension to their SPCs as a reward for having conducted pediatric clinical trials (regardless of the results of those trials). The reports also list drugs that received a "Paediatric use marketing authorisation" (PUMA), which provides 10 years of market exclusivity for drugs without patent protection that are developed specifically for children, as well as those benefiting from an additional 2 years of orphan exclusivity.

## 4.2 FDA

As noted above, the lack of patent linkage in Europe makes identification of the relevant patents for each drug a challenge. I therefore rely on the patent information provided in the US Orange Book for novel drugs launched in the US, based on the FDA's "Compilation of CDER New Molecular Entity (NME) Drug and New Biologic Approvals". The Orange Book does not include information about biologics, which are subject to different legislation, so my sample includes only new chemical entities. I use the same sources as Hemphill and Sampat[12], who describe the data in detail.

## 4.3 European Patent Office

For each US patent listed in the Orange Book for drugs approved from 1995-2024 in the US, I search for European patent equivalents at the European Patent Office (EPO). For each European patent, I obtain information on the application date; the countries for which the applicant requested protection (the designated states); and the patent status (granted, lapsed, withdrawn, etc.) based on data provided to the EPO. I also collect information on oppositions filed to patents at the EPO, or at national offices if the data is provided to the EPO. I obtain the same information for any patent listed as an equivalent in EU member states.

The legal status information includes some data on SPCs at the national level. Its completeness relies on national patent offices sharing this information, and is difficult to assess. Not all national offices provide an easy way to search for SPCs, or to extract the data in a standard form. This lack of centralized data contributes to the opaqueness of a drug's patent status throughout Europe.

[12]Hemphill and Sampat, "Patents, Innovation, and Competition in Pharmaceuticals: The Hatch-Waxman Act After 40 Years".

## 4.4 MRI Product Index

The MRI Product Index, maintained by the Heads of Medicines Agencies in the EU, provides information on products approved via the decentralized or mutual recognition procedures in the EU. I use this as a source of information on marketing authorizations, particularly for generic drugs. However, its coverage of past marketing authorizations that may have since expired or had a change in ownership is incomplete. For example, an originator product approved in 1999 but since discontinued may not appear in the index today, so the originator launch is not always available. In addition, unlike the FDA's Orange Book, the MRI Product Index does not specify which drugs are "reference drugs" for the purposes of generic approval, or indicate which drugs are bioequivalent. It is not unusual to see drugs with identical active ingredients sold under several different brand names within the same country, and unfortunately it is not possible to know whether these are as substitutable as an originator and an AB-equivalent generic.

## 4.5 IQVIA

Due to the challenges of obtaining generic marketing authorizations from each national regulator, I rely on a non-public data source, IQVIA MIDAS, for information on generic launches by country. While launch may occur with some delay after the marketing authorization has been granted, I assume that generic firms generally have the incentive to sell immediately (in contrast to originator firms[13]). Two EU countries (Denmark and the Netherlands) are not included in the MIDAS data to which I have access.

## 4.6 Sample description and definitions

The FDA approved 1033 products it classifies as new molecular entities from 1995-2023. The EMA approved 1041 products after 1995[14] that are not designated as generic/hybrid or biosimilar. I matched 552 of the FDA's NMEs to EMA approvals based on ingredient and/or brand name. Because not all drugs in Europe use the centralized procedure, I also looked for approvals in the MRI Product Index, finding 123.

[13] Margaret K. Kyle. "Pharmaceutical Price Controls and Entry Strategies". In: *Review of Economics and Statistics* 89.1 (2007), pp. 88–99; Luca Maini and Fabio Pammolli. "Reference Pricing as a Deterrent to Entry: Evidence from the European Pharmaceutical Market". In: *American Economic Journal: Microeconomics* 15.2 (2023), pp. 345–83. DOI: 10.1257/mic.20210053. URL: https://www.aeaweb.org/articles?id=10.1257/mic.20210053.

[14] Some drugs first launched in the US may arrive with a delay in Europe, so I do not cut off the EMA approvals in 2023.

In the MIDAS sales data, which covers through 2022, I matched 748 products in the US. Of the FDA NMEs, 727 have at least one patent listed in the Orange Book, and 483 of these products are matched to either EMA or MRI approval information.

To determine the patent status of new drugs, I begin with the 727 FDA NMEs that are listed in the Orange Book. Of these, 673 have at least one equivalent EP patent. In total, there are 4219 US patents associated with these NMEs, and 3202 EP equivalents.

