A CRITICAL ANALYSIS OF THE JUDICIAL DISCRETION IN PATENT INFRINGEMENT AND INJUNCTIONS UNDER INDIAN LAW

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ABSTRACT

Interim injunctions in patent infringement disputes are important in protecting patent rights and societal interests, especially in sectors such as pharmaceuticals. This paper examines the manner in which Indian courts have exercised judicial discretion in granting interim injunctions by focusing on three key aspects: establishing a prima facie case, assessing patent validity, and considering public interest. This paper focuses on the thresholds for identifying the prima facie case, assessing patent validity, and the inclusion of the public interest factor, which differ among judgments, leading to uncertainty. In the absence of clear guidelines on what constitutes these aspects, courts often face difficulties and inconsistencies when deciding interim injunction cases. This paper addresses these issues by placing Indian practice within a broader comparative framework, drawing insights from approaches in other jurisdictions, such as UK and the US. The researcher aims to demonstrate the importance of developing a structured yet flexible framework for interim relief, ensuring predictability and consistency in judicial outcomes.

This paper also highlights, through an analysis of leading Indian cases like Dalpat Kumar v. Prahlad Singh, Roche v. Cipla, and Bayer v. Natco, practical conflicts and judicial reasoning required in balancing competing concerns at the interim stage. This paper emphasizes the benefits of integrating comparative insights to refine judicial standards, improve consistency, and also to promote equitable outcomes. The researcher aims to provide a deeper understanding of how Indian courts can develop a balanced framework that safeguards rights, ensures timely relief, and protects public welfare while addressing gaps in the current approach to interim injunctions.

Keywords: Patent Infringement, Interim Injunctions, Judicial Discretion, Prima Facie Case, Patent Validity, Public Interest

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STATEMENT OF PROBLEM

In India, the exercise of judicial discretion in granting interim injunctions for patent infringement cases currently suffers from a lack of clarity and consistency. This uncertainty arises from the absence of a structured framework and clear guidelines for courts to follow when assessing the key criteria for granting an injunction: establishing a prima facie case, evaluating patent validity, and considering the public interest. The problem is that the absence of codified guidelines and a structured judicial approach has led to a situation where the outcome of an interim injunction application is largely based on the individual judge's interpretation rather than on a uniform, well-defined legal standard. This lack of clarity creates significant challenges. For patentees, it makes it difficult for them to enforce their intellectual property rights effectively. For alleged infringers, it creates legal uncertainty and may result in unjust or disproportionate interim relief. For the public, particularly in sectors like pharmaceuticals, the unpredictable application of the "public interest" factor can adversely affect access to affordable medicines and restrain competition.

HYPOTHESIS

A structured framework for granting interim injunctions in patent infringement cases is essential in India for ensuring consistency, timely and equitable relief, and for safeguarding public welfare.

RESEARCH QUESTIONS

1. How do Indian courts determine the threshold of a prima facie case in patent infringement disputes, and what factors influence their assessment at the interim stage?

2. How do Indian courts evaluate patent validity during interim proceedings, and how does this assessment influence the requirement of showing irreparable harm for granting interim injunctions?

3. How can Indian courts balance public interest, particularly in the pharmaceutical sector, against the rights of patentees when deciding interim injunctions?

RESEARCH OBJECTIVES

• To analyse the manner in which Indian courts exercise judicial discretion in granting interim

injunctions in patent infringement cases.

• To evaluate the judicial thresholds applied for establishing a prima facie case, assessing patent validity, and considering public interest.

• To identify inconsistencies and gaps in Indian judicial approaches that leads to unpredictability in injunction outcomes.

• To compare Indian practices with approaches from other jurisdictions (UK and US) and draw insights.

• To suggest ways to create a fair, clear, and consistent framework for interim injunctions in India.

RESEARCH METHODOLOGY

The paper uses doctrinal methodology with statutes and case laws as its primary sources and research papers, articles as its secondary sources. The focus of the paper is the judicial exercise of discretion in granting interim injunctions in patent infringement disputes, which primarily requires examining statutory provisions and judicial precedents rather than empirical field data. The doctrinal method enables a systematic analysis of primary legal sources and landmark judgments. These materials provide the foundation for understanding how courts have interpreted and applied the principles governing interim injunctions. Secondary sources, such as scholarly articles, commentaries, and comparative legal studies, supplement this analysis by highlighting critical perspectives and offering insights from other jurisdictions such as the UK and US.

EXISTING LEGAL SITUATION

In India, the legal framework governing interim injunctions in patent infringement disputes is not codified under a single statute. Instead, it is primarily shaped by judicial precedents, equitable principles, and the following statutory provisions:

- Code of Civil Procedure, 1908 (CPC) : The CPC, under Order XXXIX Rules 1 and 2, empowers courts to grant temporary injunctions where property or rights are at risk of being wasted, alienated, or infringed, or where breach of contract or other injury is

threatened.

