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[Tukil Suresh](#)\*

Posted Date: 5 February 2026

doi: 10.20944/preprints202602.0423.v1

Keywords: patent; pharmaceutical; drug; generic; patient well-being



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Review

# Navigating the Pharmaceutical Patent Landscape: Impact of Patent Cliffs on Innovation and Accessibility

Tukil Suresh

Independent Researcher, Singapore; tukil.suresh.ts@gmail.com

## Abstract

This research paper analyses the impact of patent cliffs on both pharmaceutical firms and patients, focusing on the dynamics that emerge when brand-name drugs lose patent protection. Through an extensive literature review, the paper examines the various strategies employed by firms to mitigate the financial consequences of patent cliffs. Despite these efforts to preserve revenue, these strategies often have unintended consequences for patients, including limited access to affordable medications and delayed availability of generics. Moreover, the paper explores how certain firms, in their pursuit of profit, have sometimes overlooked ethical considerations, legal regulations, and patient well-being. The analysis further highlights the ethical dilemma faced by the pharmaceutical industry, which involves balancing the pursuit of profit with the responsibility to ensure access to essential treatments. This paper concludes by discussing the need for a more ethical approach to patent management that prioritises patient health without compromising the financial sustainability of the industry.

**Keywords:** patent; pharmaceutical; drug; generic; patient well-being

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## Introduction

The protection of intellectual property rights is a very serious and widely discussed topic in the pharmaceutical industry. Intellectual property rights give the creator an exclusive right over the use of his/her creation, in this context, a drug, for a certain period of time (*World Trade Organisation, n.d.*). As research and development costs continue to increase exponentially due to the rapid development and advancement of technology, intellectual property rights protect an innovator's right to profit from their drug for a specified period, potentially offsetting the losses acquired during the research and development process. This means that intellectual property rights are crucial in ensuring that pharmaceutical companies have the competitive advantage to profit and grow (*National Library Board Singapore, 2021*). This then fuels future drug development and innovation.

There are 5 main types of intellectual property rights in the pharmaceutical industry. Namely, they are patents, trademarks, copyrights, trade secrets, and regulatory exclusivities. The crux of this paper will be regarding patents. Formally, a patent is defined as an exclusive right granted for an invention. Patents benefit inventors by providing them with legal protection of their inventions (*World Intellectual Property Organisation, n.d.*). Patents on drugs and other discoveries are typically twenty years from patent approval until expiration, although other factors can alter this standard timeframe. (*Hayes A., 2022*) Patents also benefit society by providing public access to technical information about these inventions, and thus accelerating innovation. Although patents generally prove beneficial, there is one significant detriment that cannot be overlooked.

The issuance of patents gives rise to a phenomenon known as a patent cliff. A patent cliff refers to a sharp decline in revenue or profitability when a firm's patents expire, opening them up to competition (*Hayes A., 2022*). When a drug is still under the protection of a patent, generic drug makers are unable to produce these drugs or sell them since only the innovator has production and

distribution rights. Once the patent has expired, these generic drug makers are now able to produce these drugs and create biosimilars. This means that the market is now flooded with a plethora of similar drugs. Since market supply of drugs increases with the expiration of a patent, the price of the drug drops sharply, resulting in a loss of revenue for pharmaceutical companies.

As such, this paper aims to discuss and analyse the impacts of patent cliffs on innovation in the pharmaceutical industry as well as drug accessibility and affordability for the patient population. In addition, the strategies used by pharmaceutical companies to mitigate the effects of these patent cliffs will also be elaborated on.

## The Patent Cliff Phenomenon

As previously mentioned, a patent cliff refers to a sharp decline in revenue or profitability when a firm's patents expire. In this section, I will elaborate more on how patent cliffs affect drug companies, pricing, and market dynamics. Furthermore, I will delve into the examples of Nexium, a blockbuster drug, and Metformin, a generic drug, to illustrate how patent cliffs relate pharmaceutical firms to one another and how they influence the market and industry as a whole.

