Competition Law Regulation of Pharmaceutical Patent Evergreening Strategies ——A Comparative Study of India and the EU for Uzbekistan's Institutional Design

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Abstract: Patent evergreening strategy means to extend the market monopoly period beyond the core patent term by filing secondary patents, it poses a major challenge to drug accessibility and market competition. This article adopts a combined methodology of comparative law and normative analysis to examine two main regulatory paths: India's ex ante model, which blocks evergreening strategies at the patent authorization stage by raising patentability standards; and the EU's ex post model, which corrects patent abuse through competition law enforcement. This article evaluates the respective advantages and limitations of the two models with the help of landmark cases such as the Gleevec case, the EU AstraZeneca case, the Servier case and the Teva/Copaxone case. On this basis, this article examines the current legal framework of Uzbekistan and identifies key institutional gaps: the lack of enhanced patentability standards for secondary pharmaceutical patents, the existence of broad intellectual property exemption clauses in competition law, and limited patent examination capacity. Accordingly, this article proposes a two-stage framework combining preventive screening at the patent grant stage with corrective intervention at the market conduct stage, and puts forward specific recommendations across four dimensions: substantive standards, examination capacity, opposition procedures, and competition law coordination. The research demonstrates that during WTO accession negotiations, Uzbekistan can establish an anti-evergreening institutional framework that both meets the requirements of the TRIPS Agreement and balances the incentivization of pharmaceutical innovation with public access to medicines.

Keywords: pharmaceutical patents; patent evergreening; competition law; TRIPS Agreement; Uzbekistan; generic drugs

I. Introduction

(I) Research Background and Research Questions

Medicines are special commodities vital to public health, and their market competition order directly affects drug accessibility and affordability. According to the report released by the European Commission in 2024, between 2018 and 2022, European competition authorities issued a total of 26 antitrust decisions in the pharmaceutical sector, averaging approximately 5 per year, indicating sustained intensification of enforcement (European Commission, 2024). The patent system provides necessary incentives for pharmaceutical innovation by granting inventors temporary market exclusivity, but it may also be abused to maintain monopoly positions and impede generic drug market entry. Patent evergreening refers to the practice whereby originator pharmaceutical companies, as core patents approach expiration, file numerous secondary patents around the same drug—covering new polymorphs, new dosage forms, new uses, new salts, etc.—to extend the drug's effective exclusivity period far beyond the core patent term. This strategy has become a focal issue in international competition law enforcement and academic research.

Uzbekistan is the most populous country in Central Asia, with a population of approximately 38.24 million as of early 2026, and is also the largest pharmaceutical market in Central Asia. According to statistics from the IQVIA, the market was valued at approximately USD 2.14 billion in 2025, surpassing Kazakhstan to rank first in Central Asia. At present, Uzbekistan is at a critical stage of economic transformation and WTO accession negotiations. Although the current Law on Inventions, Utility Models and Industrial Designs provides for patent term extension and compulsory licensing provisions for pharmaceuticals, institutional gaps remain in regulating anti-competitive patent conduct

such as patent evergreening. Meanwhile, according to the 2024 annual Consumer Price Index report of the Agency of Statistics under the President of the Republic of Uzbekistan, the pharmaceutical sub-index rose 26.2% year-on-year in 2024, far exceeding the overall inflation level, a figure that reflects the evident inadequacy of competition mechanisms in the pharmaceutical market. Against this background, exploring how to build an anti-evergreening regulatory framework drawing on international experience has direct reference value for Uzbekistan's legislative practice.

(II) Research Methods and Materials

This article adopts a combined methodology of comparative law and normative analysis. The selection of India and the EU as comparative jurisdictions is based on three considerations. First, the two represent the two most typical institutional paths for regulating patent evergreening: India directly blocks evergreening strategies at the authorization stage by raising patentability standards, while the EU corrects patent abuse at the market conduct level through antitrust enforcement tools; they stand at opposite ends of ex ante prevention and ex post correction. Second, both have produced judicial precedents of global benchmark significance, such as India's Gleevec case (Novartis AG v. Union of India, 2013) and the EU's AstraZeneca case (2005/2012), Servier case (2014/2024), and Teva/Copaxone case (2024), providing rich material for comparative analysis. Third, the two represent different stages of development and institutional logics. As a major developing country, India's experience has the most direct relevance for Uzbekistan, which is in the institution-building phase; as a mature competition law system, the EU's refined behavioral regulation tools can point the direction for the improvement of Uzbekistan's competition law.