- Section 151 CPC: This provision safeguards the court's inherent powers to act ex debito justitiae (in the interest of justice). Section 151 enables them to intervene in situations not expressly covered, ensuring that justice is not defeated by procedural gaps. Courts have repeatedly emphasised that this power and must be exercised only when no other remedy is available under the CPC. Section 151 CPC preserves the court's inherent powers to issue injunctions to secure the ends of justice even where specific provisions may not apply. Section 151 CPC cannot be used to override or circumvent express provisions of law, but rather to supplement them where necessary to prevent abuse of process and secure the ends of justice.

- Specific Relief Act, 1963: This Act provides the substantive framework for injunctions in India. Section 36 recognises preventive relief through injunctions, laying the foundation for courts to restrain wrongful acts before they cause harm. Section 37 distinguishes between temporary injunctions and perpetual injunctions. Temporary injunctions are granted at any stage of a suit and are regulated by the CPC (Order XXXIX).

INTRODUCTION

The protection of patent rights constitutes a fundamental aspect of economic policy in developing nations, as it provides incentives for innovation and ensures a continuous flow of technological advancement.[2] Jurisdictions lacking an effective legal regime for patent enforcement often experience stagnation in technological growth and limited industrial competitiveness.[3] Consequently, for a developing economy such as India, the establishment and maintenance of a robust patent protection framework is indispensable to fostering technological progress and sustainable economic development.[4] However, India's judicial infrastructure continues to face systemic challenges, most notably, significant case backlogs and delays that hinder the efficient adjudication of patent disputes.[5] These institutional

[2]Reichman, J. H., Legal Hybrids Between the Patent and Copyright Paradigms, 94 Colum. L. Rev. 2432 (1994).
[3] Lerner, J., *The Importance of Patent Enforcement for Innovation*, 55 Journal of Economic Perspectives 1 (2002).
[4] Maskus, K. E., Intellectual Property Rights in the Global Economy (Peterson Institute, 2000).
[5] Law Commission of India, Report No. 230: Reforms in the Judiciary (2009).

inefficiencies can ultimately undermine the economic benefits intended by patent legislation.[6] While comprehensive judicial reforms may be the ideal long-term solution, the urgency of ensuring immediate protection for patent holders necessitates more expedient interim measures.[7] In this context, the grant of interim injunctions serves as an effective judicial tool to safeguard patent rights during the pendency of infringement proceedings.[7] Such relief allows courts to restrain alleged infringers even before a final determination of the parties' rights, thereby preserving the patent holder's exclusive interests during the patent's limited lifespan, typically twenty years under the Patents Act, 1970.[8] Without such interim protection, patentees risk losing the commercial and strategic value of their inventions due to continued infringement throughout prolonged litigation.[9] Permanent injunctions, though available after adjudication, are often rendered ineffective due to procedural delays. In contrast, interim injunctions offer an immediate and pragmatic form of relief that can prevent irreparable harm.[10] Nevertheless, the grant of such relief remains discretionary, requiring courts to weigh relevant factors, including prima facie rights, balance of convenience, and public interest.[11] The inherent flexibility of this judicial mechanism makes it particularly suited to the Indian context, where the need for rapid protection must be balanced against broader economic considerations.[12] The authority of civil courts in India to issue interim injunctions is derived from Order XXXIX of the Code of Civil Procedure, 1908 (CPC).[1] The principal objective of granting such relief is to preserve the status quo ante between the disputing parties during the pendency of litigation.[2] This ensures that a party alleging wrongful conduct is not subjected to irreparable harm before the final adjudication of rights.[3] An interim injunction, however, is not a remedy available as of right.[4] Its grant lies entirely within the judicial discretion of the court, which must assess the specific facts and circumstances of each case to determine whether temporary relief is warranted.[5] The underlying rationale is that, in cases where the alleged unlawful conduct of a party could render the outcome of litigation meaningless, the issuance of an interim injunction becomes essential to preserve the subject matter of the dispute.[6] While Order XXXIX CPC empowers the court to grant such injunctions, it does not explicitly lay down the substantive standards governing the exercise of this discretion.[8] Nevertheless, through a consistent line of judicial precedents, the Indian Supreme Court has articulated a well-established tripartite test for granting interim relief, namely, the existence of a prima facie case, the balance of

[6] Basheer, S., The "Efficacy" of Indian Patent Law: The Growing Influence of the Judiciary, 1 Indian J.L. & Tech. 15 (2005).
[7] Feroz Ali Khader, The Law of Patents – With a Special Focus on Pharmaceuticals in India (LexisNexis, 2011).
[8] F. Hoffmann-La Roche Ltd. v. Cipla Ltd., (2009) 40 PTC 125 (Del).

convenience in favor of the applicant, and the likelihood of irreparable injury if relief is denied.[9] These principles, though judicially evolved, now function as the formal framework guiding the equitable exercise of discretion under Order XXXIX.[10]

1. DETERMINING THE THRESHOLD OF A PRIMA FACIE CASE IN PATENT INFRINGEMENT DISPUTES AND FACTORS INFLUENCING THEIR ASSESSMENT AT THE INTERIM STAGE.