Firstly, Patent cliffs significantly impact pharmaceutical companies by causing a sudden decline in revenue when the exclusive rights to a blockbuster drug expire. When a drug company's patent expires, other drug manufacturers are now able to start producing the drug generically, without restrictions. As more generic drug manufacturers enter the market, the price of the drug drops sharply. The production of generic drugs costs about 80% to 85% less than that of branded drugs (*Straka et. al., 2015*). This shows that a patent cliff causes a pharmaceutical firm to lose a significant portion of its revenue due to the steep decline in price brought about by generic drugs entering the market.

Patent cliffs remain a challenge for the industry, especially for companies heavily reliant on a few blockbuster drugs. As firms' revenue decreases, they are left with less funds for future innovation as well as research and development (R&D). This drastically decreases the pace of discovery of new drugs and medications, limiting various processes and progress in the pharmaceutical industry. There is also the possibility that some firms may choose to leave the market. When the profits earned by the firm do not even cover the cost of production of the blockbuster drug, the firm will be operating at a loss, and will not be able to spend anything on increasing its market dominance and on sustaining itself in the industry, let alone spend on future R&D. As such, to minimise losses, the firm will have to stop production. Hence, patent cliffs pose a serious threat to pharmaceutical companies since they limit the potential for innovation and R&D as well as increase the chances of firms being driven out of the industry.

To illustrate this, we can consider the drug Esomeprazole, which is commonly sold and manufactured under the brand name Nexium by global pharmaceutical giants AstraZeneca and Pfizer. Nexium is a proton pump inhibitor that decreases the amount of acid produced in the stomach (*Sinha, 2024*). It was approved for commercial use and sale by the Food and Drug Administration (FDA) on March 31, 2005 and was not deemed eligible for patent term extension (*United States Patent and Trademark Office, 2005*). In 2012, Pfizer acquired exclusive global rights from AstraZeneca to market non-prescription Nexium (*Pfizer, 2014*). The patent for Nexium which gave AstraZeneca, and later on Pfizer, exclusive production rights over the drug expired in 2014 (*Clinical Trials Arena, 2014*). In 2013, the drug generated an astounding revenue amount of \$3.87 billion worldwide.

After the expiry of its patent, the FDA approved the first generic of prescription Nexium in January 2015. Nexium is still a brand-name product but is more popularly dispensed by pharmacies as generic esomeprazole (*Berger, 2023*). Generic esomeprazole is made by many pharmaceutical manufacturers. If a healthcare provider prescribes Nexium, the pharmacist will likely dispense esomeprazole unless a patient or the healthcare provider specifically requests the brand name. After generic versions became available, its sales dropped sharply, with revenue falling by nearly half to \$2 billion by 2015 (*Bhattacharya, 2015*). Reports also show that AstraZeneca made several deals in

2013 to build up a strong enough pipeline to counter the Nexium losses with new sales (Staton, 2013). This highlights how severe the loss of revenue must have been when Nexium went off patent.

On the flipside, it is also important to consider how a patent cliff may prove beneficial to firms that specialise in the manufacture of generic drugs. One such example of a generic drug that generated far more revenue than its branded counterpart would be Metformin. Metformin is currently manufactured by about 76 pharmaceutical companies (Pharmacompass, n.d.). The blockbuster version of this drug is known by its brand name Glucophage, and is manufactured by Merck. Both drugs, Glucophage and Metformin, are used to treat type 2 diabetes by regulating blood sugar (Cleveland Clinic, n.d.). The patent for Glucophage expired in the year 2000 (Express Scripts, n.d.). Today, Glucophage and Metformin are used almost interchangeably, with the latter being more popular amongst the patient population.

Statistics also show that Metformin has generated far more revenue as compared to branded Glucophage. Comparing sales figures for 2022, Metformin generated about \$268.95 million in 2022 and the market is predicted to grow to around USD 386.91 million, by 2030 due to the rising number of patients with type 2 diabetes (Zion Market Research, n.d.). However, in 2022, Glucophage generated a mere \$22 million in revenue for Merck (Merck Healthcare Group, 2023). Hence, it can be inferred that the revenue and thus profits earned by the generic drug manufacturers producing Metformin significantly outweigh that reaped by Merck in producing branded Glucophage. Therefore, the effects of the patent cliff in 2000 has had a serious effect on Merck, even up to 2022, causing it to miss out on a large portion of earnings.

