

Reforming Patent Term Extensions: Aligning Pharmaceutical Exclusivity with Public Health Needs

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Abstract

The patent term extensions (PTEs) and supplementary protection certificates (SPCs) are meant to provide an opportunity to the pharmaceutical innovator to compensate for the delay in receiving regulatory approval to launch the pharmaceutical products into the market. It has been shown that having exclusivity through PTEs or SPCs isn't simply about recouping investment, and that it also stops access to cheaper generic versions of the drugs. A comparison of PTEs/SPCs is presented for the major jurisdictions, namely the US, European Union, Japan, Australia, and India. A thorough study was done for the drugs Lipitor, Gleevec, Revlimid, and Humira, revealing how benefits from long patents have allowed these companies to tightly control the market and collect large profits. This article suggests a list of policy recommendations to assist PTEs/SPCs systems to align with public health goals, a 5-year global limit extension, one extension per drug, a necessary public interest review, data-based paediatric exclusivity, all-inclusive exclusivity of 15 years from the date of regulatory approval, and creation of a uniform standard by international organisation. The policy recommendations are important for ensuring there is a balance between incentives for pharmaceutical innovation and public access to affordable medicines.

Keywords: Patent term extensions, Supplementary protection certificates, Access to medicines, Exclusivity, Regulatory approval, Generic drug.

1. Introduction

A patent is a territorial exclusive right given by the Government for a limited period of time to the patentee for disclosing the invention to the public, which qualifies the patentability criteria of novelty, inventive step, and industrial applicability so that the patentee can exclude others from using, selling, importing the invention without the patentee's consent [1]. The objective is to give the exclusive right to the patentee by the government so that the patentee can recoup the investment spent to develop the invention and reinvest for future inventions [2]. The standard term of a patent is 20 years from the date of filing, which is established under the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement [3]. Patent Term Extensions (PTEs)

are given in the field of pharmaceutical and biotechnological sectors to compensate the innovator for the time taken by the regulatory authority to approve the product for launch in the market. Through PTEs, companies can maintain their exclusive sales in the market, hoping to boost incentives for new inventions. The benefits go to the innovators, but there are two problems with the system. The higher price of medicines and the delayed launch of generic drugs prevent many patients from using the drugs they need. Both access to the medicine by the public and rewards for innovators should be considered. For new products to be approved, these industries have to spend a significant amount of time on clinical trials, which greatly reduces their years under patent. Thus, PTEs function as an alternative to fill in. It is very significant since making new drugs costs billions of dollars. Providing extended protection through PTEs becomes vital for businesses to recoup the investment, which prompts them to create new medicines [4]. The PTEs started in 1984 in the USA through the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417), also known as the Hatch-Waxman Act (1984). Thereafter, South Korea (1987), Japan (1988), the European Union (1993), and Australia (1998) followed the extension mechanism due to regulatory delays [5, 6].

The pharmaceutical industry demands a lot of research in chemistry and biology so as to introduce a new drug to the market. If 10 drug molecules are allowed to enter the clinical trial, then only one gets approval for launch. The pharmaceutical industry route from initial identification to regulatory clearance to commercial readiness spans approximately 12 to 15 years [7, 8]. Developing a single new drug costs innovators extensive sums of money at every stage of development. The research established that expenses for developing pharmaceutical drugs in 2019 spanned between 161 million and 4.5 billion USD [9]. Pharmaceutical companies use market protection terms to set drug prices that permit reimbursement of the substantial costs spent on research, including research failures, thus supporting their business longevity. After generic competition enters the market, the original brand-name drug normally loses 80% of its market. The first launch of generics causes prices to decline by 20-30%, while additional competitors can reduce prices up to 90% of their original amount [10]. The extended patent term causes drugs to become more expensive, which results in elevated healthcare expenses while making essential medications less available [11].

If we look at the situation from a public health perspective, then PTEs create competition between innovation promotion and medicine affordability. The World Health Organization (WHO) has shown concern regarding high medication costs generated by prolonged patent protections, mainly affecting developing and middle-income nations and their ability to obtain lifesaving medicines. Public health improvements heavily depend on the availability of generic medicine in this context [12]. The public health sector requires both pharmaceutical innovations and generic competition in order to arrive at its maximum benefits. Innovator companies are

highly instrumental when it comes to the development process of new and superior drugs and medical breakthroughs. Generic pharmaceutical companies both improve accessibility due to affordable medications, thus increasing the affordability of treatment and availability for a wider range of patients. Appropriate balance of both innovation and competition benefits the public health objectives simply because over-concern on one aspect either limits new drug development or makes it difficult for access to existing drugs. Policies need to support innovation efforts together with the timely release of generic medicines for achieving overall societal advantage [10].