Data materials are primarily drawn from peer-reviewed academic research, official institutional reports (such as the European Commission's Pharmaceutical Sector Inquiry Report series and the OECD's 2025 report on Competition Risks across the Pharmaceutical Value Chain), and reports from internationally recognized non-governmental research

institutions (such as the Initiative for Medicines, Access & Knowledge (I-MAK)'s 2018 Overpatented, Overpriced report). Uzbekistan's domestic legal norms are based on the official legal texts published in the official legal database lex.uz, supplemented by English translations from the WIPO Lex database for cross-verification.

II. Theoretical and Empirical Basis of Patent Evergreening Strategies

(I) Conceptual Definition and Theoretical Analysis

Patent evergreening is not a statutory term but rather a descriptive concept developed in academic discourse and competition enforcement practice. It refers to the strategic conduct of originator pharmaceutical companies that, as core patents approach expiration, file numerous secondary patent applications around the same drug—including new polymorphs, new salts, new formulations, new uses, new processes, etc.—to effectively extend the drug's exclusivity period. These secondary patents often lack substantial technical contributions; their primary function lies not in disclosing new knowledge but in constructing legal barriers to impede generic drug market entry (I-MAK, 2018).

(II) Welfare Impact

From the perspective of economic welfare, the negative impacts of patent evergreening are multifaceted. First, it extends the market exclusivity period of originator drugs, causing consumers and healthcare systems to continue bearing the burden of high prices. Empirical research by the U.S. Food and Drug Administration on drugs experiencing initial generic entry between 2015 and 2017 shows that generic prices decline progressively as the number of generic competitors increases: with two generic competitors, average manufacturer prices fall to 54% below the pre-competition brand price; with four competitors, prices fall by approximately 79%; and with six or more competitors, prices decline by more than 95% (Conrad & Lutter, 2019). Patent evergreening strategies directly postpone the onset of such price competition. Moreover, patent evergreening distorts the allocation of R&D resources: pharmaceutical companies are incentivized to invest resources

in low-innovation-value improvements that extend the protection period rather than in breakthrough new drug development. It also raises market entry barriers, restricts competitor participation, and undermines dynamic market efficiency. Radelli (2021) further pointed out from a normative perspective that the essence of this practice is to obtain excess profits at the expense of the right to life and health of vulnerable groups, creating a fundamental contradiction with the patent system's original purpose of rewarding inventions and promoting knowledge sharing. This constitute the ethical basis for countries to regulate patent evergreening.

(III) Discussion on the Innovation Value of Secondary Patents

Of course, the assessment of secondary patents is not entirely negative. Some secondary innovations do possess independent therapeutic value, for example, new formulations that significantly improve bioavailability, new salts that reduce side effects, and new administration regimens that improve patient compliance. Such innovations should not be conflated with pure evergreening strategies. Some scholars are also concerned that overly strict anti-evergreening provisions may limit incremental innovation, which is equally important during the drug optimization phase.

However, the above concerns do not negate the necessity of anti-evergreening regulation. The key to anti-evergreening regulation lies not in prohibiting secondary patents, but in requiring secondary innovations to meet a certain substantive threshold, such as substantial improvement in therapeutic efficacy. This precisely enables a balance between encouraging valuable incremental innovation and curbing purely strategic conduct. The TRIPS Agreement reserves sufficient policy space for member states in setting patentability standards, and such regulatory measures have a solid legal basis under international law.

III. Comparative Legal Examination of India and the EU on Regulating Patent Evergreening

(I) The Indian Model: Source Regulation Centered on Section 3(d) of the Patents Act

India has adopted the most strict legislative stance in regulating patent evergreening. The Patents Act, as amended in 2005, introduced Section 3(d), which stipulates that new forms of known substances cannot be patented unless the applicant demonstrates significantly enhanced efficacy. This provision aims to block evergreening strategies at the source of patent authorization.

