Available online on 15 Jun, 2025 at https://ijdra.com/index.php/journal
International Journal of Drug Regulatory Affairs
Published by Diva Enterprises Pvt. Ltd., New Delhi
Associated with RAPS & Delhi Pharmaceutical Sciences & Research University

Review Article

Open Access

Drug Patent, Regulatory Exclusivity, and other protection rights (PTA, PTE and SPC) in Pharmaceutical Development in the United States and Europe

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Abstract

Understanding eligibility for drug patents and exclusivities is essential for protecting innovations in the competitive pharmaceutical sector. When a pharmaceutical company develops a new drug, a patent protects this invention from unauthorized use, ensuring that the inventor can recoup the research and development costs throughout the product's lifecycle.

This article discusses the various types of protections for pharmaceutical products granted by intellectual property offices and regulatory authorities, highlighting the differences and similarities between the United States and Europe. By demonstrating patent protection and regulatory exclusivity, the article provides insight into the specific regulations and criteria that must be met to obtain a patent and the associated exclusivity rights.

In the United States, there are Patent Term Adjustment (PTA) and Patent Term Extension (PTE), and in Europe, there is the Supplementary Protection Certificate (SPC). This article illustrates these protection rights and compares their main features. Additionally, it presents straightforward scenarios that outline the key elements that influence the determination and calculation of the protection period, as well as the timely launch of products into the market.

Keywords: Drug Development, Patent, Exclusivity, United States Patent and Trademark Office (USPTO), United States Food and Drug Administration (USFDA), European Medicines Agency (EMA), European Patent Office (EPO), European Supplementary Protection Certificate (SPC), Patent Term Adjustment (PTA), Patent Term Extension (PTE)

Article Info: Received 05 Apr 2025; Review Completed 17 May 2024; Accepted 25 May 2025

Cite this article as:
Mohamed Fadlemula RA. Drug Patent, Regulatory Exclusivity, and other protection rights (PTA & PTE and SPC) in Pharmaceuticals Development in US and Europe. Int. J. Drug Reg. Affairs [Internet]. 2025 Jun 15 [cited 2025 Jun 15]; 13(2):17-24. Available from: http://ijdra.com/index.php/journal/article/view/753

DOI: https://doi.org/10.22270/ijdra.v13i2.753
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1. Introduction

1.1. United States

The process of discovering a new drug is lengthy and exorbitant. In the United States, a study found that the cost of developing a single drug ranges from $161 million to $4.5 billion (adjusted for 2019 dollars). This high cost attributed to important factors such as therapeutic targets, development complexity, and the size of the firm. (1)

Primarily, drugs that have high prices this mainly related to the cost of the whole process of innovation and development of these drugs which takes a long term. Relying on therapeutic area, data, and modeling assumptions, there was a study that represents the cost of research and development of a new drug ranges from $314 million to $4.46 billion. (2)

1.2 Europe

The Statistical Members of the European Federation of Pharmaceutical Industries and Associations (EFPIA) reported that €41.5 billion was invested in research and development (R&D) in 2021. (3)

Development of a new drug for a specific disease is defined under a brand name. Protection of the drug by patent rights ensures its pharmaceutical company is authorised to manufacture and market this drug and primarily profits from its sales. (4)

Marketing exclusivity is ultimately an incentive for drug innovators. It's a defined period that is acquired after drug approval from regulatory authorities, which is granted to the manufacturer to market their product without encountering competition from other manufacturers of duplicate or reformulated products.

Manufacturers of alternative formulations or generic versions for the same active ingredient did not get acceptance or approval for their applications during the exclusivity period granted to the innovator. Each type of exclusivity has a different timeframe. The exclusivity timeframe is not considered an extension to the patent. (5)

Patents and regulatory exclusivity are conducted independently. This demonstrates that the invented drug may have both, only one or neither type of protection. (6)

2. Patent

2.1. Drug Patents in the United States

A patent is a property right awarded to an innovator by the United States Patent and Trademark Office (USPTO), which permits the innovator or sponsor to prevent other companies from manufacturing and selling the invention throughout the United States.

