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Article

Fair and Equitable Treatment in International Investment Law: The Tension with Pharmaceutical Patent Regulation

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Abstract: This paper examines the tension between the fair and equitable treatment (FET) standard in international investment law and states' regulatory autonomy in pharmaceutical patent governance. As pharmaceutical patents increasingly intersect with trade, investment protection, and public health, the open-textured formulation of the FET standard has expanded into disputes over patent revocation, compulsory licensing, and pricing regulation. This paper argues that the core difficulty is the tendency of investment claims to recast ordinary patent regulation as an issue of investor reliance, thereby compressing the public law character of pharmaceutical regulation into a private law narrative centered on economic injury. The analysis develops three primary claims. First, pharmaceutical patent regulation differs structurally from classic investment administration because it operates within a dynamic knowledge regime characterized by scientific uncertainty and significant distributive effects on public welfare. Second, arbitral tribunals must adopt a more disciplined approach to legitimate expectations, avoiding the inference of regulatory freezes or quasi-vested entitlements based merely on investment-backed patent portfolios. Third, a contextual reading of the FET standard, informed by comparative public law and international health norms, offers a coherent method to reconcile investor protection with domestic policy space. Ultimately, while states remain bound by good faith and procedural fairness, investment law must not serve as an indirect mechanism for constitutionalizing maximal patent protection in the pharmaceutical sector.

Keywords: investment law; pharmaceutical patents; regulatory autonomy; public health; equitable treatment; legitimate expectations

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1. Introduction

The relationship between international investment law and pharmaceutical regulation has become increasingly difficult to describe in conventional terms. Investment law emerged as a framework for protecting foreign property against arbitrary state interference, yet pharmaceutical patent governance belongs to a policy field in which legal standards are expected to evolve as science, industrial strategy, and public health needs change. When these two normative projects meet, the friction is not merely doctrinal. It concerns the institutional question of who should bear the cost of regulatory adaptation in a sector where innovation incentives, access to medicines, and sovereign health responsibilities are deeply intertwined [1, 2].

The fair and equitable treatment standard sits at the center of this tension. Its language is broad enough to cover abusive conduct, denial of justice, lack of due process, frustration of legitimate expectations, and forms of regulatory arbitrariness. That breadth has given the standard practical importance, but it has also made it unusually sensitive to judicial framing [3]. In disputes involving pharmaceutical patents, the same regulatory

act can be described either as a routine recalibration of patent policy or as a destabilizing interference with an investor's settled expectations. The result is a legal vocabulary that often appears neutral while silently privileging one understanding of the state-investor relationship over another.

This paper focuses on that shift in framing. It asks how the fair and equitable treatment standard should operate when a host state adjusts the conditions under which pharmaceutical patents are granted, maintained, reviewed, or commercially exploited. The question matters because pharmaceutical patents are not simple exclusionary assets [4]. They are public-law constructs issued within a regulatory environment that determines market entry, therapeutic substitution, reimbursement conditions, competition from generics, and the affordability of treatment. A tribunal that approaches patents as static proprietary interests may therefore misunderstand the legal setting in which they exist.

The paper advances a restrained but firm argument. States should not be free to treat foreign pharmaceutical investors unpredictably or in bad faith. At the same time, the fair and equitable treatment standard should not be interpreted in a way that converts the normal instability of patent regulation into presumptive treaty breach [3, 5]. A pharmaceutical investor can legitimately expect procedural regularity, transparency, coherence, and freedom from targeted discrimination. It cannot, without more, expect that scientific thresholds, patentability doctrines, pricing controls, or health-sensitive licensing tools will remain fixed over time.

The discussion proceeds in five steps. It first revisits the doctrinal evolution of fair and equitable treatment and identifies the elements most relevant to intellectual property-intensive investment disputes. It then examines why pharmaceutical patent regulation creates a particularly demanding setting for the application of that standard. The third part develops a framework for distinguishing protected expectations from impermissible claims to regulatory immobility. The fourth part considers how arbitral reasoning should incorporate public health and intellectual property norms without dissolving the autonomy of investment treaties. The paper concludes by proposing a narrower and more institutionally defensible understanding of fair and equitable treatment in this area [6].

This paper situates its analysis within ongoing debates over the institutional design of investor-state dispute settlement and the proper scope of regulatory autonomy [7]. The tension between investment protection and state sovereignty is not merely a matter of treaty interpretation but also reflects deeper disagreements about whose conception of the rule of law should prevail in investment arbitration. The pharmaceutical patent context brings these disagreements into sharp relief, because it forces tribunals to navigate between the investor's interest in legal stability and the state's responsibility to adapt patent policy to evolving scientific, public health, and distributive priorities.

2. Fair and Equitable Treatment and the Structure of Investment Protection

Fair and equitable treatment has long been one of the most contested standards in international investment law because its apparent simplicity masks a wide range of possible meanings. In some treaty texts, it appears as part of a minimum standard of treatment linked to customary international law. In others, it is drafted as an autonomous obligation with no explicit textual limitation. Arbitral jurisprudence has therefore developed unevenly, sometimes treating the standard as a guarantee against egregious misconduct and sometimes using it to review the quality, consistency, and reliability of domestic governance in much broader terms [8].

Despite these differences, several recurring elements can be identified [6]. Tribunals frequently connect fair and equitable treatment with transparency, due process, freedom from arbitrariness, protection of legitimate expectations, and consistency in state conduct. The concept of legitimate expectations has been especially influential because it gives investors a doctrinal language through which economic planning can be translated into legal grievance. Yet its attraction also explains the standard's expansion. Once a tribunal accepts that an investor may rely not only on specific commitments but also on a broader

regulatory climate, the line between protection from abuse and insulation from policy change becomes difficult to maintain.