The Gleevec case (Novartis AG v. Union of India) is a milestone in the judicial application of this provision. In 2013, the Supreme Court of India confirmed in this case that efficacy under Section 3(d) should be strictly interpreted as therapeutic efficacy in the pharmaceutical field, and cannot be broadly interpreted as improvement in physicochemical properties. In this case, Novartis argued that the beta crystalline form of imatinib mesylate had approximately 30% higher bioavailability than imatinib in its free base form. The Court's reasoning proceeded on two levels: first, under the logic of Section 3(d), the comparison benchmark should be the immediate precursor substance, i.e., imatinib mesylate, rather than the earlier free base form, and the comparator chosen by Novartis was itself inappropriate; second, even if there were an improvement in bioavailability, the applicant must still demonstrate through clinical data that this improvement indeed makes a substantial improvement in therapeutic effect, and Novartis precisely failed to submit such evidence. The Court accordingly rejected Novartis's patent application, this judgment should not be interpreted as a complete rejection of incremental innovation in the fields of chemistry and pharmaceuticals. Improvement in bioavailability is not inherently irrelevant to therapeutic efficacy under all circumstances, but the applicant bears the burden of proof.

The study by Abbas (2024) further demonstrates that, despite sustained pressure from high-income countries and branded pharmaceutical companies, the Indian model is fully compatible with the TRIPS Agreement and has the potential for adoption by other WTO member states. However, the cross-national empirical study by Sampat and Shadlen (2017)

also revealed an important finding: merely introducing substantive restrictive provisions in law is insufficient to fully realize anti-evergreening effects; high-quality examination and enforcement capacity and accessible patent opposition procedures are equally essential. For Uzbekistan's institutional development, this finding carries significant cautionary implications.

(II) The EU Model: Comprehensive Governance Primarily Based on Ex Post Regulation through Competition Law

1. Institutional Evolution and Basic Stance

Unlike India, the EU primarily relies on the competition law path to regulate the abuse of patent evergreening ex post. In 2008, the European Commission launched a competition inquiry into the pharmaceutical sector. The following year, it published the Final Report (European Commission, 2009), which systematically documented the practices of originator pharmaceutical companies using patent clusters, patent litigation, patent settlement agreements, and other means to impede generic drug competition. On this basis, the EU gradually developed a comprehensive regulatory framework based on Articles 101 and 102 of the Treaty on the Functioning of the European Union (TFEU). Its basic stance is that strategic patent conduct may be lawful under the patent law framework, but once a dominant undertaking utilizes the patent system as a tool for extending monopoly and excluding competition, the competition authorities are obligated to intervene.

2. Jurisprudential Contributions of Landmark Cases

EU competition law has produced three landmark precedents in this area, each addressing different types of anti-competitive conduct.

The AstraZeneca case concerned two types of conduct by AstraZeneca regarding its anti-ulcer drug omeprazole: first, making systematic misleading representations when applying for supplementary protection certificates (SPCs) to multiple national patent offices, in order to obtain extended protection to which it was not entitled; second,

deregistering the marketing authorization for a specific dosage form to block the reference pathway for generic drug manufacturers. This case established several important legal principles: the legality of conduct under patent law or pharmaceutical regulatory law does not immunize it from competition law scrutiny; dominant undertakings are held to a higher standard of compliance when submitting information to pubic authorities; establishing misleading representations does not require proof of subjective intent, objective and evident lack of transparency is sufficient.

The Servier case concerned the French pharmaceutical company Servier's signing of reverse payment patent settlement agreements with five generic drug manufacturers to extend the market exclusivity of its antihypertensive drug perindopril. Under these agreements, generic drug manufacturers agreed to delay market entry or abandon patent challenges in exchange for value transfers. This case provided an important jurisprudential basis for combating reverse payment agreements.

The Teva/Copaxone case found that Teva had abused its dominant market position through two types of conduct: first, repeatedly filing and withdrawing divisional patent applications around Copaxone, a drug for multiple sclerosis. Specifically, Teva withdrew applications at a critical stage of the original patent opposition proceedings, so that competitors both had to face the patent and were unable to obtain legal certainty through the opposition procedure. This practice artificially prolonged the effective protection period. Second, Teva also conducted a systematic disparagement campaign against competitors' generic drug products. The particular significance of this case lies in the fact that it is the first time competition law has identified the divisional patent strategy itself as an abuse of a dominant position, further expanding the reach of the enforcement toolkit.