As per the literature, PTEs create advantages for major pharmaceutical firms over the innovative breakthroughs in their medical products. The problem becomes worse because pharmaceutical firms employ "evergreening" practices by making minor changes to existing pharmaceutical products to gain fresh patents that extend exclusive market rights [10].

2. Patent Term Extension Policies in Different Jurisdictions

2.1. United States

Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417)/Hatch-Waxman Act (1984): The Foundation of PTEs in Pharmaceuticals.

The pharmaceutical industry's structure shifted through major changes because of the Hatch-Waxman Act, which introduced two key provisions:

The PTE provision of 35 U.S.C. § 156 enables patent holders to gain additional term coverage, which counts lost time during regulatory approvals.

The Bolar Exemption within 35 U.S.C. § 271(e)(1) enables generic drug producers to perform essential research and testing tasks before patent expiration so they can launch products as soon as patents expire.

The regulation of PTEs under 35 U.S.C. § 156 intends to provide patent holder reimbursement primarily to pharmaceutical and biotechnology sectors when their products undergo necessary pre-market regulatory reviews by entities such as the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) [13].

2.1.1. Legal Framework (35 U.S.C. § 156)

Under the provisions of 35 U.S.C. § 156, patent holders can secure an additional 5 years to reimburse for regulatory review delays. The total market exclusivity period from the date of the FDA approval is limited to 14 years to give patent owners reasonable compensation for a time loss during the review process, also protecting competitors from lengthy monopolies so that the generic company can launch the product [14, 15]. The length of the PTE is calculated by the U.S. Patent and Trademark Office (USPTO) in partnership with the FDA based on the review process's total duration [15].

2.1.2. Eligibility Criteria for Patent Term Extensions in the U.S. [16]

A patent can get PTE under 35 U.S.C. § 156 if it qualifies under the following conditions:

The patented product must be an item requiring prior regulatory approval to sell and include pharmaceutical drugs and biologicals, medical devices, food additives, or colour additives.

The term of the patent has never been extended before.

The term of the patent has not expired.

The time taken for the documentation process during the regulatory approval must be solely responsible for marketing delays.

After receiving FDA or USDA approval, the patent owner needs to submit a PTE application within the 60-day window.

No other patent for the same product got an extension for the regulatory review, i.e., only a single patent term extension for each product.

2.2. European Union

The European Union (EU) manages pharmaceutical and plant-protection-product patent extensions through its Supplementary Protection Certificate (SPC) system. SPC serves as compensation because it provides an additional period of exclusivity to manufacturers of pharmaceuticals and plant-protection products for their long regulatory approval period. Despite the fact that SPC operates in the same way as PTE in the U.S. and Japan by granting market exclusivity after the expiry of patents, they act as independent intellectual properties. The market exclusivity of an SPC will last for a maximum of 5 years after patent expiry. Under Regulation (EC) No 1901/2006, an SPC can get an additional six months extension if the pharmaceutical covers paediatric drugs and meets the required Paediatric Investigation Plan (PIP). This extension provides compensation for the additional clinical trial expenses and testing needed under the PIP in order to confirm child-friendly safety and effectiveness of medicines [5, 17].

2.2.1. Legal Framework for Patent Term Extensions in the EU

The SPC system was implemented by Regulation (EC) No 469/2009 for medicinal products and Regulation (EC) No 1610/96 for plant protection products [18, 19].

The SPC system offers exclusivity duration extension of 5 years immediately after the expiration of the patent to manufacturers, although the combined exclusivity period cannot exceed 15 years from the first EU marketing authorization date. An additional 6-month extended period of Special Protection Certificate exists for paediatric medicines [17, 18].

2.2.2. Eligibility Criteria for SPCs in the EU [20]

The following conditions need to be fulfilled to obtain an SPC:

A patent covering medicinal or plant-protection products is in force at least in one of the member states of the EU.

The product gained EU marketing approval.

Within six months after obtaining marketing approval, the SPC application needs to be filed.

