LexScriptaMagazine.com ISSN: 2583-8725 Vol. 04 - Q1 Jan - Mar, 2026

ISSN: 2583-8725

# Lex Scripta Journal

Quarterly Online and Print Edition

# Law & Policy

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# EDITORIAL TEAM

**LEX SCRIPTA MAGAZINE OF LAW AND POLICY** (VOL-4, ISSUE-1)


ISSN-2583-8725
Vol - IV, Issue - I
Published by INTEGRITY EDUCATION INDIA

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Printed in India @ New Delhi

ISSN: 2583-8725

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LEX SCRIPTA MAGAZINE
JOURNAL MAGAZINE BY INTEGRITY EDUCATION INDIA

LexScriptaMagazine.com ISSN: 2583-8725 Vol. 04 - Q1 Jan - Mar, 2026

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# The Interface of Competition Law and Intellectual Property: Addressing Evergreening Concerns

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# The Interface of Competition Law and Intellectual Property: Addressing Evergreening Concerns

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**Abstract**
*The interface between competition law and intellectual property (IP) law presents a complex regulatory challenge, particularly in the context of patent evergreening. While IP law seeks to incentivize innovation by granting temporary monopolies, competition law aims to prevent anti-competitive practices and market distortions. This paper critically examines how evergreening—defined as the strategic extension of patent protection through minor modifications—creates tension between these two legal regimes. Focusing on the Indian framework, the study analyses the role of Section 3(d) of the Patents Act, 1970 in curbing frivolous patent extensions, alongside the enforcement mechanisms under the Competition Act, 2002 in addressing abuse of dominant position.*
*The research adopts a doctrinal and comparative approach, evaluating key judicial pronouncements and regulatory interventions that attempt to balance innovation incentives with public interest, particularly in the pharmaceutical sector. It further explores how evergreening practices can restrict market entry, delay generic competition, and inflate drug prices, thereby raising significant concerns for access to medicines in developing economies. Comparative insights from jurisdictions such as the United States and the European Union are incorporated to assess alternative regulatory strategies and their effectiveness.*
*The paper argues that while India has developed a relatively robust legal framework to address evergreening, enforcement inconsistencies and interpretative ambiguities persist. It concludes by recommending a more integrated approach, emphasizing coordination between patent authorities and competition regulators, clearer policy guidelines, and a stronger focus on consumer welfare. Such a framework is essential to ensure that the protection of innovation does not come at the cost of fair competition and public health.*

**Keywords:** *Competition Law, Intellectual Property Rights, Evergreening, Patents Act 1970, Competition Act 2002, Pharmaceutical Sector, Access to Medicines, Market Dominance*

## Introduction

This interface between competition law and intellectual property law is perhaps one of the most intellectually complex and economically sensitive areas of law in modern systems. This is not so much a case of merely overlaps of legal domains, as it is a problem where two distinct sets of legal regulatory principles clash[1]. It appears that in the case of intellectual property law the underlying principle is that innovation requires an incentive which is the short-lived right to exploit it exclusively. In competition law the idea is that this exclusive right should not solidify into a durable market foreclosure, compromising consumer welfare and market efficiency.[2]

This problem is nowhere clearer than in the pharmaceutical market, where social and commercial value collide in the drive for innovation. Bringing a new pharmaceutical product to market requires years of research and development, clinical testing, and regulatory approval which entails tremendous sunk costs with uncertain profits. Intellectual property rights, in particular patent rights, provide a necessary legal certainty[3] to invest such amounts and effort. However once that right is secured it may be extended through the strategic creation of secondary patents [4](e.g., on new formulations or methods of treatment) or through patent lifecycle management and even regulation manipulations. All of these tactics, bundled under the term 'evergreening,' provide fertile ground for competition law.[5]

Evergreening is more of a complex of behaviours rather than one distinct legal action or conduct. These acts are neither always unlawful under patent law, nor always legal under competition law but fall at the threshold where the use of an IP right can achieve anti-competitive effects, i.e. Distort the market and delay the entry of generic alternatives.2

Within the EU legal order, the problem has been approached by a jurisprudence developed primarily under Article 102 TFEU concerning the abuse of dominance. The issue revolves around the circumstances in which the exercise of an IP right will be considered an abuse within the competition law context. This chapter will discuss this problem area: exploring its doctrinal developments, political and legal conflicts, and its specific manifestation in the pharmaceuticals market.