The interpretation and application of the requirement of a prima facie case have been the principal sources of controversy in both India and the United Kingdom (UK). The law governing interim injunctions in the UK underwent a complete transformation following the landmark decision of the House of Lords in American Cyanamid Co. v. Ethicon Ltd.[11] The innovative approach adopted in American Cyanamid significantly influenced patent infringement litigation, making it easier for patent holders to secure interim injunctions and safeguard their rights during the pendency of a suit.

However, the Supreme Court of India has been hesitant to adopt this approach and continues to adhere to the earlier, more rigid interpretation of a prima facie case—requiring the establishment of a "strong" case and a high likelihood of success at trial, based on pre-trial evidence. Nevertheless, certain recent Supreme Court decisions have acknowledged American Cyanamid and recognized its relevance in the Indian context. Despite this, the interpretation and practical application of the American Cyanamid principles in India differ considerably from those in the UK, leading to ongoing uncertainty and debate.

Understanding the position and evolution of the law in the UK offers valuable insight into the Indian legal framework and its effect on the enforcement of patent rights through interim injunctions. Before American Cyanamid, the legal position in the UK closely resembled that in India. This is best illustrated by the House of Lords' decision in J.T. Stratford & Sons Ltd. v. Lindley, where an interim injunction was denied in a trade dispute on the ground that the applicant failed to establish a prima facie case.[12] The House of Lords held that establishing a prima facie case required the litigant to demonstrate, through pre-trial evidence, the existence

[9] Novartis AG v. Mehar Pharma, 2005 (30) PTC 160 (Bom).
[10] Order XXXIX Rule 1 & 2, Code of Civil Procedure, 1908.
[11] American Cyanamid Co v Ethicon Ltd, [1975] A.C. 396.
[12] J.T. Stratford and Sons v. Lindley, [1965] A.C 269

of the legal rights in dispute. Since the applicant in that case failed to show that the relevant provisions of the Trade Disputes Act, 1906 applied to him, the Court concluded that no prima facie case was made out and therefore refused to grant the injunction. The Stratford decision reflected an extremely strict approach to the grant of interim injunctions in the UK.

This rigid judicial attitude toward the exercise of discretion in granting interim injunctions raised significant concerns, which were later addressed in the Court of Appeal's decision in Hubbard v. Vosper. [13]The Court held that merely establishing a prima facie right or an arguable case was not always sufficient to justify an interim injunction. It emphasized that such relief is inherently flexible and discretionary, and must be granted only after a holistic consideration of the entire dispute. The Hubbard judgment marked a deliberate departure from the stringent standard laid down in J.T. Stratford & Sons, aiming to restore flexibility in judicial discretion over interim relief. However, the view that a mere prima facie right or arguable case was inadequate was ultimately overturned in American Cyanamid, which established a more balanced and pragmatic approach.

The decision of the House of Lords in American Cyanamid Co. v. Ethicon Ltd. marks a turning point in the evolution of the law on interim injunctions in the United Kingdom.[14] In this case, the House of Lords granted an interim injunction restraining the infringement of a patent concerning surgical sutures. The Court criticised the rigid judicial standards that had traditionally governed the grant of interim injunctions and reaffirmed the flexible nature of judicial discretion in such matters.

The most significant reform introduced by American Cyanamid was the reinterpretation of the requirement of establishing a prima facie case. The Court held that it was sufficient to show a triable issue or bona fide dispute, rather than to prove a strong likelihood of success at trial. The comparative strength of the parties' cases was relegated to a secondary, tie-breaking consideration relevant only to the balance of convenience. Thus, a litigant seeking an interim injunction was no longer required to establish his legal rights through pre-trial evidence conclusively; it was enough to demonstrate that a genuine and substantial legal question existed.

[13] Hubbard v. Vosper, [1972]2 W.L.R. 389.
[14] American Cyanamid Co v Ethicon Ltd, [1975] A.C. 396.

This decision had a profound and positive impact on civil litigation, particularly in the context of patent infringement. Patent holders found it considerably easier to obtain interim injunctions without the onerous requirement of proving their patent rights based on technical, untested evidence. The American Cyanamid approach soon came to be regarded as laying down the general principle of law governing interim injunctions in the UK.