The term of a new patent is 20 years from the date the patent application was filed in the United States.

Innovators may apply for a patent from the United States Patent and Trademark Office (USPTO) at any point during the development lifecycle of the innovative drug, and the application can encompass a wide range of claims. Nonetheless, the term of a patent can be affected by many factors. Prior to approval, FDA Form 3542a was used to submit Patent information with original New Drug Applications (NDAs) and certain supplemental applications (sNDAs). After approval, FDA Form 3542 is used to submit patent information, which is subsequently published in the Orange book (Approved Drug Products with Therapeutic Equivalence Evaluations). The patent information for unapproved applications will not be published by the FDA in the Orange Book.

The patents that the FDA deems for the process of submission of patent information:

- Patents that claim the active ingredient(s)
- Drug patents encompass formulation and composition patents.
- Patents for a specific approved drug indication or method of utilizing the product.
- Other additional patents are mentioned in detail on FDA Form 3542. (7)

Manifestation of the following three key elements is required to grant a successful patent:

- The invention accomplished its intended purposes.
- Novelty
- Non-obviousness (invention development unknown to the professionals in the same invention field).

Pharmaceutical patents can enclose a vast range of claims related to a single drug, involving its formulation, administration technology, indications for treating specific diseases, and methods of active ingredients. At any stage of a drug's development, patent applications are able to be submitted and granted. (6)

2.2. Drug Patent in Europe

The period of a European patent is 20 years from its filing date. (8)

Any intervention must fulfil particular criteria to acquire a patent, such as being novel and encountering inventive steps. The process starts by submitting a patent application to the patent office. The application will be reviewed, and based on their examination; the appropriate decision will be made on whether to grant the patent or application rejection. National patent applications should be submitted through an appropriate national patent office whenever the protection is requisite in only one European country.

There are two main alternatives to the protection required for multiple European countries:

European Patent: Known as the traditional option. The process commences by filing a European patent application with the European Patent Office (EPO). After granting the European patent, it is then necessary to "validate" with the national patent office in each country where protection is sought. In addition to other requirements that are needed in each country, such as fees or translation. Recently, the European patent encompasses 44 countries.

Unitary Patent: Any European patent that was granted on or after June 1, 2023, can also be settled on the new Unitary Patent System, which is performed by seeking 'unitary effect' to be accredited to that patent.

The Unitary patent covers 18 EU countries (and also plans for more in the future) that do not require performing a national validation. Furthermore, in a country that is not engaged in the Unitary Patent System, the traditional validation process remains required.

The fees will be paid annually to the European Patent Office (EPO) instead of separate fees. (9)

In conformity with the rules of the European Patent Convention (EPC), the new Unitary Patent is established on the European patent that is accredited by the European Patent Office (EPO). (10)

By 2025, over 48,000 unitary patents have been registered by the European Patent Office (EPO). (11)

a) Patent Cooperation Treaty (PCT) Applications

Inventors aiming for global patent protection can submit an international application, which is effective patent filing in the USA and EU. The advantage of the PCT filing strategy not only affects the protection but also minimizes expenses and any other administrative challenges. On the other hand, it provides a single international filing date and delays the decision to enter national phases in specific countries.

b) U.S. Patent Cooperation Treaty (PCT) Applications

The United States is participating in the Patent Cooperation Treaty (PCT), which allows inventors to submit a single international patent application that protects the patent across multiple countries. The PCT application process begins with an international phase, followed by national phases in the intended countries. The process of filing a PCT application through the USPTO involves an international search and preliminary examination.

c) European PCT Applications

Submitting a PCT application through the EPO will offer special benefits, such as a unified international filing process and preliminary examination. When PCT applications transition to the European phase, they are assessed by the EPO to ensure they meet European patentability criteria. The PCT pathway is considered a

cost-effective procedure for obtaining patent protection in Europe and other PCT member nations, offering strategic advantages and flexibility for granting international patents. (12)

3. Patent Term Adjustment and Patent Term Extension in the United States

There are two types of patent term extensions:

3.1. Patent Term Adjustment (PTA)

3.2. Patent Term Extension (PTE)

3.1. Patent Term Adjustment (PTA)

The Patent Term Adjustment (PTA) is considered a recouping measure for patent applicants, which provides additional time to establish a market presence. In the United States, the patent term is 20 years from the date of application filing.