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[1] Ansgar Ohly, Intellectual Property and Competition Law: The European Perspective, 4 J. Intell. Prop. L. & Pract. 343, 345–347 (2009).

[2] A. Kur and T. Dreier, European Intellectual Property Law (Edward Elgar 2013).

[3] Henry G. Grabowski & John M. Vernon, Returns to R&D on New Drug Introductions in the 1980s, 13 J. Health Econ. 383, 385–389 (1994).

[4] Christopher-Paul Milne & Joyce Tait, Evolution Along the Government–Governance Continuum: FDA's Orphan Products and Fast Track Programs, 1 Food & Drug L.J. 1, 5–8 (2010).

[5] William M. Landes & Richard A. Posner, The Economic Structure of Intellectual Property Law 294–300 (Harvard University Press 2003).

## Theoretical Frameworks of IP and Competition Law

### Intellectual Property Law as Incentive for Innovation

At the theoretical level, IP rights including patent rights rely on utilitarian theories of economics. The basic justification is that innovation produces public goods that tend to be under-produced in a free market. [6]Innovation suffers from the fact that without some form of legal protection for the innovators it is easy for them to be imitated by competitors who have not incurred the costs of R&D and innovation; consumers will benefit from the imitations but without compensating the original innovator, the return may be too low to encourage the initial investment and innovation[7].

This is especially true of pharmaceutical innovation, which may cost billions of dollars of investment and has very high risks of failure and time to the market and product. It is therefore argued that patents (which traditionally exist for a limited duration, usually 20 years) are a necessary incentive mechanism to ensure adequate investment in dynamic efficiency4. However, it has been argued that this type of justification[8] for patents is not based on rewarding any and all innovation but rather the type of innovation[9] which may not be forthcoming under competition alone. So, the whole concept of patents implicitly involves a division between genuine innovative steps and trivial incremental changes. This is where the question of evergreening becomes prominent.[10]

Evergreening strategies are often associated with methods of exploiting the available patent regime to obtain new patents. These strategies often exploit aspects of the patent law system, such as continuation applications, new patents on formulations, dosage regimes, combinations of drugs, and various regulatory tricks that would allow the renewal of the period of exclusivity. These various methods in combination are not usually directly unlawful in patent law terms but raise questions about the extent to which IP protection should or is allowed to continue to operate to restrict competition and consumer access to products.

### Competition Law as Market Correction Mechanism

Competition law works on a much different theoretical basis and has different aims than intellectual property law. Primarily it aims at ensuring market efficiency and avoiding market foreclosure, not directly incentivizing innovation. Under EU competition law Article 102 TFEU prohibits the abuse of dominance

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[6] Kenneth J. Arrow, Economic Welfare and the Allocation of Resources for Invention, in The Rate and Direction of Inventive Activity 609, 615–620 (Princeton University Press 1962).

[7] F.M. Scherer & David Ross, Industrial Market Structure and Economic Performance 622–626 (3rd ed., Houghton Mifflin 1990).

[8] Edmund W. Kitch, The Nature and Function of the Patent System, 20 J.L. & Econ. 265, 271–275 (1977).

[9] Rochelle C. Dreyfuss, Pathological Patenting: The PTO as Cause or Cure, 104 Mich. L. Rev. 1559, 1562–1566 (2006).