The applicant must submit extension requests to each EU member state that contains their underlying patents because National Patent Offices issue SPCs.

2.2.3. Recent Reforms and Proposed Changes to the SPC System

2.2.3.1. SPC Manufacturing Waiver [Regulation (EU) 2019/933]

The SPC system accepted a new provision that permitted generic producers of the EU to manufacture products that come under SPC protection for export purposes outside EU territories. This reform strategy speeds up generic drug market entry and enhances the operational strength of the EU pharmaceutical industry [21].

2.2.3.2. A Unitary SPC System

The European Commission has submitted a plan to formulate a Unitary Supplementary Protection Certificate (uSPC) system to follow the Unitary Patent. This system will improve the extension of patent protection for medicinal and plant protection products in EU Member States. As per the new EU system for unitary patent protection, the EU level examination and grant of the uSPC will be carried out by the European Union Intellectual Property Office (EUIPO) in order to minimise the costs and legal risks of the patent users. It would also establish the uSPC as a unified legal protection range in all member states where the Unitary Patent exists, thus eliminating the need to file for a national SPC. This particular reform is believed to enhance innovation through the reduction of existing complex and differing legal frameworks of protection for patents across the member states of the EU [22].

2.3. Japan

Japan has introduced PTE to compensate for regulatory delays for the approval of pharmaceuticals, veterinary products, and agrochemicals. Japanese PTE has a similar concept to US PTE and SPC mechanism in the EU, with the goal to provide innovators with suitable market exclusivity [23].

2.3.1. Legal Framework for Patent Term Extensions in Japan

As per Article 67(2) of the Japanese Patent Act (Patent Law No. 121 of 1959 with amendments), PTE can be provided up to 5 years for the time lost on the regulatory approvals needed for marketing authorization. This protects inventors from undue losses for the delayed launch of pharmaceuticals or agrochemical products [23, 24].

Unlike the US and EU, Japan allows multiple PTEs for a single patent or product if it meets Japanese statutory criteria [23].

2.3.2. Eligibility Criteria for PTE in Japan [23, 24]

The patent should protect a product that needs official regulatory approval to enter the market, and the product is pharmaceutical or veterinary medicine, or an agrochemical.

The applicant is required to show that there was a delay in commercialization because it required long periods of regulatory approval by competent bodies such as the Pharmaceuticals and Medical Devices Agency (PMDA) or the Ministry of Agriculture, Forestry, and Fisheries (MAFF).

PTE request should be filed within a period of 3 months from the date of marketing authorization.

The period of extension is a maximum of 5 years, and a patent cannot have a total life of more than 25 years from the date of filing, including 5 years of extension.

PTE is provided only to counter regulatory delay during the first approval process for new active ingredients or for a new formulation of already existing pharmaceutical products.

2.4. Australia

The Australian patent law enables standard pharmaceutical substance patents to obtain 5-year PTE. Australian PTEs function according to their purpose by providing compensation to patent holders of the pharmaceutical industry for the time lapsed to fulfil mandatory regulatory requirements for commercial launch [6].

2.4.1. Legal Framework for Patent Term Extensions in Australia

As per Section 77 of the Patents Act 1990 (Cth), Australia offers PTEs to standard patents for an extension to a maximum term of 5 years to compensate for delays that diminish the exclusive marketing period of patented pharmaceutical products. The duration for PTE is calculated by deducting 5 years from the time period between the date of filing of the patent as defined under Section 65 of the Patents Act 1990 and the first regulatory approval date.

Table 1 | Calculation of PTE in Australia [25]

The period between the filing date of the patent and the date of the earliest first regulatory approval	PTE
5 years or less	Nil
Greater than 5 to 10 years	0 to 5 years
10 or more years	5 years

2.4.2. Eligibility Criteria for PTE in Australia

The following set of requirements must be fulfilled by applicants seeking a PTE in Australia:

As per Section 70(2) of the Patents Act 1990 (Cth), the patent should claim either a pharmaceutical substance per se or a pharmaceutical substance produced through recombinant DNA technology.

As per Section 70(3a) of the Patents Act 1990 (Cth), the pharmaceutical substance needs to appear on the Australian Register of Therapeutic Goods (ARTG).

As per Section 70(3b) of the Patents Act 1990 (Cth), the time gap between the date of filing the patent application and the first regulatory approval is at least 5 years.