Patent Term Adjustment (PTA) was established in 1999 by the United States Congress. According to 35 U.S.C. § 154(b), it provides for an extension of a specific number of days to the patent term due to delays that occur during the application prosecution process by the Patent and Trademark Office (PTO).

In calculating the PTA, five categories of delays should be considered:

PTA days are divided into A-delay, B-delay, C-delay, Applicant Delay (non-responsiveness to Office Action), and Overlap Delay (which occurs between two or more delays).

Calculation of Patent Term Adjustment (PTA) is as follows:

PTA = Days of {PTO Delay} - Days of {Applicant Delay}

Days of PTA = A-delay + B-delay + C-delay – Applicant delays – Overlap Delay (13)

3.2. Patent term extension (PTE)

PTE is recouped by inventors for the time lost due to regulatory delays during the process of drug approval at the United States Food and Drug Administration (USFDA). PTE is granted only for the drug's active ingredient. (14)

Patent Term Extension Requirements:

Some criteria must be fulfilled for the patented drug to be eligible for PTE:

- The patent should include a claim for the product itself and the manufacturing method.
- The Patent term should be valid.
- No extension had been made previously for the patent term.
- The owner of the patented drug must file an application for the Patent term extension.
- A review should take place prior to the product's commercial marketing permission.
- The patented drug must receive FDA approval for commercial sale.
- No synchronization with other patent term extension for the same regulatory review period for this product.

There are two limitations on the PTE period:

- The utmost term for the patent extension is five years.
- From the FDA product approval date, the comprehensive remaining patent term (with PTE) is finite to fourteen. (15)

Patent Term Extension (PTE) was established in 1984 when Congress enacted the Drug Price Competition and Patent Restoration Act, commonly referred to as the Hatch-Waxman Act.

The regulatory review period in the United States consists of two phases: a testing phase and an approval phase.

The testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins.

The approval phase begins with the first submission of a marketing application for the drug product and lasts until the FDA confers the marketing authorisation of the drug. A maximum of five years of Patent Term Extension (PTE) may be granted, depending on the duration of both approval phases. (16)

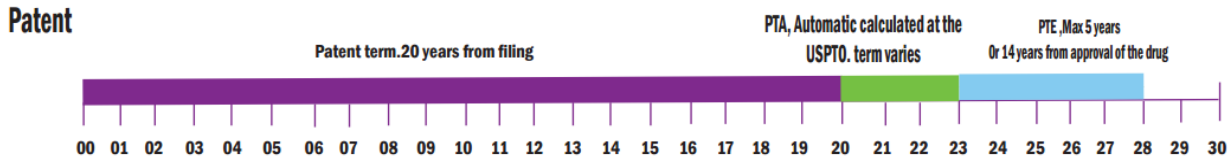

Figure 1. Patent term, PTA and PTE

4. Supplementary Protection Certificate (SPC) in Europe

A Supplementary Protection Certificate (SPC) is an intellectual property right that applies to the active ingredients of both human and veterinary medicines that need marketing authorization. The SPC system was created to compensate patent owners for the reduction in effective patent duration caused by the time taken to secure marketing approval for their products. However, regulatory delays alone do not justify the issuance of SPCs.

SPCs are awarded at the national level, and at present, there is no SPC that is applicable throughout Europe.

Thus, the SPC applications should be submitted to the national patent offices of the intended countries. The national SPC application in the European countries where

the European Unitary Patent is valid relies on this Unitary Patent.

In the EU/EEA, the potential of extending the SPC term to an additional six months can be accorded if clinical results from an approved pediatric investigation plan (PIP) are provided. The PIP must be approved for the specific territory or country. The extension request can be made at any time up to two years before the SPC's normal expiration.