[10] DiMasi, Grabowski & Hansen, Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs, 47 J. Health Econ. 20, 24–28 (2016).

that may affect trade between Member States and may impede or distort competition.[11]
The modern conception of competition law is highly consumer welfare oriented, focusing on issues such as prices, output limitations, innovation foreclosure and reduced choice. Importantly, it does not object to dominance in itself but only to its abusive use5.
This may seem problematic to competition authorities and the consumers but it is precisely in the field of innovation and highly research-based products like pharmaceuticals, where the concept of dominance should be addressed by competition law rather than allowing other legal regimes to unduly expand an IP right. Pharmaceutical products will always require patents to incentivize development; that is the reality of that specific industry. However, there are concerns that the system is being abused where the use of a patent is, in conjunction with other factors and strategic market behavior, allowed to lead to sustained foreclosure of the market to rivals who might compete on price and other factors.

**Interaction and Complementarity of IP Law and Competition Law**

Although the two legal regimes are viewed as antagonistic, they complement each other in aiming to the achieve a better, competitive and efficient market. As was discussed IP law incentivizes R&D for future innovation and competition law ensures current and future market contestability through prohibition of certain behaviour that could lead to market foreclosure. Together they create dynamic efficiencies in the market. With regard to pharmaceuticals it can be argued that, although they need protection by way of IP to drive innovation, they should not have protection beyond the legitimate boundaries of the system if that system is to promote consumers welfare, because an overly restrictive approach would impede dynamic efficiency as well6.Evergreening therefore represents a position where IP rights and competition law appear to clash as actions may not be directly unlawful in patent law terms, but may yield anticompetitive effects that could be considered abuses of dominance within the meaning of competition law.

**EU legal approach to the intersection of competition law and IP rights**

**Early Period- formalist approach and the autonomy of IP rights**

The early case law of the ECJ established and reinforced the notion of autonomy of IP rights. The reasoning was that grant of an IP right is exclusively within national jurisdiction, and therefore outside the scope of competition law. It was not the IP rights per se, but their abuse, which can fall under competition law provisions; "the existence of a patent is not at all contrary to the Treaty. If a patent existed and had the effect of preventing the importation of the patented product

[11] Ioannis Lianos and D. Geradin, Handbook on European Competition Law (Edward Elgar 2013). (Market power and dominance theory)

from another Member State into a Member State, that prohibition on imports could not be justified by the mere existence of the patent alone. ... The refusal of an exclusive license does not necessarily constitute abuse, but it may in particular circumstances."14 As such the Court always maintained a careful distinction between patent law as such and its enforcement.
This approach protected legal certainty and assured Member states of their jurisdiction over their IP rights, while preserving the EU legal order's ability to control how dominant firms operate within its territory.15 As time passed this strict formalism became problematic as complex behaviors aimed at extracting consumer surplus began to develop that were not outright patent infringements, but may have had a similar or equal result in suppressing competition.

**The introduction of the "Exceptional Circumstances" test**

This formalism soon gave way to the "exceptional circumstances" test, as demonstrated by Volvo v Veng (1984),16where the ECJ held that although refusal to grant a license is not normally an abuse of dominance, it may be under exceptional circumstances. In its subsequent case law, such as Magill (1995),17 the Court held that "refusal of the copyright owner to license the necessary elements may give rise to an abuse within the meaning of Article [102 TFEU] if, for example, the refusal is related to a product or service the market for which is a separate product or service market, it is intended to maintain the copyright owner’s dominant position on that market, that absence of licensing prevents the appearance of a new product for which there is a potential consumer demand, and it is so that it cannot be justified by objective considerations" (emphasis added).
The high barrier for compulsory licensing was upheld in later cases such as IMS Health,18 where the Court explicitly stated that it should not re-interpret copyright law or effectively create mandatory compulsory licensing regimes out of the concept of abuse of dominance.