I define the nominal patent term as the years between the first EU marketing authorization and expiration of last Orange Book patent equivalent associated with a drug. The ”basic” patent term is the years between first EU marketing authorization and expiration of ”basic” patent, which is assumed to be the earliest equivalent of an Orange Book patent with a drug product or drug substance claim. Trial duration, which is important for calculating the SPC term, is the years between the basic patent application date and first marketing authorization.

# 5 Legal protections across markets

## 5.1 Patents

A summary of Orange Book patents and their EP equivalents is provided in Table **??**. The Orange Book includes information about whether a listed patent includes a drug substance or product claim, which are usually present for primary or ”basic” patents. On average, drugs have about 5 patents listed in the Orange Book in the US and 5 equivalent EP applications. However, only about 3 are granted in the EU due to oppositions/rejections/withdrawals. As shown in Table 3, these negative outcomes are more likely for secondary patents without a drug substance or product claim, with opposition rates and rejection rates 2-3 times higher.

Table 2: Summary of Patents by NDA Approval Year

| FDA approval year | US NMEs approved | NMEs with OB patents | Average number of OB patents | Average number of DS/DP patents | NMEs with EP equivalents | Average number of EP equivalents | Average number of DS/DP EP equivalents |
|---|---|---|---|---|---|---|---|
| 1995 | 30 | 26 | 2.60 | 1.75 | 21 | 2.33 | 1.67 |
| 1996 | 59 | 42 | 2.76 | 2.11 | 35 | 3.34 | 2.33 |
| 1997 | 43 | 33 | 2.63 | 1.50 | 27 | 2.52 | 1.33 |
| 1998 | 36 | 25 | 3.06 | 1.25 | 21 | 3.10 | 1.50 |
| 1999 | 37 | 30 | 3.65 | 2.10 | 25 | 3.20 | 2.33 |
| 2000 | 29 | 22 | 3.59 | 1.75 | 17 | 3.47 | 2.00 |
| 2001 | 29 | 24 | 3.45 | 1.82 | 22 | 3.00 | 2.67 |
| 2002 | 23 | 17 | 4.52 | 3.14 | 15 | 3.20 | 2.67 |
| 2003 | 27 | 19 | 3.56 | 3.80 | 17 | 4.41 | 5.14 |
| 2004 | 36 | 19 | 2.72 | 3.47 | 19 | 3.26 | 3.36 |
| 2005 | 20 | 13 | 4.40 | 3.31 | 13 | 3.77 | 2.75 |
| 2006 | 22 | 17 | 5.23 | 4.18 | 15 | 5.87 | 3.40 |
| 2007 | 18 | 15 | 5.44 | 4.47 | 15 | 5.67 | 4.47 |
| 2008 | 25 | 20 | 4.72 | 3.55 | 18 | 4.56 | 3.39 |
| 2009 | 26 | 19 | 3.69 | 3.28 | 18 | 5.06 | 3.56 |
| 2010 | 21 | 11 | 3.52 | 4.09 | 11 | 6.09 | 3.55 |
| 2011 | 30 | 22 | 3.60 | 3.33 | 20 | 6.05 | 5.11 |
| 2012 | 39 | 31 | 5.64 | 4.32 | 30 | 6.33 | 5.43 |
| 2013 | 26 | 23 | 7.46 | 5.41 | 23 | 7.78 | 6.00 |
| 2014 | 42 | 28 | 7.45 | 6.18 | 28 | 9.43 | 6.82 |
| 2015 | 45 | 31 | 5.31 | 4.84 | 30 | 7.10 | 6.59 |
| 2016 | 22 | 14 | 5.59 | 4.93 | 14 | 8.00 | 6.93 |
| 2017 | 46 | 32 | 5.46 | 5.62 | 31 | 6.35 | 5.79 |
| 2018 | 59 | 37 | 6.41 | 5.22 | 35 | 6.74 | 5.71 |
| 2019 | 47 | 33 | 5.57 | 5.12 | 33 | 5.82 | 4.97 |
| 2020 | 54 | 36 | 3.96 | 3.70 | 33 | 5.82 | 5.03 |
| 2021 | 50 | 35 | 4.00 | 3.94 | 34 | 6.06 | 5.18 |
| 2022 | 37 | 22 | 2.89 | 3.67 | 22 | 5.05 | 4.62 |
| 2023 | 55 | 31 | 2.60 | 3.21 | 31 | 3.90 | 3.25 |