To apply for an SPC, one must submit an application to the national Patent Office of the relevant country within one of the following two timeframes: either six months from when the first marketing authorization is granted in that country or six months from the grant of the basic patent. (11)

After a product receives marketing authorization, it can gain up to five additional years of market exclusivity through a Supplementary Protection Certificate (SPC) if it is covered by a patent. Submission of SPC application requires patent validity, and the patented product should have been granted marketing authorisation (MA).

According to Article 13 of Regulation (EEC) No. 1768/92 states the following:

i) The SPC term begins when the patent expires and grants the same rights against infringement as the patent for the product it covers.

ii) The SPC duration is calculated by taking the time between the submission of the basic patent application and the first marketing authorization within the European Economic Area (EEA), minus five years.

iii) The SPC term cannot be longer than five years from the date the SPC becomes effective.

Here are two scenarios of how to determine the SPC term

In the first scenario, the patent application was submitted in 2003 (expiration should be in 2023) and the first marketing authorisation (MA) was granted in 2015, the SPC term is calculated as follows:

(2015 – 2003) – 5 years = 7 years (though the maximum duration is limited to 5 years). Therefore, despite of the patent expiring in 2023, the exclusivity period for the product with the marketing authorisation (MA) will continue until the SPC expires in 2028 as illustrated below in Figure (2). (16)

5. Regulatory exclusivities

5.1. Regulatory exclusivities in the United States

Regulatory exclusivity is a general term that encompasses any proprietary rights granted by the FDA.

There are two main types of regulatory exclusivity:

a) Data exclusivity

b) Marketing exclusivity.

Data exclusivity safeguards the safety and efficacy information, which is commonly referred to as the data package that is submitted by the innovator company. This protection prevents generic companies from using that data to support their own FDA marketing approval applications for a certain period. However, it does not stop generic companies from submitting their own data packages. On the other hand, marketing exclusivity prohibits a competing company from receiving FDA approval, regardless of whether it has its own safety and efficacy data.

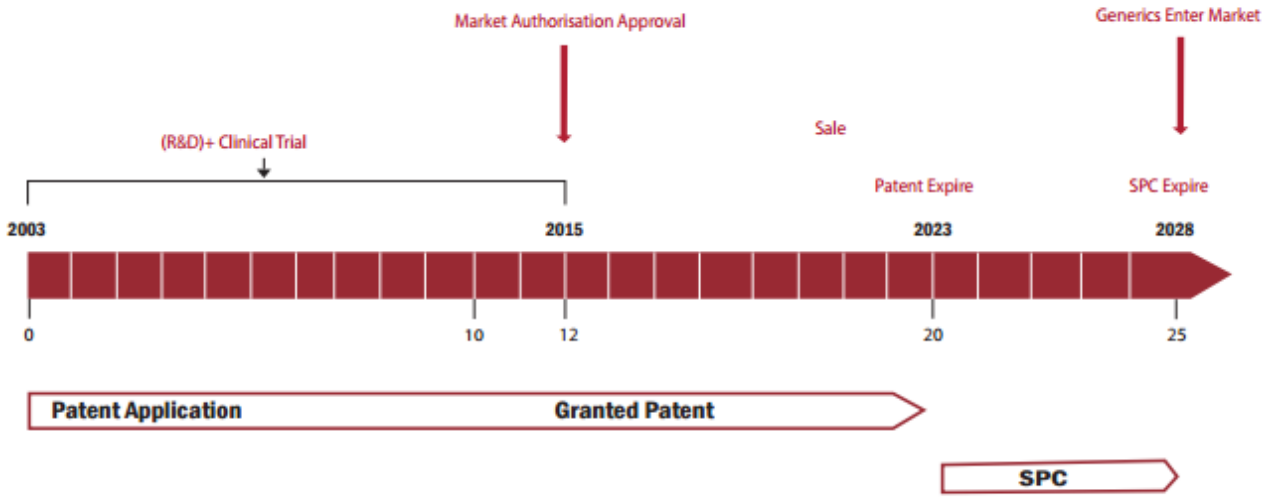

Figure 2. Exclusivity period for the product with the marketing authorisation will continue until the SPC expires in 2028

In the second scenario, the patent application was submitted in 2021 the marketing authorisation (MA) is acquired in a short time frame. SPC calculated as follows: (17)

(2026 – 2021) – 5 years = 0 year (No eligibility for SPC protection). Therefore, the patent will expire in 2041 as illustrated below in figure (3).