A more recent illustration of its beneficial influence can be found in Servier Laboratories Ltd. v. Apotex Inc., decided by the Patents Court of the Chancery Division of the High Court. In that case, the Court granted an interim injunction restraining the sale, importation, and distribution of a generic drug alleged to infringe Servier's patent. Notably, the applicant's evidence was imperfect and not entirely convincing. Nevertheless, the Court held that a prima facie case was established under the American Cyanamid standard, since the applicant had demonstrated the existence of a bona fide dispute or triable issue. Despite the evidentiary weaknesses, the Court was bound to recognize the existence of a prima facie case and grant an interim injunction subject to other conditions. This decision exemplifies how the moderate judicial standard articulated in American Cyanamid enhanced protection for patent holders and contributed to the stability and growth of the patent regime. [15]

In contrast, the legal position in India regarding interim injunctions has remained uncertain even after American Cyanamid. The Supreme Court has alternated between two conflicting approaches—one consistent with American Cyanamid ("pro-Cyanamid") and another adhering to the traditional, stricter interpretation ("anti-Cyanamid").

In United Commercial Bank v. Bank of India, the Supreme Court held that establishing a prima facie case required only demonstrating a bona fide dispute or serious issue, adopting a view similar to that in American Cyanamid, though without expressly relying on it. [16]

Subsequently, in Power Control Appliances v. Sumeet Machines Pvt. Ltd., the Supreme Court explicitly approved American Cyanamid and granted an interim injunction restraining trademark and copyright infringement.[17] However, the Court simultaneously relied on an earlier Madras High Court decision that required the applicant to prove that his legal right had been infringed and that he was likely to succeed at trial. This dual reliance revealed that, despite

[15] Servier Laboratories Ltd. v. Apotex Inc., [2006] EWHC 2137 (Pat).
[16] United Commercial Bank v. Bank of India, A.I.R, 1981 S.C. 1426 [Supreme Court].
[17] Power Control Appliances and Ors. v. Sumeet Machines Pvt. Ltd., (1994) 2 S.C.C 448 [Supreme Court].

its apparent endorsement of American Cyanamid, the Court had not fully embraced its principles. The litigant still bore the burden of proving his legal rights on the basis of pre-trial evidence and demonstrating a substantial chance of success. The inconsistency was perpetuated when the Court in Colgate Palmolive (India) Ltd. v. Hindustan Lever Ltd. cited Power Control Appliances as authority for adopting the American Cyanamid approach.[18]

The Colgate Palmolive case, however, stands as the Supreme Court's most definitive endorsement of the American Cyanamid principle. The Court held that a prima facie case exists if the litigant can show a triable issue or a serious legal question between the parties, expressly approving American Cyanamid as correctly stating the law on interim injunctions. Conversely, in SM Dyechem Ltd. v. Cadbury (India) Ltd., the Supreme Court reverted to the pre-American Cyanamid position. It held that a court must assess the comparative strength of each party's case to determine whether a prima facie case exists, relying on Series 5 Software v. Clarke. However, closer analysis of Series 5 Software and Colgate Palmolive reveals inconsistencies in the reasoning adopted in SM Dyechem. [19]

A similar stance was taken in M. Gurudas v. Rasaranjan, where the Court added further confusion by prescribing the additional requirement of establishing a bona fide contention and a serious question alongside the prima facie case. This created uncertainty about whether these were distinct conditions or cumulative requirements for granting interim injunctions.[20]

In Ramdev Food Products Pvt. Ltd. v. Arvindbhai Rambhai Patel, the Supreme Court reaffirmed the traditional, stricter view. It held that a prima facie case exists only when the applicant demonstrates a strong case on the basis of affidavits and other pre-trial evidence, showing a reasonable likelihood of success at trial. The Court clarified that merely raising a triable issue or serious dispute is insufficient. This approach, which relied on Colgate Palmolive and American Cyanamid, paradoxically contradicted the principles laid down in those very cases. [21]

Thus, while American Cyanamid revolutionized the law on interim injunctions in the UK, its reception in India has been divided and inconsistent. Indian courts continue to oscillate between

[18] Colgate Palmolive India Ltd. v. Hindustan Lever Ltd., A.I.R. 1999 S.C. 3105 [Supreme Court].
[19] M/s SM Dyechem Ltd. v. M/s Cadbury (India) Ltd., 2000 (4) S.C.A.L.E. 713 [Supreme Court]
[20] M. Gurudas and Ors. v. Rasaranjan and Ors., A.I.R. 2006 S.C. 3275 [Supreme Court]
[21] Ramdev Food Products Pvt. Ltd. v. Arvindbhai Rambhai Patel, A.I.R. 2006 S.C. 3304 [Supreme Court].

the liberal and flexible approach endorsed in American Cyanamid and the traditional, rigid requirement of proving a strong prima facie case based on pre-trial evidence.