As per Section 71 of the Patents Act 1990 (Cth), an application for PTE needs to be filed within six months from the first placing the product on the ARTG or patent grant date (whichever is later).

The extended patent term can never surpass a total of 5 years. An extension of the patent term here is limited to 25 years starting from the initial patent application date [25].

Australia restricts PTEs only to pharmaceutical substances, while the US applies PTEs across pharmaceuticals and biologics as well as medical devices [6].

2.5. India: No Formal Patent Term Extensions

The patent system of India tries to maintain not only the promotion of innovative incentives, but also affordable medicine, especially in the pharmaceutical field. Section 53 of The Patents Act, 1970 (India) makes no provision in India for patent extension, and it is unable to give PTEs to compensate for regulatory delays as the EU, the US, Japan, and Australia do. India maintains a 20-year standard patent term.

2.5.1. Legal Framework for Patent Term in India

In India, Patent Law is covered under The Patents Act, 1970 (as amended in 2005). Section 53(1) of the Act explicitly states:

“Subject to the provisions of this Act, the term of every patent granted after the commencement of the Patents (Amendment) Act, 2002, and the term of every patent which has not expired and has not ceased to have effect, on the date of such commencement, under this Act, shall be twenty years from the date of filing of the application for the patent.”

India differs from the US, EU, Japan, and Australia in not awarding PTEs or SPCs to compensate for regulatory delay. Regulatory approval delays do not change the 20-year period of mandatory protection of Indian patents. The Central Drugs Standard Control Organization (CDSCO) is India's pharmaceutical regulatory authority that approves all pharmaceutical products. The drug approval process in India takes several years and reduces the duration of market exclusivity of patents, but the standard 20-year term of patents does not change [26, 27].

The evergreening of patents is prevented by Section 3(d) of The Patents Act, 1970, by refusing patents for inventions that have trivial modifications of already established drugs. The provision prevents more than one patent award because of minor differences unless such modifications produce significant therapeutic benefits. Novartis's imatinib mesylate (beta crystalline form) was the subject of substantial patent opposition in India, and in a historic court ruling by the Supreme Court of India. The Supreme Court of India refused Novartis's patent based on lack of enhanced efficacy under Section 3(d) of The Patents Act, 1970 [28].

3. Challenges and Criticisms of the PTE System

3.1. Delayed Generic Entry and High Drug Prices

The main criticism of PTE and SPC is that they delay the generic drug from entering the market, hence prolonging the high cost of drugs. Access to generics has to be timed because it is cheaper by 95%, hence it enables affordable public health care. Medical experts recommend that PTE and SPC are mostly advantageous to innovator pharmaceutical companies that hold great power in the marketplace, and do not benefit the patients who are in need of affordable medical attention [29].

3.2. Evergreening and Strategic Patent Extensions

Evergreening of patents by the innovator companies is a general issue, and by this, they attempt to maintain drugs in the market by getting several patents on even slightly changed versions or methods of delivery of their medications. Maximum extension time in the US, EU, Japan, and Australia is limited to 5 years, but brand owners file secondary patents to extend market exclusivity outside this period [30].

3.3. Unequal Benefits Across Sectors

Pharmaceuticals and biotechnology industries gain the most benefits from the PTE/SPC system because it handles regulatory affairs that occur specifically in these industries. The software and the electronic and mechanical engineering sectors are not similarly covered when products suffer delays before being placed in the market [5, 6, 16, 23]. On the other hand, this is also backed up by Article 27.1 of the TRIPS agreement, which states “..... *patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced*”.

4. Patent Term Extension and Analysis of Selected Blockbuster Drugs

The average PTE in the US is 1058 days (~ 2.9 years), the minimum PTE is 12 days, and the maximum PTE granted for one particular patent (US3737433) is 2494 days (~ 6.83 years), which is more than 5 years [31]. In the EU, the average duration of SPCs granted is 3.5 years [32].