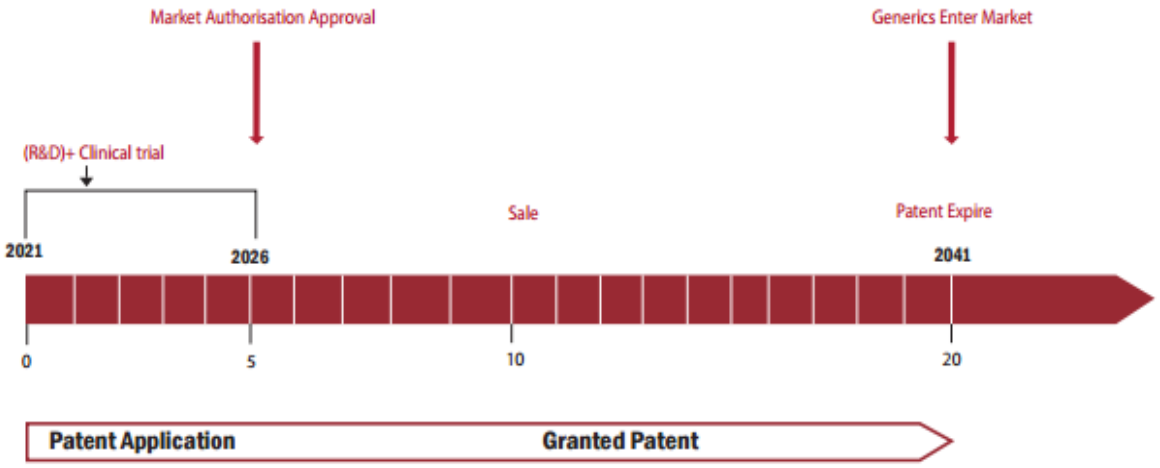

Figure 3. No eligibility for SPC protection. Therefore, the patent will expire in 2041

Table 1. Comparison of the main features of SPC and the Patent Term Extensions (PTE) (18)

Parameters	US (PTE)	EUROPE(SPC)
Authority to grant PTE/SPC	U.S. Patent and Trademark Office (USPTO)	National Patent Office
First induce of PTE/SPC	1984	1993
Submission of request	Within 60 days of receiving marketing approval and before the patent expires.	Within 6 months of either market authorisation approval or grant of the patent, depending on which occurs later.
Maximum term of extension	5 Years	5 Years
Maximum number of extensions per patent	One	One
Calculation of period of extension	Period consisting of half of the testing phase of the product and the entirety of the approval phase by the government authority	Period between the filing date of the patent and the date of marketing approval, reduced by a period of 5 years
Maximum remaining term from product approval until end of extended term	14 years	15 years
Paediatric extension permitted	Yes (6 months)	Yes (6 months)

For many companies, the distinctions between data exclusivity and marketing exclusivity may seem more significant than they actually are. The high costs associated with generating the clinical data and other information needed for FDA marketing approval can be a barrier for many firms. The distinction is more relevant for those companies that have the resources to create their own data packages for FDA submission. (19)

The various forms of exclusivity are outlined in 21 CFR 314.108. There are multiple types of marketing exclusivity, each differing in length and the corresponding criteria that must be met. Some exclusivity is determined by the classification of the product, others by the condition being treated, and some by the targeted patient group. (5)

The types of exclusivity include:

a) New Chemical Entity (NCE) Exclusivity – 5 years

NCE is conferred to a drug that contains no active ingredient previously approved by the FDA in any other application under Section 505(b) of the Act.

Typically, a salt of an approved drug does not qualify as a new active ingredient and is therefore ineligible for NCE exclusivity.

The FDA will grant NCE exclusivity under the following conditions:

- The active ingredient has not been previously approved.
- A fixed combination where at least one active ingredient is new, even if the product also includes an active ingredient that has been previously approved.
- A fixed combination where neither active ingredient has been previously approved.