Table 3: Summary of Orange Book Patent Outcomes

| Substance | Product | US Patents (N) | EP Patents (N) | EP Grant (%) | EP Opp (%) | EP Rej (%) |
|---|---|---|---|---|---|---|
| False | False | 3900 | 3288 | 26.60 | 8.90 | 29.90 |
| False | True | 1554 | 1381 | 21.40 | 9.90 | 20.70 |
| True | False | 633 | 547 | 12.10 | 3.50 | 12.60 |
| True | True | 2139 | 1985 | 11.40 | 2.70 | 11.00 |

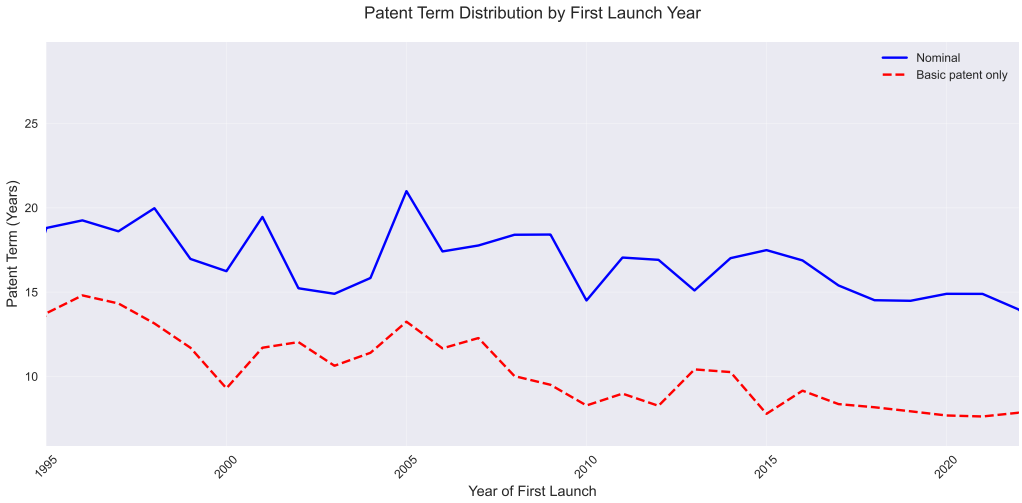


Figure 2: Computed across all EU (plus UK) countries.

As in the US, these secondary patents extend the nominal patent term by many years beyond that of the basic patent. Figure 2 shows how the basic and nominal patent terms have evolved over time, by year of first EU launch. Both have declined, and the gap between the two (which corresponds to the extension beyond the basic term) has increased relative to the 1990s. It is particularly important to note that the average term remaining on the basic patent has been less than 10 years for much of the last two decades. These patterns are consistent with those described in Hemphill and Sampat[15] for the US market.

There is significant heterogeneity in patent protection at the country level, as shown in Table 4. Patent applicants designate countries for protection to the EPO, and are most likely to seek protection in large countries (Germany, France, the UK). Countries with more recent membership in the EU are listed as designated states less often. In addition, patents are more likely to lapse in smaller countries. Figure 3 shows that many patents, even some in the largest markets, are not renewed to the full term of protection.[16]

[15]Hemphill and Sampat, "Patents, Innovation, and Competition in Pharmaceuticals: The Hatch-Waxman Act After 40 Years".

[16]Durations greater than 20 years reflect SPCs, or occasionally, erroneous information on expiration dates in the legal events data from the EPO.