Table 2 | Periods of extension in different jurisdictions [5, 15, 18, 23-25, 33]

Jurisdiction	Max Extensions Per Patent	Max Extension Period (Years)	Pediatric Extension (Months)	Max Remaining Term Post-Approval (Years)
USA	1	5	6	14
EU & UK	1	5	6	15
Japan	Unlimited	5	Nil	Nil
Australia	1	5	Nil	15
India	None	None	None	None

4.1. LIPITOR (Atorvastatin)

Atorvastatin, commonly marketed under the brand name Lipitor, is a statin medication used to lower abnormal lipid levels and reduce the risk of cardiovascular disease in high-risk individuals. Lipitor (Atorvastatin calcium) is protected by 4 patents (US4681893, US5273995, US5385929, US5686104) as per the US FDA records [34]. US4681893 received PTE of 1213 days under 35 U.S.C. § 156, which extended the expiry to 24 September 2009. In the EU, the equivalent patent EP0247633B1 expired on 28 May 2007, and the drug product got SPCs from 1624 to 1807 days. In the UK, Sweden, and Austria, the validity of SPCs was till November 2011, and in Germany, it was till May 2012. In Australia, the PTE was till 18 May 2012 for the equivalent patent AU601981B2. The generic version of atorvastatin calcium could have been launched by March 2010 in the US by Ranbaxy. However, the litigation between Pfizer and Ranbaxy extended the launch of the generic till November 2011. The delay in generic entry occurred until May 2012 because of the postponed broader generic competition. During this exclusivity period, the FDA could not approve marketing applications for generic versions submitted by other manufacturers. As per the Hatch-Waxman Act of 1984, the first company to file an Abbreviated New Drug Application (ANDA) will get 180 days of marketing exclusivity, and in this case, it was Ranbaxy [35]. Therefore, Ranbaxy's 180-day exclusivity was intended to reward patent challenges, and at the same time, block other generic entries due to ongoing litigation and FDA delays.

Table 3 | The revenue figure of Lipitor worldwide [36-38]

Year	1999	2000	2001	2002	2003	2004	2005	2006
Sales (USD Billions)	3.80	5.03	6.45	7.97	9.23	10.86	12.19	12.89
Year	2007	2008	2009	2010	2011	2012	2013	
Sales (USD Billions)	12.67	12.40	11.43	10.73	9.57	3.95	2.31	

Lipitor, launched in 1997, achieved its highest sales in 2006 when it produced 12.89 billion USD worth of earnings that amounted to 27% of Pfizer's total revenue. Lipitor achieved exceptional performance even during its final years under patent protection when it generated 12.40 billion USD in 2008, 11.43 billion USD in 2009, 10.73 billion USD in 2010, followed by 9.57 billion USD in 2011. From 1997 to 2011, Pfizer earned 128.3 billion USD in revenue, and Pfizer became the number 1 pharmaceutical company in the world. After the end of exclusivity in November 2011 in the US and most of the countries under the EU, the revenue of Lipitor fell drastically (less than 4 billion USD) in 2012, followed by 2.31 billion USD in 2013 [38, 39]. The cost of atorvastatin (Lipitor) was more than 5 USD a tablet prior to the end of exclusivity in November 2011, fell by 95%, and was reduced to 31 cents a tablet when the generic version was launched [40].

4.2. GLEEVEC (Imatinib mesylate)

Gleevec/Glivec is used for treating chronic myeloid leukemia, developed by the scientists of Novartis, launched in 2001 [41].

US5521184 protects Gleevec (Imatinib mesylate) in the USA, and its equivalent patents in the EU, Japan, and Australia are EP0564409B1, JP2706682B2, and AU666709B2. The original expiry date of the US patent was 28 May 2013, but it got a PTE of 586 days, and the extended life went till 04 January 2015. In the EU, Gleevec got SPCs from 1184 days (in Great Britain and Ireland) to 1324 days (in Luxembourg), and the expiry of SPCs went up to November 2016. In Japan, it got a 5-year extension for the patent JP2706682B2, and the extended life went up to 05 April 2018. In Australia, the Australian patent AU666709B2 got 1230 days PTE, and the patent's life was extended from 02 April 2013 to 13 August 2016.

Table 4 | The net sales figure of Gleevec/Glivec worldwide [42]

Year	2004	2005	2006	2007	2008	2009	2010	2011
Sales (USD Billions)	1.63	2.17	2.55	3.05	3.67	3.94	4.26	4.66
Year	2012	2013	2014	2015	2016	2017	2018	2019
Sales (USD Billions)	4.67	4.69	4.75	4.66	3.32	1.94	1.56	1.26

After the launch of the 400 mg Gleevec tablet in 2003, Novartis increased the price of the drug 22 times, and between 2010 and 2015, the company raised the price 12 times. In 2013, the company raised the price of the drug by 20% [43]. The net sales figure of Gleevec/Glivec was more than 4 billion (USD) in the years 2010 to 2015, and after the expiry of PTE in the US in 2015, the sales figure dropped to 3.32 billion (USD) in 2016.