This begs the question of whether branded drugs can co-exist with their generic versions. In short, many pharmaceutical companies have come up with methods to ensure the continued survival of their branded drugs, even with the release of generic versions upon patent expiry. Branded pharmaceutical companies often produce their own authorised generic versions of the drug once the patent expires. This allows them to maintain some market share while offering a lower-priced alternative to traditional generics. This strategy can help the branded company offset some of the revenue loss caused by generic competition (Strader, 2013). Even after patent expiration, branded drug companies may differentiate their products through variations like extended-release formulations or combination therapies, which are harder to replicate by generic manufacturers. For instance, Pfizer's Lipitor brand marketed extended-release formulations even after the generic versions were available (Feldman, 2014). Some branded companies also use heavy marketing and brand loyalty to retain a portion of the market despite the availability of generics. Consumers might continue to prefer the brand name drug because of perceived quality or familiarity, even if the generic is cheaper. For example, many doctors continue prescribing the branded version, particularly when a patient has previously used it with positive results (Montgomery, 2015). The above-mentioned strategies to mitigate the negative effects of a patent cliff will be analysed more in-depth in the following sections.

## Strategies to Mitigate the Patent Cliff

As can be seen from the above section, patent cliffs pose a severe threat to the profitability of pharmaceutical firms that produce blockbuster drugs. Hence, such firms tend to follow a specific set of strategies to overcome and mitigate these negative effects and retain their profits. The most popular strategies include product differentiation, authorised generics as well as brand loyalty.

Product differentiation is the marketing of generally similar products with minor variations that are used by consumers when making a choice. This can be in the form of evergreening, where companies make minor tweaks to their drug and rebrand it in order to extend the lifespan of patents that are about to expire. Often, these patents are based not on entirely new technical solutions but rather on minor changes to previously protected products or processes. The purpose of these modifications is to extend patent exclusivity without the necessity to create a completely new product (Uyen, n.d.). Product differentiation is useful in the sense that it allows firms to make up for R&D costs without investing even more time and money to formulate new drugs. This helps keep costs as

low as possible, ensuring that the profits recovered are a maximum. However, the flipside of things should also be considered. Healthcare professionals and advocates argue that product differentiation and evergreening stifle innovation. They believe that firms generating revenue from tweaking old drugs will not see any need to develop new medicines and will not be incentivised to spend on R&D to innovate new medications.

Furthermore, when the patent of branded drugs or their tweaked versions get extended, generic drugs are unable to enter the market, decreasing levels of competition in the industry. This decreased competition leads to higher drug prices due to the lack of substitutes and lack of choices on patients' end.

A key instance of evergreening can be seen in the case of Copaxone, a prescription medication manufactured by Teva Pharmaceuticals to treat relapsing forms of multiple sclerosis (*Teva, n.d.*). Originally, Copaxone had been sold and patented as glatiramer acetate. Teva's basic patent for glatiramer acetate expired in 2015. The company then filed several serial divisional patent applications focused on the manufacturing process and the dosing regimen of glatiramer acetate. After rebranding, Teva was able to secure a patent for Copaxone, which only differs slightly from glatiramer by brand name and dosing regimen. Copaxone is currently protected by 5 patents which expire in 2030, delaying the entry of generics into the market by 15 whole years. This product differentiation or evergreening of Copaxone led to a cost to consumers of \$4.3 to 6.5 billion dollars over two and a half years (*Wikipedia, n.d.*). Therefore, it is logical to conclude that product differentiation in the form of evergreening results in reduced competition due to delayed entry of generics into the market, driving up drug prices and thus increasing profits for firms.