3. Systematic Monitoring Mechanism

Following the 2009 pharmaceutical sector competition inquiry, the European Commission established a regular monitoring mechanism, continuing to publish

Pharmaceutical Industry Competition Enforcement Reports, with the latest edition covering 2018 to 2022 (European Commission, 2024). This institutional arrangement of an inquiry–enforcement–monitoring cycle provides organizational support for sustained high-level enforcement in the pharmaceutical sector. As Gurgula (2020) pointed out, once the conduct of a dominant undertaking in obtaining or exercising patents deviates from the course of competition on the merits and instead becomes a means of excluding competition, competition law has sufficient grounds to intervene, even if such conduct is formally in compliance with patent law.

(III) Comparative Evaluation of the Two Models

The Indian model and the EU model each have their strengths, representing policy choices at different stages of development.

The strength of the Indian model lies in its simplification of regulatory logic through source regulation. Without complex competition law analysis, it can directly prevent secondary patents lacking substantive innovation from being granted at the patent examination stage. For developing countries whose competition law enforcement systems are not yet mature, this path entails lower institutional operating costs and higher predictability. However, its shortcomings are equally apparent. The empirical study by Sampat and Shadlen (2017) demonstrates that inadequate examination capacity seriously undermines the effectiveness of substantive provisions. Abbas (2024) has documented in detail the external pressures facing the Indian model—the sustained challenges from the Office of the United States Trade Representative and multinational pharmaceutical companies to Section 3(d). The more fundamental limitation is that Section 3(d) addresses the problem of pre-authorization gatekeeping; it is powerless against already-authorized evergreening patents and post-authorization anti-competitive market conduct.

The value of the EU model lies in its refined regulation of market conduct. It can differentiate between improvements with genuine innovation value and purely strategic

behavior, and its enforcement tools cover a variety of conduct types—including misleading representations, reverse payment agreements, divisional patent abuse, and systematic disparagement—providing strong adaptability. However, ex post regulation is costly, requiring substantial competition law expertise and enforcement resources. The enforcement cycle is also often lengthy; for instance, the Servier case took ten years from the Commission's decision to the final judgment. Moreover, post-intervention is difficult to fully remedy market damage that has already occurred.

For Uzbekistan, the most practical path is not to choose between the two models in an either/or fashion, but to combine them: using Indian-style source blocking as the foundational architecture, supplemented by EU-style competition law intervention as a complement.

IV. Legal Status Quo and Institutional Gaps in Uzbekistan

(I) Basic Situation of the Current Legal Framework

The legal framework governing pharmaceutical patents in Uzbekistan primarily consists of three basic laws: the Law on Inventions, Utility Models and Industrial Designs, the Law on Medicines and Pharmaceutical Activities, and the Competition Law.

Article 6 of the Law on Inventions, Utility Models and Industrial Designs stipulates that inventions must satisfy three conditions for grant: novelty, inventive step, and industrial applicability. Article 5 provides that the patent protection term is 20 years from the filing date, with an extension of up to 5 years available upon the patentee's request. Compulsory licensing provisions are principally found in Article 11^1 (added by Law No. O'RQ-908 of February 15, 2024) and Article 32. However, unlike Section 3(d) of India's Patents Act, this law lacks dedicated provisions targeting secondary patents. The current law does not clearly stipulate whether new forms of compounds are patentable, objectively leaving room for evergreening strategies.

The relevant provisions of the current Competition Law deserve particular attention. Article 18 prohibits the abuse of a dominant market position and superior bargaining power, and Article 19 prohibits anti-competitive agreements and concerted practices. But more critically, the second paragraph of Article 3 expressly provides that this law shall not apply to relations relating to the exclusive rights of intellectual property, except for cases involving the prohibition of unfair competition. The except clause here is limited to acts of unfair competition within the meaning of Article 21, and does not cover the two more fundamental antitrust scenarios: abuse of a dominant position and anti-competitive agreements. This exemption clause constitutes a fundamental obstacle to competition law intervention in anti-competitive patent conduct. Under the principals established in the EU's AstraZeneca case, the legality of conduct under other legal frameworks cannot prevent the application of competition law. Unfortunately, Uzbekistan's current legal text systematically rules out this possibility.

(II) Institutional Gaps and Practical Challenges

The challenges facing Uzbekistan in anti-evergreening regulation can be examined from four dimensions.