In Australia and the EU, exclusivity expires in 2016, which is reflected in the sales figure of 2017 (1.94 billion USD). In Japan, the exclusivity expires in 2018, and the sales figure dropped to 1.26 billion (USD) in 2019. The annual treatment price of Gleevec in the USA was 26,400.00 USD when it was launched in 2001, and the annual price was >120,000.00 USD in 2015. Sun Pharma launched the first generic of imatinib mesylate in February 2016 in the USA, and the price was 30% less than the branded Gleevec [44].

4.3. REVLIMID (Lenalidomide)

Initially, Revlimid (lenalidomide) was approved as a capsule for oral use by the US FDA in 2006 for multiple myeloma treatment with dexamethasone in patients who received previous therapies. In 2015, the approval for Lenalidomide in combination with dexamethasone extended to cover multiple myeloma patients at their initial diagnosis who cannot receive stem cell transplants [45].

US5635517 protects Revlimid (lenalidomide) in the USA, and its equivalent patents in the EU, Japan, and Australia are EP0925294B1, JP4065567B2, and AU715779B2. The original expiry date of the US patent was 24 July 2016, and after getting PTE of 1167 days, the extended life went till 04 October 2019. In the EU, Revlimid got SPCs from 1786 days (in Great Britain and Ireland) to 1826 days (in Switzerland), and the expiry of SPCs went up to July 2022. In Japan, it got 2 years 5 months 13 days extension for the patent JP4065567B2, and the extended life went up to 06 January 2020.

Initially, Revlimid's total revenue figure was 321 million USD in 2006. Gradually, it increased to 774 million USD in 2007, and it touched billion (1.32 billion USD) for the first time in 2008 [46]. Gradually, the revenue of Revlimid increased every year till 2021, and Celgene company generated 53.46 billion USD worldwide revenue from 2006 to 2018 (Table 5).

Table 5 | The net revenue of Revlimid (lenalidomide) worldwide [46-51]

Year	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
Sales (USD Billions)	0.321	0.774	1.32	1.71	2.47	3.21	3.77	4.28	4.98	5.80
Year	2016	2017	2018	2019	2020	2021	2022	2023	2024	
Sales (USD Billions)	6.97	8.18	9.68	10.80*	12.10	12.82	9.98	6.09	5.77	

*This is calculated as per the % change (12%) of sales data in 2020 from 2019 [52].

After 2022, the sales of Revlimid started decreasing, and in 2023, Revlimid (lenalidomide) generated revenues of 6.09 billion USD (Table 5), and this is because of the launch of a generic version in March 2022 [53]. The Celgene company was

specialized in drug manufacturing for cancer and inflammatory disorders. During 2019, the company was acquired by Bristol Myers Squibb (BMS) [52]. In 2005, Revlimid (lenalidomide) underwent a substantial increase in pricing, and after the acquisition by BMS, the price of Revlimid (lenalidomide) increased once more to reach 763 USD per pill. This followed the initial surge from 215 USD in 2005 to 719 USD in 2019. In 2025, the price of a 21-day supply (25 mg once daily on days 1-21 of a 28-day cycle) of BMS had reached 18,723 USD, up from 4,515 USD in 2005 [54]. During 2020, Celgene reached a settlement with DRL (Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories Inc.) in US patent litigation that granted DRL a limited volume license to sell generic lenalidomide (Revlimid) in the US market starting after March 2022, although an earlier license was already granted to Natco Pharma. Under their settlement terms, Celgene granted DRL the authorization to sell unlimited generic lenalidomide (Revlimid) beginning 31 January 2026, and therefore, there is no hope for substantial price reductions for Revlimid in the US market before 31 January 2026 [55].

4.4. HUMIRA (Adalimumab)

Humira (Adalimumab) is an approved medicine for treating adult patients who experience moderate to severe rheumatoid arthritis. Humira manages to relieve pain while improving physical ability and preventing joint deterioration, resulting in meaningful disease improvement after administration [56]. The FDA approved Humira in the US on 31 December 2002 for AbbVie Inc [57]. It got approval from the European Medicines Agency (EMA) on 8 September 2003 [58]. The Adalimumab product is covered by a US patent (US6090382) filed on 09 February 1996, and expired on 31 December 2016 after getting the PTE of 326 days under 35 U.S.C. § 156. The equivalent EP patent EP2357200B1 expired on 09 February 2017, and Humira did not get any SPC in the EU. Humira is approved in the USA, Canada, Mexico, China, Japan, Australia, and Brazil [59].