2. THE ROLE OF INTERIM VALIDITY ANALYSIS IN SHAPING THE IRREPARABLE HARM STANDARD IN INDIAN PATENT INJUNCTIONS

Irreparable harm is a central but contested component of interlocutory (interim) injunction doctrine. Under the American Cyanamid framework, courts must assess whether damages would be an adequate remedy, but scholars have long questioned whether the irreparable-injury prong produces just, efficient, or predictable outcomes. Indian jurisprudence in pharmaceutical patent cases has adapted this doctrine in light of public-health imperatives, credibility of patent challenges, and market dynamics.

1. The American Cyanamid doctrine and its Critique

The American Cyanamid decision (House of Lords, 1975) remains the cornerstone of interim injunction doctrine in common-law jurisdictions. Lord Diplock established a tripartite test: (1) a serious question to be tried, (2) whether damages would be an adequate remedy (i.e., irreparable injury), and (3) the balance of convenience. Crucially, Diplock noted that "[i]f damages … would be adequate … no interlocutory injunction should normally be granted."[22]This standard seeks to prevent overbroad early injunctions while preserving judicial discretion. However, the concept of irreparable harm — damage not fully compensable in money has been challenged on doctrinal and policy grounds.

Some critiques the rigid application of the irreparable-harm prong. Critics argues that the requirement often serves as a blunt tool: courts demand a near-certainty of non-monetary injury even where damages might strongly compensate a party, effectively elevating irreparable injury to a quasi-automatic barrier to injunction unless the strongest cases are made. [23]This leads to under- or over-protection depending on judicial temperament, undermining the equity goals of interlocutory relief.

While some critique by calling for a recalibration of the irreparable-harm threshold through a more policy-sensitive, comparative lens. [24]There is an argument that the traditional test

[22] American Cyanamid Co. v. Ethicon Ltd., [1975] A.C. 396
[23] Jean-Paul Groleau, Interlocutory Injunctions: Revisiting the Three-Pronged Test, 38 Advoc. Q. 344 (2012).
[24] Norman Siebrasse, A Policy Analysis of Interlocutory Injunctions, 29 C.I.P.R. 109 (2012).

overemphasizes speculative harms and fails to account for broader economic or public-interest costs (such as access to markets) that may not fit neatly into "irreparable injury" as classically defined. Also, they advocate for flexible balancing that gives due weight to both economic disruption and future uncertainty.

The irreparable-harm requirement, while theoretically limiting, may in practice distort litigation strategies: plaintiffs may manufacture "irreparable" risk or defendants may press speculative validity arguments to avoid injunctions. This paradox raises concerns about judicial workload, delay, and strategic behavior. Thus, scholars argue that while Cyanamid created a sound framework, its irreparable-harm limb can be both overinclusive (blocking injunctions even when damages suffice) and underinclusive (failing to account for non-monetary harms).

2. The Indian Judicial Turn: Patent Injunctions and Irreparable Harm

2.1. The Role of Roche v Cipla and Public-Interest Considerations

A seminal case in Indian patent jurisprudence is F. Hoffmann-La Roche Ltd. v. Cipla Ltd.[25] In refusing an interim injunction for Erlotinib (Tarceva) against Cipla's generic, the court weighed the public's access to a life-saving drug. The court held that "several unknown persons … would be deprived of life-saving drug which damage cannot be restituted in monetary terms … it is irreparable."[26] This articulation elevates public-interest harm to third parties as a non-compensable injury.

It is contented that if the injunction were granted, the Court would in effect be stifling the right to health so far as patients who would have or could have access are concerned.[27] The decision thus crystallizes a principle in India: irreparable harm must account not just for the patentee but for public health externalities.

2.2. Credible Challenge, Prima Facie Validity, and Irreparable Harm

In Roche v Cipla, the court also emphasized the need for the patentee to make a strong prima facie case[28]. It scrutinized Roche's non-disclosure of patent applications (Polymorph B),

[25] F. Hoffmann-La Roche Ltd. v. Cipla Ltd., FAO (OS) 188/2008 (Del. H.C. Dec. 24, 2008) (Div. Bench).
[26] F. Hoffmann-La Roche Ltd. v. Cipla Ltd., FAO (OS) 188/2008 (Del. H.C. Dec. 24, 2008) (Div. Bench).
[27] Shirin Syed, Access to Medicines and the Indian Judiciary: Analysing the Roche–Cipla Dispute (Policy Brief, 2009).
[28] F. Hoffmann-La Roche Ltd. v. Cipla Ltd., FAO (OS) 188/2008 (Del. H.C. Dec. 24, 2008) (Div. Bench).

finding that this undermined the case for a robust prima facie right. The court explicitly rejected the notion that patents enjoy a strong presumption of validity, contrasting them with trademarks. [29]Thus, irreparable harm arises only when the underlying right is demonstrably strong.

Later Indian jurisprudence, including Merck v Glenmark,[30] reaffirmed this interplay: courts have denied or granted injunctions based on whether the patent faces a credible challenge.[31] Since validity can be uncertain and may shape future exclusivity, the possibility of non-monetary injury depends decisively upon robustness of the patent.