NCE is defined in 21 CFR 314.108 as part of the Price Competition and Patent Term Restoration Act of 1984. (7,20)

b) Biologic Exclusivity – 12 years

Biologics are conferred a much longer exclusivity period than small-molecule drugs. A total of 12 years of market protection, the initial 4 years are for data exclusivity. During this time, the FDA cannot accept biosimilar applications that depend on data from the original drug manufacturer. This extended exclusivity is intended to promote innovation and support the development of these new therapies, which often require significantly more time to develop than traditional small-molecule drugs.

Biologics are outlined in the Patient Protection and Affordable Care Act of 2010 (PPACA), commonly referred to as Obamacare, which is part of Title VII of the Act.

c) Orphan Drug Exclusivity (ODE) -7 years.

The FDA categorizes a drug for a rare condition or disease, labeling it as an orphan drug. Once the FDA approves a marketing application for this orphan drug no other company's version will be approved for the same disease or condition for seven years unless these companies submit a new drug that is different from the approved orphan drug.

ODE is governed by 21 CFR 316.31 and the Orphan Drug Act of 1983 (ODA).

d) Qualified Infectious Disease Product (QIDP) Exclusivity – 5 years (added to any existing exclusivity)

QIDP exclusivity is conferred to products designed to treat serious or life-threatening bacterial and fungal infections. This exclusivity provides a 5-year extension to any current exclusivity that the product qualifies for.

The QIDP designation is part of the Generating Antibiotic Incentives Now (GAIN) Act, which was outlined in the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA).

e) Paediatric Exclusivity - 6 months

Paediatric exclusivity is an additional exclusivity to existing marketing exclusivity or patent protection. Typically, products without remaining patent life or exclusivity do not qualify for paediatric exclusivity.

This exclusivity is not restricted to the specific product studied in the paediatric population; it extends to all formulations, dosage forms, and indications of the applicant's products that have the same active ingredient.

Paediatric Exclusivity is outlined in the Best Pharmaceuticals for Children Act (BPCA) and Section 505(A) of the Food and Drug Administration Modernization Act (FDAMA) of 1997. (7,21)

f) Clinical Investigation Exclusivity (CIE) – 3 years

Three year exclusivity may be awarded for a product that includes a previously approved drug and if the marketing authorization application features a report of new clinical investigations (excluding bioavailability studies) that were crucial for the drug product's approval.

This CIE is outlined in the Drug Price Competition and Patent Term Restoration Act of 1984. (7,22)

g) Competitive Generic Therapy (CGT) / Generic Drug Exclusivity (GDE)

This exclusivity is granted by the FDA to the first manufacturer that submits an Abbreviated New Drug Application (ANDA) and gets the rights to market their generic product for 180 days.

Although the CGT period is shorter than the brand drugs and biologics, 180 days is significant for manufacturers of generic products in the generic drug market. The manufacturer of the generic product becomes the primary alternative with a lower price than the brand drug and takes advantage of this exclusivity to gain widespread acceptance over hospitals and retail pharmacies.

CGT is also governed by the Drug Price Competition and Patent Term Restoration Act. (5-7)

h) Patent Challenge (PC):

PC is 180 days, which is granted for Abbreviated New Drug Applications (ANDAs) only. (23)

i) Priority Review Voucher (PRV)

PRV is not a type or form of exclusivity, but it acts as a motivation for the inventors who develop new therapies intended for a neglected tropical disease like Chagas disease, malaria, leishmaniasis, and rare Paediatric conditions in the United States.

The inventors benefit from a priority review voucher by getting reduction of FDA review time from 10 months to 6 months, along with its recognizable potential for sale at exorbitant prices that range from $67.5 million to $350 million to other companies for use on different medications. (24)

j) The Role of Exclusivity

Exclusivity is designed to promote a balance between new drug innovation and generic drug competition. (21)

5.2. Regulatory Exclusivities in Europe

In Europe, most of the marketing authorisation applications take place through a centralized system with the European Medicines Agency (EMA) that approval covers all EU/EEA member countries.