The next strategy to be analysed is Authorised Generics. An authorised generic drug is the same as the brand-name drug but does not use the brand name on the label. In addition, an authorised generic version of a tablet or capsule may have a different color or marking (*Food and Drug Administration, 2024*). This strategy would allow the firm producing the blockbuster drug to continue existing the market amongst generic drug makers even after the expiry of their patent. Since the firm is still able to compete in the market, it will be able to generate some revenue from the sale of the authorised generic. However, considering the perspective of pharmaceutical firms, this is not as effective as evergreening since this method is unable to completely eliminate all competition, meaning that profit will not be maximised. Furthermore, the presence of competition suggests that firms are not able to charge as high of a price for their authorised generics. Even so, the production of authorised generics is favourable for patients. Authorised generics increases the contestability of the market, and as a result the number of available treatment choices for the patient increases. Lower drug prices due to increased competition also makes treatment more accessible and affordable for a larger portion of the patient population.

A recent example of an authorised generic drug is generic Victoza. In June 2024, Teva Pharmaceuticals launched an authorised generic version of Victoza, a medication originally developed by Novo Nordisk for the treatment of type 2 diabetes (*Teva, 2024*). Novo Nordisk had originally patented Victoza and its active ingredient, but this patent expired in 2022, allowing Teva to recreate a generic version of the drug instead. Through this, Teva was able to profit off of Novo Nordisk's formulation, without investing much into R&D.

Following this, the third strategy to be discussed is brand loyalty. Brand loyalty is very important to the pharmaceutical industry since patients are more likely to choose the treatment option or drug that is viewed as the safer option, and this is most often the more reputable drug. By utilising advertising strategies to their advantage, pharmaceutical firms are able to cultivate a certain brand image and cultivate brand loyalty. Doctors are also more likely to prescribe drugs that are more-well known since they are more trusted and are assumed to be of higher quality.

Some may argue that doctors may prescribe branded drugs due to more systematic factors like industry practices or insurance. Insurance companies typically have lower copays for generic drugs since they pay less (*Haelle, 2023*). However, it is important to note that this does not fully negate the influence of brand loyalty. Brand loyalty is deeply rooted in perceptions of quality, safety, and trust,

which are cultivated through years of consistent marketing, successful treatment outcomes, and direct experience. Doctors and patients often rely on these perceptions when making decisions about prescriptions. Moreover, in cases where patient outcomes are closely monitored, physicians may prefer to prescribe the branded version to avoid variability that can sometimes occur with generics. Although generics are bioequivalent, small differences in inactive ingredients or drug formulations can affect tolerability or efficacy for certain patients. For instance, a doctor may continue prescribing a branded drug to a patient who has experienced success with it, rather than risk switching to a generic alternative that the patient might not tolerate as well.

A good example of a drug with high brand loyalty is Synthroid or levothyroxine sodium, a medication commonly used to treat hypothyroidism. Even though there are several generic versions of levothyroxine available, Synthroid, manufactured by AbbVie, is often prescribed by doctors and preferred by patients. This is due to several reasons. Firstly, Synthroid has established a long-standing reputation for reliability and efficacy, having been on the market since the 1950s. This history has fostered a sense of trust and familiarity among healthcare providers and patients alike, contributing to its brand loyalty.

Secondly, levothyroxine is a medication with a narrow therapeutic index, meaning small variations in dosage can significantly impact the patient's condition. Some doctors and patients perceive branded Synthroid to have more consistent potency and absorption compared to its generic counterparts, even though the FDA ensures that all generics meet stringent bioequivalence standards. This perception often drives doctors to prescribe Synthroid over generics.

Lastly, AbbVie has invested significantly in marketing and educational initiatives aimed at healthcare professionals and patients. These efforts reinforce the idea that Synthroid is a superior choice, further increasing its preference in clinical practice. Additionally, the brand loyalty extends to patients who may have achieved stable thyroid hormone levels with Synthroid and are reluctant to switch to a generic due to fear of experiencing variability in their treatment outcomes.

Now that a few common strategies employed by pharmaceutical companies to mitigate the effects of patent cliffs have been explored and analysed, it is crucial to discuss how the expiration of patents and the rise of generics affect drug affordability and public health and the ethical considerations that come with using the above-mentioned strategies.