2.3 Market Effects and Price-Erosion

More recently, Indian courts have recognized that interim generic entry can cause "irreparable market effect." For example, in a recent Delhi High Court order (2025), the court articulated that if infringers operate during litigation, they may drive down prices, and those prices may "not recover after the patentee ultimately prevails."[32] This reflects a recognition of price-spiral dynamics: once generics enter, even a successful plaintiff may never recoup pre-entry market conditions. This argument aligns with economic critiques of irreparable injury: it's not just about access, but about the commercial viability of the patentee post-litigation.

2.4 Institutional and Procedural Challenges

Courts must balance not just legal rights, but broader health and socio-economic welfare. The irreparable-harm inquiry in India is deeply institutional: judges weigh R&D incentives, the role of patent working (whether the patented drug is manufactured in India), and affordability. Injunctions in pharma cases are not just about protecting IP but about protecting "life-saving products" for unknown patients. Thus, irreparable harm is embedded in a public-health frame, and not merely an abstract legal imbalance.

3. Comparative Analysis

3.1 Public Interest vs. Economic Right

[29]F. Hoffmann-La Roche Ltd. v. Cipla Ltd., FAO (OS) 188/2008 (Del. H.C. Dec. 24, 2008) (Div. Bench).
[30] Merck Sharp & Dohme Corp. v. Glenmark Pharms. Ltd., 55 PTC 236 (Del. H.C. 2014).
[31] Merck Sharp & Dohme Corp. v. Glenmark Pharms. Ltd., 55 PTC 236 (Del. H.C. 2014).
[32] Delhi High Court, Order on Injunction in Pharmaceutical Market-Entry Case (2025).

One of the strongest divergences between the Cyanamid doctrine and Indian practice centers on public interest. In Cyanamid, irreparable harm is assessed mostly through the lens of private injury and financial remedy. In contrast, Indian courts treat public-health harm as central. Roche v Cipla explicitly protects access to medicines, even when that means denying a patentee's request for an injunction[33]. This policy embedding represents a moral-economic recalibration of irreparable harm where third-party harm is weighted equivalently (or more) than the patentee's monopoly.

3.2 Validity as a Gatekeeper

Another point of comparison is how validity scrutiny feeds into the irreparable injury inquiry. Under American Cyanamid, courts avoid deep merits analysis in many interlocutory cases; irreparable harm is considered separately from the strength of the case. But scholars have criticized this separation because a weak claim should not justify hard equity. Indian courts actively collapse that separation: in practice, the prima facie validity challenge influences whether irreparable harm even arises. If a patent is weak (non-disclosed, credibly challenged), courts refuse injunctions precisely because the underlying right is uncertain and any exclusion could be unjust. This gatekeeping both limits over-injunction and respects the uncertainty inherent in patent validity.

3.3 Market Dynamics and Irreversibility

A further comparative insight concerns irreversible market effects. There is concern that injunctions might disrupt markets in non-obvious ways, but these concerns are less systematically developed in common-law doctrine. Indian courts, by contrast, explicitly articulate concern about price erosion and "irreparable market effect": lower prices, once established, may not rebound, even after litigation. This doctrine reflects a sophisticated understanding of pharmaceutical economics. Indian judges recognize that damages might compensate for sales volumes but cannot rewind market structure, patient behavior, and cost perception.

3.4 Institutional Contexts and Discretion

Finally, there is a divergence in the institutional context. In the UK or other Cyanamid-derived

[33] F. Hoffmann-La Roche Ltd. v. Cipla Ltd., FAO (OS) 188/2008 (Del. H.C. Dec. 24, 2008) (Div. Bench).

systems, courts are primarily concerned with equitable risk-balancing and procedural fairness. In India, the court's discretion to deny injunctions is exercised in a more normative, policy-laden context, taking into account public health, working of patents, TRIPS obligations, and socio-economic welfare. This institutional embedding has been criticized and defended. Some argue that judicial activism (in denying injunctions on public-interest grounds) undermines patent rights; others say it corrects for market failures and prioritizes public welfare.

This comparative analysis reveals both convergence and divergence. While both systems use the three-prong test (prima facie case, irreparable harm, balance), Indian courts apply the test with additional normative layers that reflect their socio-economic and public-health context.

From a policy and doctrinal perspective, the Indian approach may offer a promising reform model for jurisdictions grappling with access-innovation trade-offs. Nevertheless, the increased complexity and discretion also impose challenges: risk of unpredictability, evidentiary burden on judges, and potential chilling of innovation.