Table 4: Summary of country-level patent status

| Country | Designated state | SPCs (count) | Mean duration | Median duration | Lapsed early |
|---|---|---|---|---|---|
| AT | 3149 | 171 | 15.62 | 18.73 | 2301 |
| BE | 3164 | 188 | 15.93 | 20.00 | 1993 |
| BG | 2230 | 0 | 12.10 | 10.94 | 2055 |
| CH | 3171 | 164 | 15.98 | 20.00 | 1933 |
| CY | 2600 | 223 | 13.45 | 12.86 | 2236 |
| DE | 3182 | 198 | 16.75 | 20.00 | 1909 |
| DK | 3010 | 113 | 14.99 | 16.00 | 2536 |
| ES | 3094 | 17 | 16.98 | 20.00 | 1527 |
| FI | 2728 | 115 | 14.40 | 14.93 | 2415 |
| FR | 3182 | 260 | 16.82 | 20.00 | 1588 |
| GB | 3176 | 185 | 17.64 | 20.00 | 1386 |
| GR | 3073 | 0 | 14.99 | 16.62 | 2507 |
| HR | 1389 | 0 | 9.21 | 8.80 | 1130 |
| HU | 2177 | 186 | 7.85 | 5.77 | 1573 |
| IE | 2924 | 83 | 16.17 | 20.00 | 1701 |
| IS | 1930 | 0 | 10.12 | 9.65 | 1819 |
| IT | 3174 | 131 | 16.19 | 20.00 | 1938 |
| LI | 3166 | 0 | 15.99 | 20.00 | 1914 |
| LT | 1911 | 135 | 9.87 | 9.51 | 1725 |
| LU | 3123 | 306 | 14.99 | 16.40 | 2693 |
| LV | 1791 | 0 | 9.52 | 8.87 | 1578 |
| MC | 2823 | 0 | 13.77 | 13.69 | 2813 |
| MT | 1540 | 0 | 8.31 | 8.14 | 1029 |
| NL | 3172 | 356 | 15.93 | 20.00 | 2074 |
| NO | 1389 | 108 | 8.72 | 8.45 | 866 |
| PL | 2035 | 1 | 11.21 | 10.04 | 1333 |
| PT | 2938 | 0 | 15.11 | 17.86 | 2310 |
| RO | 2154 | 19 | 11.69 | 10.80 | 1872 |
| SE | 3163 | 175 | 15.78 | 19.30 | 2217 |
| SI | 2180 | 0 | 11.94 | 10.86 | 1720 |
| SK | 2231 | 23 | 12.39 | 10.97 | 1818 |
| Overall mean | 2611.90 | 101.84 | 13.56 | 14.81 | 0 |

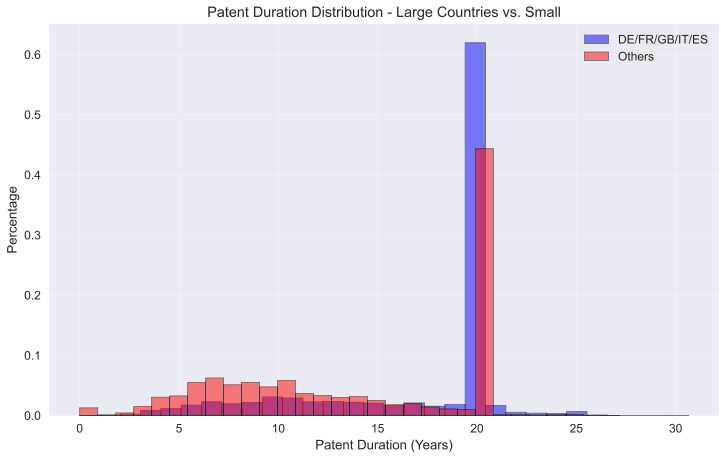


Figure 3: Computed across all EU (plus UK) countries.

It is clear that patent protection has more value in some countries than others, and it follows that extension to patent protection via an SPC is also of variable value. Table 4 includes a column with information on SPCs provided to the EPO. Despite being a small country, the Netherlands has a large number of SPCs reported; this may reflect more systematic recording of SPCs for this country. Variation across countries could also reflect different standards used by local patent offices in granting SPCs.

The geographic scope of pharmaceutical patents in Europe has increased somewhat over time, as shown in Figure 4. However, while patentholders have sought protection in more countries, there is not a corresponding increase in the number of countries in which drugs are launched (Figure 5). Even allowing for some censoring of data in recent years, there is a downward trend in the geographic scope of launch.

## 5.2 Regulatory exclusivity

For the 1041 products approved by the EMA, I could identify 67 that received an additional ”+1” year of exclusivity for a new therapeutic use, as noted in EMA EPAR documents. Ninety-one received orphan designation, with 18 of these receiving an extra 2 years of protection for having conducted pediatric trials. For non-orphan products, such trials were rewarded with a six-month extension to SPCs for 83 products.