## Ethical Considerations

With the above mentioned-strategies in mind, it is important to consider the different ethical considerations that come with patent cliffs and how firms deal with them. To evaluate these strategies, this section adopts a deontological perspective, emphasising the moral duty of pharmaceutical firms to prioritise patient welfare and fairness in healthcare. This section explores the primary ethical dilemma: balancing affordability with innovation. Patent cliffs open up the market to generic drug manufacturers, meaning that they increase the contestability of the industry, making way for more innovation. They also ensure a high number of substitutes for the same drug, ensuring that drug prices remain low and affordable for the patient population.

The strategies discussed in the previous section have the potential to increase innovation in the industry as well. Patent cliffs harm the profitability of pharmaceutical companies. Patent cliffs cause these companies to lose out on profits that they could use for expansion and R&D. R&D is by no means cheap and denying the companies their profit severely limits their ability to innovate. Thus, it can be argued that strategies to mitigate the negative effects of patent cliffs on firms is justified.

When firms recoup their lost profits through product differentiation in the form of evergreening, producing authorised generics and cultivating brand loyalty, they now have the capital to invest in more R&D and the increased profit levels act as an incentive for firms to undertake more research and formulate new drugs. With more R&D, innovation in the pharmaceutical industry is automatically driven up, giving rise to new medications that will benefit patients. Even so, this positive impact does not nearly come close to outweighing the detriments. When firms try to bypass these patent cliffs by using the above mentioned strategies like extending patents or using aggressive

branding to cultivate brand loyalty, they reduce competition in the industry, and in turn, drug prices are driven up. This also influences drug affordability as well as accessibility for patients. When generic drug makers are absent from the market, many patients are unable to afford and utilise life-saving medications, which goes against the main purpose that drugs and medications are created for – to serve the patient population. Using a deontological approach, it is clear that pharmaceutical companies have a moral duty to ensure medications remain accessible to patients, as failing to do so violates the ethical principle of justice and undermines the very purpose of healthcare. This raises a very valid question of whether the industry is unfairly prioritising profit over patient well-being.

Secondly, a few of the methods used by firms to make up for lost profit from a patent cliff are illegal. Needless to say, such methods are highly unethical. Revisiting a previous example, Teva had profited significantly off of its drug Copaxone. However, some of the methods the company had used violated several laws. The United States filed a complaint in the District of Massachusetts in August 2020 that Teva violated and conspired to violate the AKS and FCA by paying Medicare patients' cost sharing obligations (copays) for the multiple sclerosis drug Copaxone from 2006 through 2017, while steadily raising Copaxone's price. In particular, the United States alleged that Teva coordinated and conspired with multiple third parties, including a specialty pharmacy and two allegedly independent copay assistance foundations, to ensure that purported donations to the foundations were used specifically to cover the copays of Medicare Copaxone patients, which Teva knew was prohibited by the AKS, and that Teva thereby caused the submission of false claims to Medicare (United States Department of Justice Office of Public Affairs, 2024).

As such, Teva was so focused on reaping profits that it flouted several laws knowingly. Furthermore, Teva continuing to raise the prices of Copaxone goes to show how Teva valued profit much more than patient well-being. This just goes to show how making profit has become the main goal of pharmaceutical firms such that they are willing to bypass laws, and forgo patient well-being to do so. This case highlights the broader ethical issue of prioritising profit over patient access and compliance with the law. While critics may argue that focusing solely on duties could limit broader societal benefits, such as increased innovation, deontology asserts that the ends do not justify the means, especially when patient welfare is at stake. Ultimately, a deontological analysis underscores that the pursuit of profit must not come at the expense of justice and patient welfare, as these are the foundational duties of any healthcare-oriented industry.

## Conclusion

In conclusion, the impact of patent cliffs on both pharmaceutical firms and patients is complex and multifaceted. While firms adopt various strategies to mitigate the financial challenges posed by patent expiration, these strategies often have negative consequences for patient access to affordable treatments. The ethical dilemma of prioritising profits over patient welfare remains a significant issue within the pharmaceutical industry. This paper highlights the need for more ethical approaches to patent management, where the accessibility of essential medications is not compromised for the sake of corporate profits. Future research could explore potential policy reforms to address these issues and ensure a fairer balance between business interests and patient needs.

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