**The Microsoft Case and Regulatory Expansion**

The Microsoft case represents a notable increase in EU competition law enforcement concerning intellectual property rights. Microsoft was found by the European Commission to have abused its dominant position by not providing access to interoperability information to competitors so they can develop competing products in ancillary markets.
This decision has several notable elements, firstly it found that not granting a license could constitute abuse without there being a market for the license or a secondary market for the IP right itself (the original market being software applications and the secondary market for operating systems). Second, it highlighted the crucial nature of interoperability for innovative markets. Third, the decision established that dominant companies could in certain cases have a positive duty to act or facilitate competition in related markets by opening their own markets up. The decision can be interpreted as moving EU competition law

away from protecting static markets toward ensuring dynamic competition. This represents an increased willingness of EU competition authorities to interfere in markets within the technology sector that possess a network structure and where dominant players develop, control and implement standards.

## Evergreening as a structural competition concern

### Conceptual Understanding of Evergreening

Evergreening refers to "various ways of extending market exclusivity over a product, not through genuine innovation but through legal and regulatory processes". These processes include:

1. Secondary patenting for minimal modifications.
2. Patent clusters.
3. Defensive patenting to prevent rivals entering the market.
4. Reformulating a product and obtaining further regulatory protection or product hopping.

Although each process taken in isolation might not be unlawful, collectively they can delay generic products for many years thereby leading to high drug prices. Evergreening is particularly concerning as it occupies a position on the border of patent law and competition law as companies are manipulating regulatory regimes to achieve the desired outcome rather than outright infringing other companies' patent rights or agreeing to fix prices etc.

### Economic and Market Effects

Key economic and market effects of evergreening include:

1. Delay in the market entry of generic competitors;
2. Persistence of high prices for medicines;
3. Erosion of public access to medicines;
4. Negative impact on incentives for genuine innovation; and
5. Increases in litigation costs.

The aforementioned impacts are all of particular concern in relation to pharmaceutical products as drug consumption is not easily reduced and demand can be seen as relatively inelastic while a large section of the population are reliant on particular medicines and access to medicines in effect relates directly to the health and wellbeing of the population.

### Regulatory Complexity

The complexity of regulating evergreening stems from its inherent dual nature. This includes:

1. patent law, which deals with patent rights;
2. regulatory systems relating to approval; and
3. competition law itself.

Because of the nature of the rules in the separate bodies of law, no single framework addresses the practice of evergreening directly as Patent law focuses on the validity and inventiveness of the patent while competition law focuses on proving dominance and abuse after market entry. The inherent conflict in approaches to patents can allow for exploitation in terms of evergreening.

## Article 102 TFEU and Evergreening

### Dominance in pharmaceutical markets

Pharmaceutical markets often have limited relevant markets, which facilitates finding of dominance. In AstraZeneca the Court recognized that regulatory exclusiveness and IPR could support a finding of dominance. Here the focus was on an abuse involving more than a refusal to license, including deceitful information to both patent offices and regulatory authorities, aimed at maintaining a dominant position. This decision can be interpreted as being significant as it includes within Article 102 not only cases of direct market exclusion, but also cases where information is presented in a deceptive way to regulatory bodies, enabling further market exclusion to occur.

### Abuse through regulatory manipulation

The Court expanded the meaning of 'abuse' within Article 102 TFEU to include misleading actions directed towards authorities where such actions result in further market exclusion of rivals. In the case, the company gave misleading information to patent offices regarding when the market authorization had been granted, allowing it to claim supplementary protection certificates for an extended period. This means that an abuse of Article 102 is not only a question of overt behaviour on the market but can also include strategic misrepresentations made to regulatory and patent bodies to keep rivals away from the market. This is highly relevant for the issue of evergreening whereby firms may strategically manipulate regulatory rules to their advantage.

### Limitations of competition law

Competition law has a range of limitations for the purposes of addressing evergreening, such as:

1. difficulty in differentiating between lawful IPR protection and abuse of IP rights;
2. potential to chill innovation by over-deterring potential behaviour;
3. limited use of anticipatory measures due to retrospective application of rules;
4. difficulties in substantiating dominance; and
5. dependence on definition of the market and assessment of dominance.