Because relatively few products have so far benefited from exclusivity extensions, the average is only slightly higher than the baseline. Average regulatory exclusivity is around 10 years, which is approximately the average term remaining on a basic patent

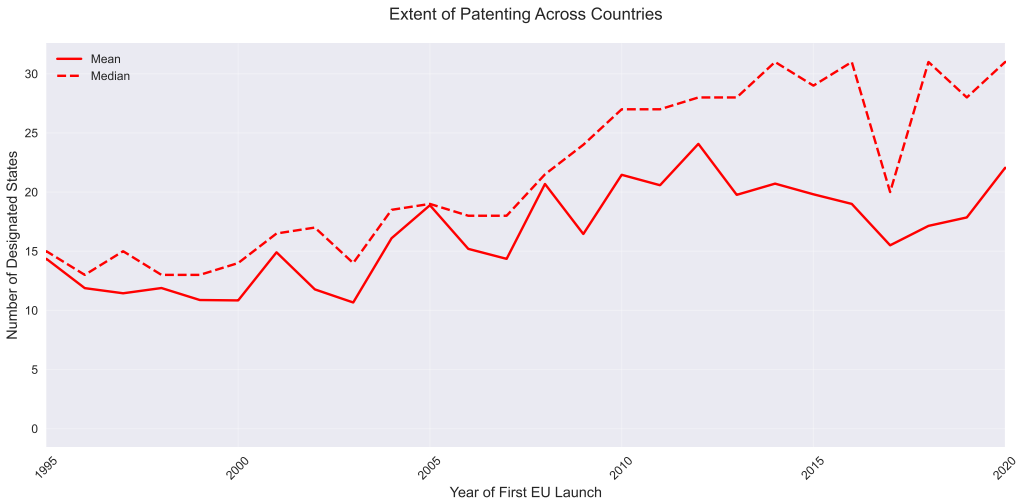


Figure 4: Computed across all EEA (plus UK) countries.

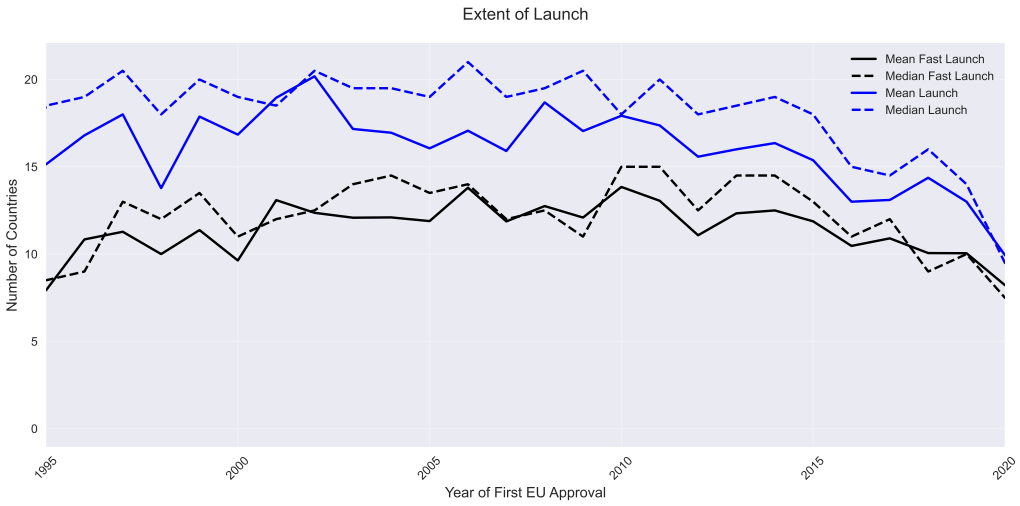


Figure 5: Based on MIDAS data for 23 countries.