3. THE PRINCIPLE OF BALANCE OF CONVENIENCE IN PATENT INJUNCTIONS: WEIGHING COMPETING HARMS AND PUBLIC INTEREST

The judicial application of the Balance of Convenience is one of the three foundational pillars, along with prima facie case and irreparable harm, that governs the grant or refusal of an interim injunction in Indian patent litigation. This factor necessitates a careful, equitable analysis by the court to determine which party would suffer the greater comparative mischief or inconvenience if the injunction were either granted or denied. The final determination is recognized by the Supreme Court as highly fact-specific and contingent upon the circumstances of each individual case.

Apart from the standard three-factor test, Indian courts rightly treat public interest as an important consideration in pharmaceutical patent infringement cases. Over time, Indian jurisprudence has evolved to recognise public interest both as an independent factor and as one examined within the balance of convenience. In pharma patent injunctions, public interest plays a meaningful and separate role, though in practice it often ends up functioning merely as a supplementary "tie-breaker."

In this sense, public interest effectively operates as a fourth factor, suggesting that the patentee

should demonstrate that granting an interim injunction would not harm public welfare. However, in reality, this burden rarely shifts to the plaintiff, as the traditional three-factor test is generally seen as sufficient. Consequently, public interest is more commonly invoked by defendants, who rely on this fourth factor to argue that the injunction should be refused. There is another compelling element called a credible challenge test that has to be satisfied by the defendant for the authenticity of the asserted patent, that is because of fact the public interest factor per se wouldn't make a potent defence.[34]

The overarching principle behind the public-interest consideration is that a patented product should be reasonably or affordably priced and made adequately accessible to the public. The earliest and most prominent discussion on public interest in pharmaceutical patent infringement arose in *Roche v. Cipla.*[35] In this landmark case, the Delhi High Court emphasized that public interest plays a vital role when the dispute concerns life-saving medicines. The Court examined public interest from two angles: ensuring public access to a crucial life-saving drug (an anti-cancer medicine), and assessing the public implications of granting an interim injunction that would uphold the patent while the infringement suit was still pending. The court culminated that the degree of damage or harm the patent owner would endure can be determined on a monetary basis.[36]

In such situations, denying access to a life-saving drug causes the public to suffer harm that can shorten the lives of many individuals who have no connection to the litigation. This harm is both irreparable and incapable of compensation, as no monetary award can make up for the loss of life or health. The ruling was groundbreaking because it introduced a new perspective that had not been considered before. It was in this case that the "credible challenge" test first took shape. This test was later affirmed and developed further in subsequent decisions, including *Bristol-Myers Squibb v. JD Joshi*,[37] *Bristol-Myers Squibb Company & Anr. v. D.*

[34] Dinesh Kumar Sharma, India: Patent Infringement Litigation In India And Interim Injunctions: Jurisprudence On "Public Interest" Continues To Evolve!, Mondaq, (Oct.10.10.2025,2.30PM),https://www.mondaq.com/india/patent/575348/patent-infringement-litigation-in-india-and-interiminjunctions-jurisprudence-on-public-interestcontinues-to-evolve.
[35] F. Hoffmann-La Roche Ltd. v. Cipla Ltd., FAO (OS) 188/2008 (Del. H.C. Dec. 24, 2008) (Div. Bench).
[36] Essenese Obhan and Ayesha Guhathakurta,India: Pandemics, Public Interest And Patent Infringement In India, Mondaq, (Mar. 03, 2022, 5.32PM),https://www.mondaq.com/india/patent/1016430/pandemics-public-interest-and-patent-infringement-in-india.
[37] Bristol Myers Squibb and Anr v JD Joshi and Anr,(2015) 64 PTC135 (Del).

Shah,[38] and *Novartis v. Cipla*.[39]

The major difference between Indian and U.S. law on this issue is that U.S. courts expressly consider "public interest" as one of the factors when deciding whether to grant an injunction, whereas Indian courts typically do not treat public interest as an independent criterion.

A significant turning point in U.S. patent jurisprudence was the Supreme Court's decision in *eBay v. MercExchange*. [40] The Court strongly criticised the Federal Circuit's long-standing practice of granting injunctions almost automatically in patent cases. It clarified that injunctions are not a guaranteed remedy for patent holders and must instead be determined on the specific facts of each case. Following this ruling, U.S. courts particularly in technology and electronics disputes have often denied injunctions and awarded only monetary damages instead.

In contrast to the U.S. approach outlined earlier, Indian courts have traditionally followed the three-part test from the English decision *American Cyanamid v. Ethicon Ltd.*[41] Under this framework, an injunction is granted only when the intellectual property owner proves: the existence of a *prima facie* case, that the balance of convenience weighs in their favour, and that they would suffer irreparable harm if the alleged infringer is not restrained. Notably, this formulation does not list "public interest" as an independent consideration. However, Justice Ravindra Bhat introduced an important shift by incorporating public-interest considerations into the second and third limbs balance of convenience and irreparable injury. In evaluating these factors, he assessed not only the competing hardships of Roche and Cipla but also the needs of cancer patients who relied on affordable medicines. As he observed:

Between the two competing public interests upholding a patent during an ongoing infringement suit versus ensuring public access to a life-saving drug the latter must prevail. Any financial loss to the patentee can be compensated, but the harm caused to patients who may be deprived of treatment is irreversible and cannot be repaired monetarily.