There are two types of regulatory data protection, known as data exclusivity and market protection, as outlined in Article 14(11) of Regulation (EC) No 726/2004. The regulatory data protection in the EU/EEA (and UK) follows an 8+2+1 formula, which grants a total of up to 11 years of exclusivity.

Data exclusivity and market protection period take place after marketing authorisation is granted, as shown in the following illustration:

a) Data Exclusivity and Market Protection: 8 + 2 Formula

Data exclusivity is a timeframe of 8 years during which the preclinical and clinical data in the submitted documentation cannot be utilized by other manufacturers or regulatory bodies for evaluating the safety and effectiveness of other products. As a consequence, any

generic companies planning to use these data should wait till this exclusivity period comes to an end.

However, the generic companies that took the data and got approval are not able to market their product until the completion of an additional 2 years, by reason of the 10-year market protection period that also starts after granting marketing authorisation.

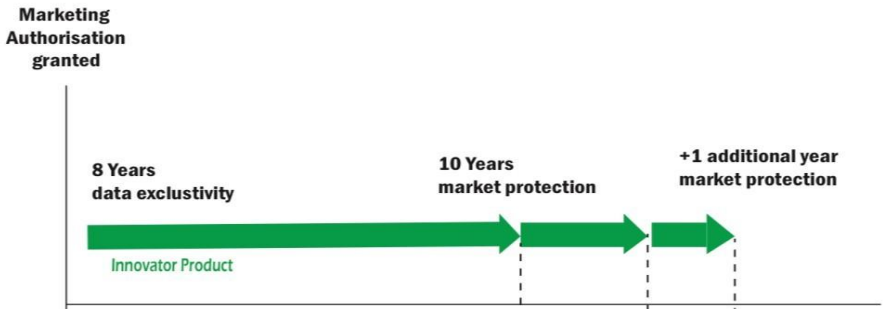

Figure 4. Data exclusivity and market protection

Data exclusivity and market protection do not prevent the submission of market authorisation applications for generic companies that are based on independently generated preclinical and clinical data. Despite that, the expenses of generating preclinical and clinical data outweigh the advantages of market entry before the end of the 8 + 2 years.

b) Market Protection Period: The 8 + 2 + 1 Formula:

Furthermore, the 10-year market protection period can be lengthened by an additional year whenever the marketing authorization holder is granted for a new therapeutic indication that is deemed to provide a significant clinical benefit in comparison to existing treatments for that indication. (25)

The market exclusivity timeframe is extended by two additional years for an orphan-designated condition when the results of specific studies are completed by a fully compliant paediatric investigation plan (PIP) and reflected in the summary of product characteristics (SmPC) addressing the paediatric population. (26)

Table 2. Comparison of the Exclusivities between US and EU

Exclusivities	US	EU
Regulatory Authority	FDA	EMA
Application name	NDA, BLA, ANDA	MAA
Exclusivity period of drugs	QIDP 3 years NCE 5years ODE 7 years Biologic 12 years	10 years
Clinical Investigation Exclusivity (CIE)	3 years	An additional year of data protection for a new indication of a well-known substance can be granted based on substantial nonclinical or clinical research.
Pediatric Exclusivity	Yes (6 months) added to the existing exclusivity.	Two additional years for the orphan-designated condition
Generic Drug Exclusivity (GDE)	180 days	No
Priority Review Voucher	Yes	No

6. Conclusion

The various types of protection rights, along with their corresponding criteria and assessment processes, are regulated by acts and directives of their respective countries in the United States and Europe.

Patents and exclusivities support innovators in recouping their investment throughout research and development as well as encouraging innovation of new pharmaceutical treatment.

Granting patent and regulatory exclusivity plays a vital role in shaping the pharmaceutical industry. The differing approaches between the United States and Europe present both potential opportunities and challenges for drug innovators to meet the requirements and maximize the benefits of the granted protections.

Acknowledgements

I would like to express my sincere gratitude to the editorial team and reviewers of International Journal of Drug Regulatory Affairs for their valuable feedback and support throughout the review and publication process. Their constructive comments have significantly enhanced the quality of article.

Financial Disclosure statement:

The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

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