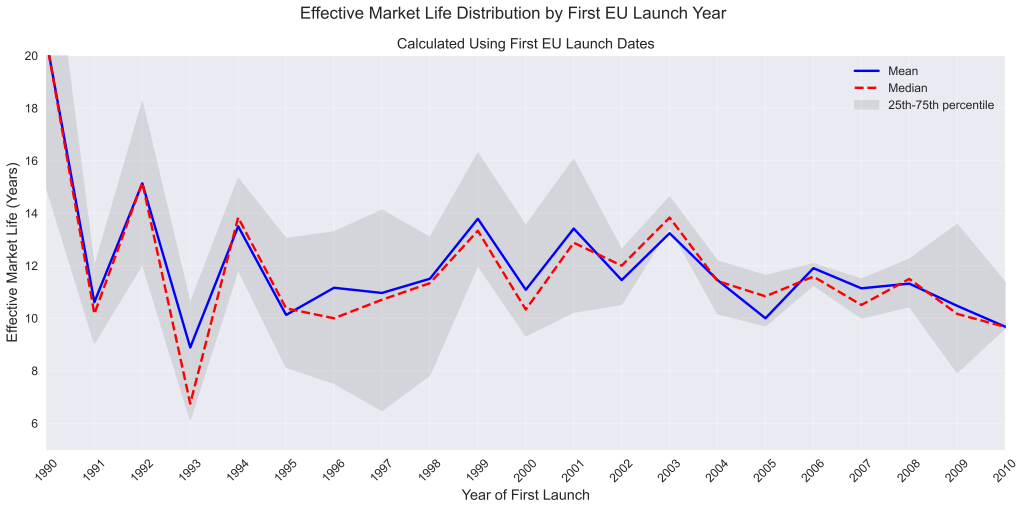


Figure 6: Based on MIDAS data for 23 countries, using the first originator and first generic launches for each drug.

when a drug is launched. SPCs – including the six-month extensions where applicable – increase the basic patent term to an average of almost 13 years.

# 6 Effective or realized exclusivity

Effective market life (EML) can be defined in several ways. At the EU level, EML is the years between the first originator authorization and the first generic launch, anywhere in EU. At the country level, EML is the years between originator and generic launch. Note that both originator and generic launch vary across countries, even when authorization dates do not. As a result, EML at the country level can differ considerably from that at the EU level.

This difference is evident in comparing Figures 6 and 7. Taking the first originator launch and first generic launch anywhere in the EU, the EML has hovered between 10 and 12 years for recent cohorts of drug launched. This suggests that generic entry occurs in at least one country fairly rapidly after the expiration of regulatory exclusivity and the basic patent. However, at the country level, the patterns are different. The EML has trended down in recent years. While the average was around 13 years for drugs first launched in 2006, this has dropped to around 10 for drugs launched in 2010 (though more recent cohorts of launches are subject to censoring).

Originator launch delays have the effect of reducing EML at the country level,

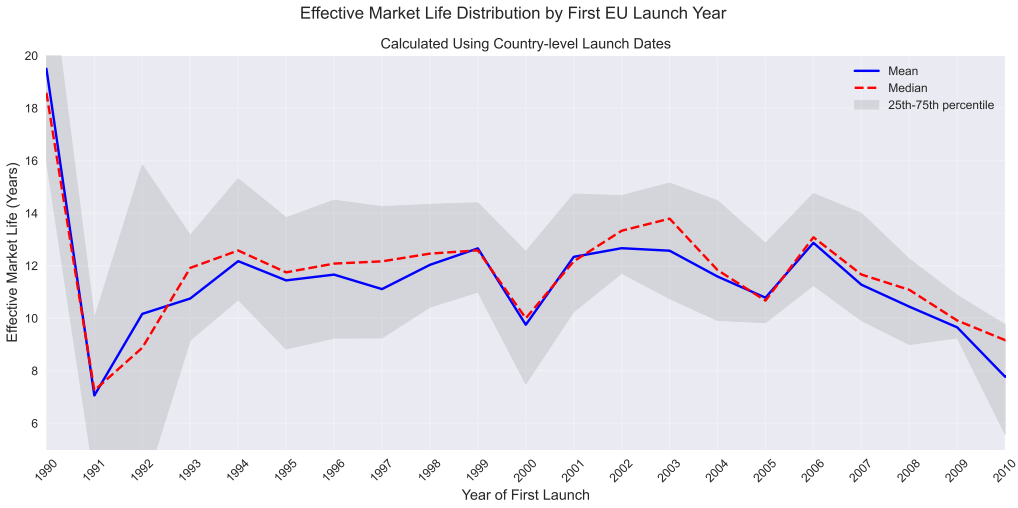


Figure 7: Based on MIDAS data for 23 countries, using the first originator and first generic launches for each drug in each country.

while generic delays have the opposite effect. Figure 6 provides an illustration of how EML at the country level compares to the legal protection available there. If the originator launches immediately and a generic enters as soon as the total legal protection term (excluding secondary patents) has expired, the ratio of EML to total legal protection is one. A ratio of less than one indicates that the originator has ceded some EML through launch delay. A ratio greater than one means that generic firms did not enter immediately, even when the strongest legal barriers were no longer in place. Clearly, both originator and generic delays are prevalent. Further details are provided in Table 5, which shows important heterogeneity across countries in the extent and speed of originator and generic launches.