Table 6 | The net revenues of Humira (Adalimumab) worldwide [59, 60]

Year	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
Sales (USD Billions)	0.28	0.85	1.40	2.00	3.00	4.50	5.50	6.51	7.93	9.26	10.66
Year	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024
Sales (USD Billions)	12.54	14.01	16.08	18.4	19.9	19.17	19.83	20.70	21.24	14.40	8.99

Since the launch of Humira, the global revenue figure increased every year, starting from 2004 (850 million USD) to 2022 (21.24 billion USD). However, global revenues of

Humira dropped to 14.40 USD in 2023 from 21.24 USD in 2022 due to Humira biosimilar competition. In 2024, the global revenue of Humira again dropped by 37.6% and in the US by 41.3% compared to 2023. Biosimilar of Humira entered the USA in 2023, but in Europe, biosimilars arrived in 2018. Biosimilar makers faced patent infringement lawsuits in the US from Humira manufacturer AbbVie that led to biosimilar product launch delays until 2023. Humira has generated more than 237 billion USD worldwide since its initial release and continues to produce profits through 2024 [59]. The US witnessed a 500% increase in Humira costs since 2003, when the medicine first sold for 13,572 USD per year, and annual pricing reached nearly 90,000 USD in 2023 [61].

5. Policy Recommendations for reforming PTE/SPC

Global Cap on Extensions: Maximum 5 years PTE/SPC should be implemented across all countries, and this will maintain potential pharmaceutical innovation opportunities.

One Extension per Drug per Jurisdiction: There should be one PTE/SPC per active pharmaceutical ingredient to prevent patent clusters that lead to extended monopolies.

Public Interest Review and Transparency: All justifications for extension approvals must be published in the public domain, and their impact on public access and prices. Similar to the environmental impact assessments, a public access impact report should be mandatory before the grant of an extension.

Synchronize Extensions with Actual Regulatory Delay: Use actual regulatory delays to determine PTE/SPC lengths instead of industry strategies, because such an approach would prevent overcompensation.

Restrict Paediatric Extensions: Paediatric exclusivity should be clinical data-driven and not automatic.

Align Data Exclusivity and PTE/SPC: To avoid stacking, total exclusivity combining data exclusivity and PTE/SPC should not cross 15 years from the date of regulatory approval.

Volume-Limited Licensing for Early Generics: To serve the critical patient, a volume-limited licensing mechanism for the generic entry of the drugs should be in place.

Global Harmonization: International standards should be introduced for granting PTE/SPC via the TRIPS Agreement or the World Intellectual Property Organization (WIPO).

6. Conclusion

The current international framework for PTE and SPC has a tremendous effect on pharmaceutical innovation, market exclusivity, as well as access to medicine by the public. First, PTE and SPC were created to reward innovator companies for regulatory

delay. However, the system has been increasingly criticized as supporting longer monopolies, prolonged entry of both generics, and increased drug prices. By looking at case studies for blockbuster drugs, namely: Lipitor, Gleevec, Revlimid, and Humira, the elongated exclusivity periods beyond the normal extension through PTE/SPC, can provide multibillion-dollar revenues for the innovator companies and delay affordable medicine for patients.

This difference between the innovation incentives to the innovator companies and public access to affordable medicines highlights the requirement for comprehensive change in existing PTE/SPC systems. A 5-year cap for the extensions, single PTE/SPC for per drug molecule, permitting extension in case of late launching of drugs, only for verified regulatory delays. Moreover, the transparency requirement for giving extensions and integrating public interest review and accountability to ensure a justified extension. Providing paediatric exclusivity only for data-driven cases and avoiding cumulative stacking exclusivity.

Lastly, unification of PTE/SPC policies in the context of internationally established mechanisms (e.g., TRIPS or WIPO) and promoting volume-limited generics licensing under times of emergency health demand may resolve the interests of innovators, the demands of health care systems, and the interests of patients. The right adjustments in PTE/SPC systems open, balanced, and equal are vital in terms of providing not only sustainable pharmaceutical innovation but universal availability of essential drugs as well.

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