This reasoning effectively places public interest within Indian injunction doctrine. Even in earlier matters such as the first Novartis EMR case, courts appear to have relied on public

[38] Bristol Myers Squibb Company & Ors v Mr D Shah & Anr, CS(OS) No. 679/2013.
[39] Novartis v Union of India, (2013) 6 S.C.C 1(India)
[40] *eBay v. MercExchange*, LLC 547 U.S. 388 (2006).
[41] American Cyanamid Co. v. Ethicon Ltd., [1975] A.C. 396.

welfare considerations to deny injunctions.

If Justice Bhat's approach continues to guide Indian jurisprudence, then in cases where public interest favours the generic manufacturer a likely scenario in disputes concerning essential medicines injunctions may increasingly be refused. Instead, patentees would be limited to monetary remedies, resembling a compulsory-licence outcome. In effect, alongside the statutory compulsory licensing provisions in Chapter VII of the Patents Act, judicial awards of damages or ongoing royalties may operate as a parallel form of de facto compulsory licensing.

A notable illustration is the case *Indoco Remedies v. Bristol Myers Squibb*, where the Delhi High Court made it clear that the material on record did not establish any compelling or "overwhelming" public interest[42]. The Court further clarified that merely asserting a presumed or speculative public interest is insufficient to lift an injunction, unless the injunction itself is untenable on the merits. This decision introduced yet another layer to the understanding of public-interest claims, raising questions about what actually qualifies as "overwhelming" public interest. The case thus reflects the continuing development of Indian jurisprudence on this doctrine.

Thus, an injunction can be lifted only if the order appears *prima facie* unsustainable on merits. Further, the court made it clear that "reasonable affordability" and "adequate availability" are valid bases for invoking public interest, provided they are supported by proper evidence. At the same time, the judgment acknowledges that additional cumulative factors may also amount to "overwhelming public interest," which could justify departure from the requirement of showing that the injunction is unsustainable though such claims must likewise be proven with credible material. The case also shows the wide discretion exercised by courts when assessing public-interest arguments.

CONCLUSION AND SUGGESTION

The study shows that Indian courts use their judicial discretion very differently while deciding interim injunctions in patent infringement cases. Even though the basic principles—prima facie case, irreparable harm, and balance of convenience—are well-known, courts do not always apply them in the same way. Because there is no fixed statutory method, judges rely on older

[42] Bristol Myers Squibb Company & Anr v Dr BPS Reddy & Ors, CS(OS) No. 2680/2008.

case laws, general equitable principles, and their own understanding of public interest. This leads to inconsistency and unpredictability in decisions.

Especially in pharmaceutical cases, courts bring in public interest and access to medicines, which is unique to India. Cases like Roche v. Cipla and Bayer v. Natco show that Indian courts may deny injunctions even when patent rights seem strong, if the medicine is essential for public health. While this approach helps patients and protects societal needs, it also creates uncertainty for patent holders.

Compared to foreign jurisdictions like the UK, and US, India still lacks a stable and predictable system for interim injunctions. Other countries have clearer legal tests, whereas Indian courts still shift between strict protection of patent rights and flexible, welfare-oriented reasoning.

Overall, this research shows that there is an urgent need for a clear and balanced framework that protects both innovation and public interest, while giving more consistency and predictability to patent enforcement in India.

Hypothesis : Indian courts exercise judicial discretion inconsistently while granting interim injunctions in patent infringement cases due to the lack of a structured legal framework.

The analysis demonstrates that Indian courts apply judicial discretion inconsistently in interim patent injunctions due to the absence of a clear statutory framework. Similar cases often receive different outcomes because courts vary in interpreting prima facie case, irreparable harm, balance of convenience, and public interest, especially in pharmaceutical matters. Comparative study also shows that India lacks the predictable standards seen in jurisdictions like the UK and US. These findings collectively support the central claim of the research. Hence the hypothesis stands proved.

SUGGESTIONS

• Adopt a uniform legal test for interim injunctions to ensure consistent evaluation of prima facie case, validity challenges, and balance of convenience.

• Set clear guidelines for validity assessment so courts avoid mini-trials and unpredictable scrutiny at the interim stage.

• Clarify the scope of public interest, especially regarding access to medicines, to maintain a fair balance with patent rights.

• Strengthen specialised IP benches with trained judges and technical experts for faster and more consistent decisions.

• Promote proportionate remedies, such as conditional injunctions or royalties, instead of rigid grant-or-denial outcomes.