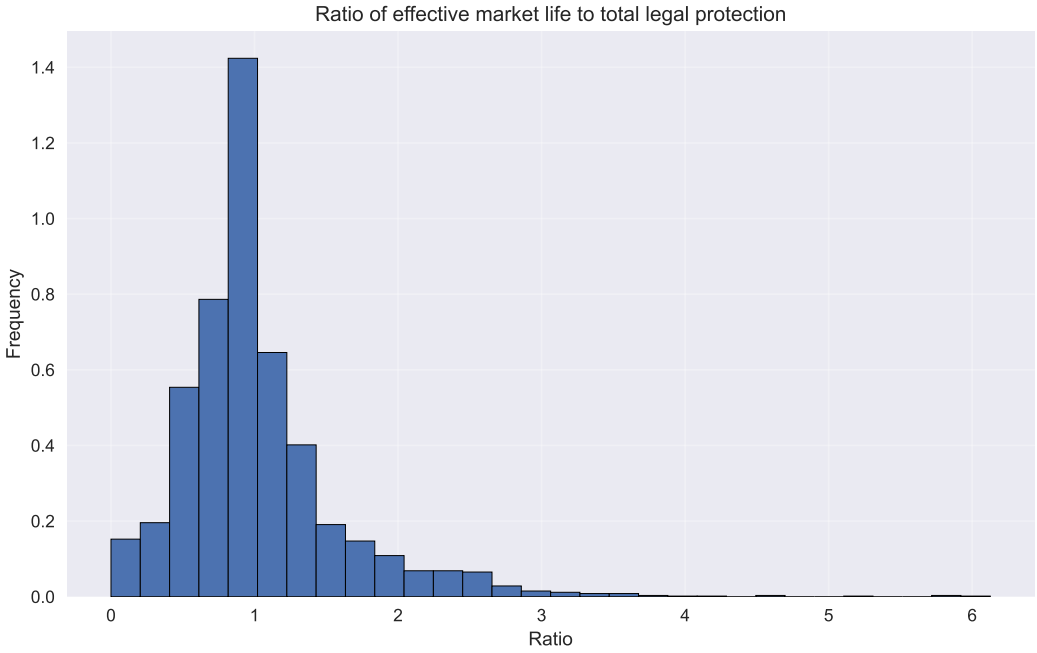
Ratio of effective market life to total legal protection
Frequency
0.0
0.2
0.4
0.6
0.8
1.0
1.2
1.4
0
1
2
3
4
5
6
Ratio

Table 5: Summary Statistics by Country

| Country | Originator Launch | Generic Launch | Originator Delay | Generic Delay | Legal Protection |
|---|---|---|---|---|---|
| Overall | 10511 | 3446 | 1.79 | 2.11 | 12.02 |
| AT | 577 | 165 | 0.95 | 1.65 | 12.23 |
| BE | 497 | 142 | 1.85 | 0.76 | 12.58 |
| BG | 365 | 139 | 4.10 | 3.00 | 11.83 |
| CH | 514 | 139 | 1.48 | 1.53 | 12.20 |
| DE | 623 | 212 | 0.65 | 1.09 | 12.65 |
| ES | 526 | 193 | 1.53 | 2.50 | 11.94 |
| FI | 501 | 157 | 1.12 | 2.82 | 11.89 |
| FR | 543 | 189 | 1.67 | 1.65 | 12.51 |
| GB | 611 | 211 | 0.94 | 1.61 | 12.25 |
| GR | 302 | 104 | 2.06 | 3.08 | 11.97 |
| HR | 377 | 144 | 3.93 | 3.16 | 11.64 |
| HU | 435 | 147 | 2.30 | 2.44 | 11.83 |
| IE | 453 | 131 | 1.55 | 2.70 | 12.02 |
| IT | 592 | 191 | 1.56 | 1.29 | 12.56 |
| LU | 258 | 64 | 1.65 | 0.28 | 12.63 |
| NO | 535 | 172 | 1.51 | 3.93 | 11.63 |
| PL | 475 | 175 | 2.33 | 3.08 | 11.75 |
| PT | 545 | 182 | 1.72 | 2.07 | 11.93 |
| RO | 380 | 140 | 3.89 | 2.95 | 11.77 |
| SE | 534 | 172 | 0.43 | 0.41 | 12.60 |
| SI | 437 | 131 | 2.54 | 3.33 | 11.82 |
| SK | 431 | 146 | 2.34 | 2.41 | 11.75 |

# 7 Discussion and conclusion

Despite differences in exclusivity and patent policies, pharmaceuticals benefit from similar effective market life in the US and Europe. Hemphill and Sampat[17] show that the average EML is 10-12 years in the US, with a decline in recent years. Europe, at least at the overall EU level, exhibits similar patterns. Although the US and EU end up at similar average EML, the US relies more on secondary patents and patent litigation to arrive there[18]. However, the fragmentation of the European market – with country-specific pricing and reimbursement policies as well as patent and SPC protection – results in both originator and generic launch delays.