**Policy evolution and institutional enforcement trends**

The EU pharmaceutical sector inquiry (2008-2009) provided a major development in the EU policy towards evergreening. In this report, widespread use of secondary patenting and litigation practices were investigated and found to significantly reduce the number of generic competitors to a product, delaying their entry to market for many years. These issues contribute significantly to health care costs and also reduce welfare. Since then there has been an increasing application of 'innovation-based' theory of harm such as 'foreclosure of future competition', instead of effects such as price rises or reduction in supply.

**Recalibrating the legal balance**

The interplay between intellectual property and competition law in relation to evergreening indicates that a gradual readjustment of their balance is taking place in the EU. While intellectual property rights remain strong the protection afforded has recently seen more scrutiny when the application thereof affects the market to an extent beyond that envisioned by patent and competition law respectively. Evergreening presents a challenge to the balance because although each form of law allows for extension of market exclusivity, one of them is used by pharmaceutical companies to manipulate the others to gain an unjust advantage, as neither can combat the overall impact on their own. In conclusion a more harmonised approach to the law, which takes account of all forms of law will benefit all stakeholders as IP law and competition law cannot act independently.

The competition law relationship with the IP regime in the context of evergreening is not a static one but a dynamic evolution. While both areas of law are designed with the primary aim of innovation and improving consumer welfare their rationale, the method and structure of how that is achieved are different. EU jurisprudence indicates a shift from a formal separation toward a more substantive approach in investigating conduct on the market, to the extent of determining dominance or the existence of exceptional circumstances and extending Article 102 to include all such anticompetitive behaviour. Nevertheless, evergreening poses a doctrinal challenge to competition law as it tests the frontiers of its enforcement. More significantly it raises questions concerning a co-ordinated approach to the relevant body of law, i.e. Patent, competition and regulatory law in order to achieve the overall aim. It is becoming clear that IPR will not be seen as a barrier to competition law enforcement, rather it will be seen as a conditional right on the basis of proportionality and consideration of market impact.

The evolving relationship between IP law and competition law as regards evergreening, as an increasing number of cases testify, mirrors a broader reorientation of European legal thought away from rigid institutional separation and towards a unified, effect-based regulatory approach. This has not only a dogmatic but also a deeper economic and policy rationale rooted in concerns over the continued dynamism of innovation-based markets, particularly in sectors such as pharmaceuticals where anti-competitive effects have a very direct bearing on

public health. A central question continually testing the borders of these two legal areas is that of the proportionality of the exercise of IP rights. The exclusivity conferred by IP is intended as a reward for and inducement to innovation and not as an eternal and unchallengeable exclusion from the market. Proportionality thus acts as a form of implicit "internal correction mechanism" in both IP and competition law: In the latter, it ensures that an intervention by the Commission under Article 102 TFEU only goes as far as is necessary to restore or re-establish competition, while in IP it attempts to limit the exclusivity awarded to that conferred by the technically-described patented invention. The practice of evergreening attempts to upset this balance by attempting to extend exclusion without a corresponding increase in therapeutic value.

Further to this, there has been an increasing recognition within the Commission, confirmed by decisions of the Court of Justice, that pharmaceutical markets are fundamentally different from many others: they do not satisfy the classical assumptions of competition law such as simple price competition, substitutability or a fully price sensitive demand. Factors such as highly inelastic demand, interference by doctor/patient decisions with direct consumer choice and a high degree of legal barriers to entry have lead to an innovation driven market where competition exists not only in price but also in research and development pipelines, patent portfolios and regulatory positioning and not just after a product has reached the market.

The European jurisprudence, and particularly the cases following AstraZeneca, demonstrates a willingness by the Court of Justice to extend the ambit of "abuse" into that of manipulating regulatory systems and not only of pre-existing competitive positions within a market. This has yet to be accompanied by a clear and overarching doctrinal framework that establishes clearly defined lines between legitimate lifecycle management and an abusive practice of evergreening. This has led to continued uncertainty over how far a pharmaceutical company can legally push for extending its monopoly while not breaching competition law rules.