At the level of substantive standards, the provisions of the Law on Inventions, Utility Models and Industrial Designs regarding novelty and inventive step examination are relatively general, lacking specialized refined guidelines for the pharmaceutical field. New forms of known compounds face no additional patentability restrictions under the current system. As the activities of multinational pharmaceutical companies in the domestic market increase, this gap may result in the grant of a large number of secondary patents.

In terms of examination capacity, pharmaceutical patent examination involves highly specialized knowledge in chemistry, pharmacy, and biology. The examination capability of Uzbekistan's Intellectual Property Office in the pharmaceutical field remains at a developmental stage, and the team of examiners with relevant disciplinary backgrounds

needs further strengthening, which directly constrains the practical effectiveness of anti-evergreening regulation.

At the level of procedural remedies, although the law has established patent opposition and invalidation procedures, the utilization of these procedures in practice is extremely limited. Generic drug manufacturers lack effective channels to challenge authorized secondary patents, and the institutional function of post-grant clearance of invalid patents has not been adequately realized.

At the level of inter-agency coordination, there is a lack of institutionalized information-sharing and coordinated enforcement arrangements between the Committee for Competition Development and Consumer Rights Protection, the Intellectual Property Office, and the Ministry of Health. Potential anti-competitive leads identified by the Intellectual Property Office during examination cannot be promptly transmitted to competition enforcement agencies, and the reverse flow of information is similarly impeded.

V. Discussion: Proposals for Uzbekistan’s Anti-Patent Evergreening Institutional Framework

(I) Introducing the Requirement of Substantial Improvement in Therapeutic Efficacy in the Law on Inventions, Utility Models and Industrial Designs

Drawing on the legislative experience of India’s Section 3(d), it is proposed that a dedicated provision be added to Uzbekistan’s Law on Inventions, Utility Models and Industrial Designs, stipulating that new forms of known compounds shall not be patentable unless the applicant provides comparative clinical or preclinical data demonstrating a statistically significant substantial improvement in therapeutic efficacy. New forms of known compounds should include common types such as salts, esters, ethers, polymorphs, metabolites, purity improvements, particle size modifications, isomers, and mixtures thereof.

This proposal is legally tenable. Although Article 27.1 of the TRIPS Agreement requires member states to provide patent protection for inventions in all fields of technology, it affords each country policy space to define the specific meanings of novelty, inventive step, and industrial applicability. Requiring new forms of known compounds to demonstrate substantial improvement in therapeutic efficacy constitutes a reasonable definition of the inventive step standard, not a discriminatory exclusion of a technological field. Paragraph 4 of the 2001 Doha Declaration expressly reaffirmed that the TRIPS Agreement should be interpreted and implemented in a manner supportive of the right to pubic health. The Gleevec case judgment has demonstrated to the international community that such provisions are fully legitimate within the WTO framework.

At the operational level, the legislative design should incorporate several core elements: clearly defining the scope of new forms of known compounds; establishing standards for substantial improvement in therapeutic efficacy; allocating the burden of proof to the patent applicant; and providing specialized detailed rules for inventive step examination in the pharmaceutical field in the implementing regulations. Furthermore, this institutional reform can create a fairer competitive environment for the domestic generic drug industry. According to data released at the presidential meeting on March 2026, Uzbekistan has over 300 pharmaceutical enterprises, of which 58 are directly engaged in drug manufacturing; the development of these enterprises will directly benefit from more rational patent granting standards.

(II) Strengthening the Patent Examination Capacity of the Intellectual Property Office in the Pharmaceutical Field

The empirical study by Sampat and Shadlen (2017) demonstrates that however sound substantive provisions may be, their effectiveness will be severely compromised without the support of high-quality examination and enforcement capacity. Accordingly, Uzbekistan needs to improve its examination capacity from multiple dimensions.

In terms of staffing, the team of professional examiners with backgrounds in pharmacy, chemistry, and biology should be expanded. In terms of examination guidelines, reference can be made to the Guidelines for Pharmaceutical Patent Examination prepared by Correa (2016) for the United Nations Development Programme, to develop national operating guidelines. These guidelines set forth specific examination criteria for common secondary patent types such as Markush claims, polymorphs, salt forms, prodrugs, and new uses, and are highly practical. In international cooperation, technical cooperation mechanisms should be established with patent offices of experienced developing countries such as India, Brazil, and Argentina, including examiner exchanges and case study seminars. In terms of institutional development, a specialized division for pharmaceutical patent examination can be established within the Intellectual Property Office to centrally process patent applications in the pharmaceutical field.