Generic launch delays have been discussed in the context of reverse payment or pay-for-delay agreements between originator and generic firms. As in the US, competition authorities raised concerns about anti-competitive consequences and brought a number of important cases, including *Servier* and *Lundbeck*. In its recent update on competition enforcement, DG Competition described several other practices that could discourage generic competition (and therefore entry), including disparagement, product hopping, and abusive rebates. Increased antitrust enforcement may have contributed to the decline in EML observed in recent years. A causal analysis of this enforcement is beyond the scope of this paper, but is an interesting topic for future research.

Generic entry may be delayed for other reasons as well, however. Generic firms usually expect very slim margins, so any fixed costs of entering a market may be difficult to cover. While harmonization of EU regulations has probably reduced the fixed cost of generic entry, some country-specific factors may remain. A unified European patent on generic entry may well affect the legal uncertainty and country-specific costs that generic firms face. Non-patent barriers may deserve more attention from researchers and policymakers, however.

Launch delays by originator firms are also an important issue. In its proposed changes to pharmaceutical regulation, the European Commission suggested modifications to current exclusivity policies to address concerns about insufficient incentives to launch, among others (see Figure 8). The European Commission, the European Parliament, and the European Council are currently negotiating these reforms. However, market fragmentation is an important determinant of originator launch strategies. First, the need to negotiate pricing and reimbursement country-by-country has the potential

[17] Hemphill and Sampat, "Patents, Innovation, and Competition in Pharmaceuticals: The Hatch-Waxman Act After 40 Years".

[18] **Hemphill:2025**; Matthew J. Higgins and Stuart J. H. Graham. "Balancing Innovation and Access: Patent Challenges Tip the Scales". In: *Science* 326.5951 (2009), pp. 370–371; C. Scott Hemphill and Bhaven N. Sampat. "Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals". In: *Journal of Health Economics* 31.2 (2012), pp. 327–339.

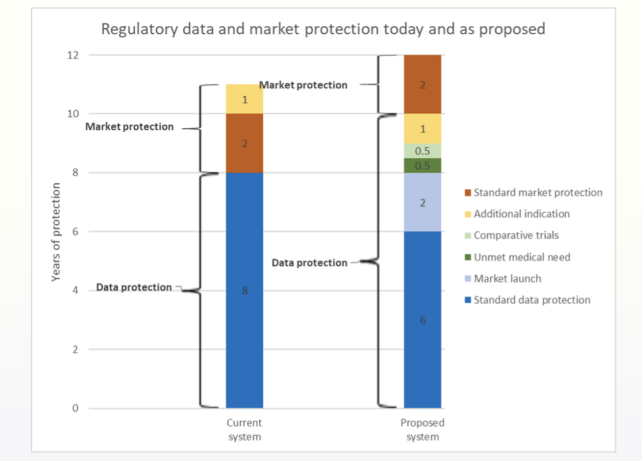


Figure 8: Source: European Commission

to introduce regulatory delays (though negotiations with the many different payers in the US market could be very similar). Second, as several researchers have argued[19], linking prices to those in other countries (external reference pricing) and parallel trade within Europe create incentives for originators to delay or forego launch in some countries. Indeed, the extent of launch has not improved recently. Not only do these delays have negative consequences for patient access, but they undermine the intended innovation incentives that underpin patent and exclusivity policies.

[19] Kyle, "Pharmaceutical Price Controls and Entry Strategies"; Margaret K. Kyle. "Strategic Responses to Parallel Trade". In: *The B.E. Journal of Economic Analysis & Policy* 11.2 (2011). DOI: doi:10.2202/1935-1682.2629. URL: https://doi.org/10.2202/1935-1682.2629; Maini and Pammolli, "Reference Pricing as a Deterrent to Entry: Evidence from the European Pharmaceutical Market".