Adding further to the confusion, a fundamental problem arises from the timing of enforcement in this interface. While competition law is fundamentally an ex post approach designed to correct harm once it has occurred, IP law operates on an ex ante basis by awarding the incentive at the time of invention. This time difference is manipulated by evergreeners to structure their patent activities and subsequent practices so that each individual step seems compliant with the law but cumulatively over time, they become a mechanism for extending monopoly. How these temporal strategies can be addressed by existing regulatory enforcement mechanisms continues to be a point of discussion.

Both in legal scholarship and policy circles throughout the EU, it is widely recognised that competition in the pharmaceutical market does not generally exist as the result of single instances of abuse by the dominant company, but rather it is the cumulative outcome of a series of individual patents, patent litigation

strategy, regulatory practices and, where appropriate, administrative actions. It is now accepted by the Commission and Courts that they cannot always simply look at each instance in isolation and need to find a way to evaluate the combined impact.

However, a parallel Institutional caution against overreaching into innovation policy with competition law exists. To aggressively scrutinize every new formulation, improvement or product differentiation through the competition lens risks destroying the incentives to research and develop new drugs, particularly in higher risk therapeutic areas, because a company might fear that if it were perceived as "over-managing" its patents and thus having its drugs "evergreened" it would face intervention under competition law and lose out on its R&D investment.

In this context, "innovation competition" has been increasingly recognised as the dominant competition mechanism. Rather than competing primarily on price, pharmaceuticals companies compete on developing superior products, better drug delivery methods, more convenient formulations or, where applicable, more efficient means of manufacturing the drug and this is indeed the ideal kind of competition they would wish to create. Evergreening challenges this form of competition by mimicking real product improvements while not necessarily increasing therapeutic benefit to patients or efficiency for the health system as a whole. Distinguishing real innovation and merely simulated innovation is very difficult however as it requires inter disciplinary medical and legal expertise.[12]

The institutional framework governing this IP-competition relationship itself dictates how the boundaries of acceptable behavior are drawn: IP offices, national and international patent bodies, competition authorities (national and EU) and various other regulatory authorities have different procedures and criteria for the patent grant on the one hand and the assessment of abuses of dominant position on the other hand. It is these institutional divisions which may, and do, offer opportunities for the development of evergreening strategies and can make coordinated policy intervention more difficult.

With the continued advancement in drug discovery technologies, particularly with the rise of biologics, complex medicines and the vast application of artificial intelligence and data analysis in drug development, both IP law and competition law will continue to face evolving challenges. These advancements offer the potential for more complex, layered and strategically organised evergreening strategies based not just on patent law but on controlling and manipulating the data associated with these complex products and development processes and thus further test the boundaries of our current analytical frameworks.

At the normative level, the future of the IP-competition interface in the pharmaceutical context is likely to be based on an emerging paradigm of

[12] Hemphill, C.S. & Sampat, B.N., “Evergreening, Patent Challenges and Market Exclusivity” (2012) J Health Econ.

"conditional exclusivity". Under this paradigm, IP rights are no longer perceived as static "givens" but rather as conditional benefits that depend upon a continued assessment of whether their application has anti-competitive effects on the market or is truly beneficial to patients and health systems. Competition law and IP law should be seen to work together as complementary, internal corrective mechanisms.[13]

Overall, the evolution of EU case law and policy demonstrates an incremental but steady approach towards the merging of IP and competition law. Evergreening acts as a valuable stress test to this evolving area of law, demonstrating both the capacities and the frailties of our existing legal framework. Although clear overreach has been addressed and will be dealt with, the overarching problem of dealing with cumulative and structurally embedded exclusionary strategy remains a challenging puzzle. The solution is as likely to lie in the refining of doctrine as it is in the ability to combine institutions and develop a better comprehension of dynamics within pharmaceutical innovation.

[13] Vines, T. & Faunce, T., “Evergreening and Public Health” (2011) Journal of Law and Medicine.

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