(III) Improving Patent Opposition and Invalidation Procedures

Patent opposition and invalidation procedures are key institutional tools for the post-grant clearance of evergreening patents. India's experience shows that even with Section 3(d) in place, it is impossible to completely prevent the grant of secondary patents; procedural remedial channels are therefore equally important. Uzbekistan should establish a post-grant opposition system, allowing interested parties to challenge the validity of patents within a reasonable period, providing generic drug manufacturers with accessible challenge channels beyond litigation. At the same time, the threshold and costs for initiating invalidation proceedings should be lowered so that small and medium-sized generic drug manufacturers can also effectively utilize this mechanism. The institutional design should also reasonably control the adjudication timeline to avoid market uncertainty caused by procedural delays.

(IV) Authorizing Competition Regulatory Authorities to Intervene in Strategic Patent Conduct

Measures internal to patent law are insufficient to address all anti-competitive conduct. Drawing on EU experience, competition law should play a complementary regulatory function.

The most urgent task is to amend the intellectual property exemption provision of Article 3 of the Competition Law. The current law excludes the field of intellectual property as a whole from the scope of competition law application, a stance that is contrary to mainstream international practice. It is proposed that the exceptions in the second paragraph of Article 3 be extended to cover abuse of a dominant position and anti-competitive agreements, thereby removing legal obstacles for competition enforcement agencies to intervene in strategic patent conduct. On this basis, it should be further clarified which patent-related conduct by dominant undertakings may constitute abuse, including: making misleading representations to patent or pharmaceutical regulatory authorities; entering into reverse payment settlement agreements with generic drug manufacturers; strategically filing and withdrawing divisional patent applications; engaging in systematic disparagement of competitors' generic drug products; and bringing vexatious patent infringement lawsuits. These conduct types directly correspond to the specific circumstances addressed in the EU's three landmark cases.

In addition to institutional-level amendments, several supporting measures are worth advancing. Consideration may be given to authorizing the Committee for Competition Development and Consumer Rights Protection to conduct sector-wide competition inquiries into the pharmaceutical market, systematically mapping the competitive landscape in the domestic market. An information-sharing and joint enforcement mechanism should be established among the competition regulatory authority, the Intellectual Property Office, and the Ministry of Health. Furthermore, drawing on EU practice, the upper limit of fines for antitrust violations in the pharmaceutical field may be appropriately raised to form an effective deterrent against multinational pharmaceutical companies.

VI. Conclusion

The patent evergreening strategy extends the drug market exclusivity period by constructing secondary patent barriers, posing a systemic threat to generic drug competition and pubic access to medicines. Effective regulation requires the coordinated operation of patent law, competition law, and pharmaceutical regulatory law. Through comparative analysis of the regulatory paths of India and the EU, combined with an assessment of Uzbekistan's legal status quo and institutional gaps, this article proposes a two-stage framework combining preventive screening at the patent grant stage with corrective intervention at the market conduct stage, and puts forward specific recommendations along four dimensions: substantive standards, examination capacity, opposition procedures, and competition law articulation. For Uzbekistan, which is at a critical stage of economic transformation and on the verge of completing WTO accession negotiations, establishing this institutional framework is not only a necessary measure to meet the challenges of the globalized pharmaceutical market but also an inherent requirement for safeguarding access to medicines for its approximately 38.24 million population. The core objective of reform has always been to find a balance suited to the country's national conditions between incentivizing genuine pharmaceutical innovation and ensuring access to essential medicines.

Research Limitations: Publicly available official classified statistics on pharmaceutical patents in Uzbekistan are limited, making it difficult to conduct a precise quantitative assessment of the actual scale of domestic patent evergreening; thematic research materials on the behavioral patterns of multinational pharmaceutical companies in the domestic market are also insufficient. The core argumentation of this article is based on comparative legal analysis, normative argumentation, and textual analysis of the legal framework. Future research may further consolidate the domestic empirical foundation through specialized surveys, structured interviews with generic drug manufacturers, and the construction of a patent–market–price linkage database.

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