This difficulty is well known in regulatory disputes. States govern through general norms, delegated administration, and periodic revision. They alter technical standards, reinterpret statutory criteria, and respond to new information. A legal order that could never disappoint investment-backed expectations would cease to be a regulatory order in any meaningful sense. For that reason, many tribunals and commentators now stress that legitimate expectations must be anchored in specific representations, targeted assurances, or other conduct capable of generating reliance that deserves legal protection. The stronger versions of the doctrine, which infer stability from a generally favorable legal environment, have become increasingly controversial [9].

The problem becomes sharper where the investment consists partly of intellectual property. Intellectual property rights are often described as assets for treaty purposes, but they are also creatures of domestic law whose existence, scope, and enforceability depend on continuing institutional judgment. This dual character matters. If investment law treats intellectual property as equivalent to tangible property while ignoring its regulatory conditionality, treaty analysis can become detached from the legal features that define the asset in the first place.

Pharmaceutical patents illustrate the point with unusual clarity. Their economic value depends not only on the formal grant of exclusive rights, but also on doctrines of patent validity, standards of utility or inventive step, data regulation, marketing authorization, competition law, procurement systems, reimbursement policies, and emergency public health powers. The patent holder operates within an integrated regulatory ecosystem rather than a simple ownership regime. As a result, changes in legal interpretation or administrative practice may reduce expected returns without necessarily violating any obligation of fairness owed under investment law.

A coherent account of fair and equitable treatment must therefore distinguish three levels of state conduct [2]. The first concerns classic forms of abuse, such as bad faith, targeted harassment, or denial of justice. The second concerns procedural and institutional defects, including opacity, unreasonable inconsistency, or failure to provide a minimally reliable decision-making process. The third concerns policy recalibration through general regulation. The first two categories are natural candidates for treaty scrutiny. The third requires greater caution, especially in sectors where technical and social conditions evolve rapidly. This paper argues that pharmaceutical patent disputes often become distorted because these categories are not kept distinct.

3. Why Pharmaceutical Patent Regulation Creates a Hard Case

Pharmaceutical patent regulation is not simply a subset of ordinary commercial law [10]. It is a site where states mediate among competing claims about innovation, access, affordability, industrial capacity, and scientific uncertainty. Patent doctrine in this field is expected to serve incentive functions, but it also affects the timing of generic entry, the cost of treatment, and the fiscal sustainability of health systems. These distributive consequences help explain why governments are reluctant to treat patent rules as frozen commitments, even where foreign investors have structured major business strategies around them.

One source of difficulty lies in the epistemic instability of pharmaceutical innovation. Patent offices and courts must evaluate claims about utility, obviousness, enablement, therapeutic significance, and incremental improvement against moving scientific baselines. A doctrinal standard that appears settled at one moment may later be viewed as overinclusive, underinclusive, or vulnerable to strategic manipulation. States often respond by tightening examination practices, refining disclosure requirements, or reinterpreting patentability criteria. From the standpoint of investment law, these developments can look disruptive. From the standpoint of patent governance, they are normal methods of preserving the integrity of the system.

A second source of tension arises from the public health character of the pharmaceutical market. Medicines are not consumed under ordinary conditions of choice. Demand is shaped by medical need, prescribing practices, insurance systems, and urgent collective concerns. Governments are therefore drawn into price negotiation, reimbursement design, stockpiling, procurement, emergency authorization, and the use of flexibilities such as compulsory licensing. Each of these interventions may affect the commercial value of a patent portfolio, but their primary rationale is not confiscatory. They reflect the premise that pharmaceuticals occupy a partially socialized market in which public authorities cannot retreat to the margins [11].

A third source of difficulty concerns the legal architecture of patents themselves. A patent does not confer an unconditional right to exploit an invention free from regulatory interference. It creates a temporary exclusionary position subject to statutory limits, validity review, compulsory licensing mechanisms, and interaction with other branches of law. In the pharmaceutical field, the patent holder may have invested heavily in research, manufacturing, and regulatory submissions, yet that commercial commitment does not transform patent law into a stabilization clause. If this distinction is overlooked, the investor's sunk costs begin to perform doctrinal work that treaty text never assigned to them.

These features make pharmaceutical patent disputes especially vulnerable to category error. An investor may frame the revocation of a patent, a shift in utility doctrine, or a licensing measure as evidence that the legal environment has become unfair. But the relevant question is not whether the measure reduced value or upset expectations in a colloquial sense. The question is whether the state acted in a way that investment law should characterize as arbitrary, non-transparent, discriminatory, procedurally deficient, or contrary to a specific commitment. Without that discipline, fair and equitable treatment risks becoming a vehicle for reviewing the substantive correctness of domestic patent policy.

The hard case, then, is not created by the fact that pharmaceutical regulation affects investment. Many forms of regulation do that. The hard case arises because the investor's complaint often draws persuasive force from the importance of pharmaceutical innovation, while the state's defense draws force from the importance of public health. Both narratives are normatively attractive. A sound legal approach must resist the temptation to resolve this tension through abstract balancing alone and must instead ask what kind of legal interest the treaty actually protects in this context.

4. Legitimate Expectations without Regulatory Freeze

The doctrine of legitimate expectations should be handled with particular care in disputes involving pharmaceutical patents. Its central insight is unobjectionable: a state should not invite or induce investment through sufficiently concrete assurances and then reverse course in a manner that defeats justified reliance. The difficulty begins when expectation is detached from identifiable state conduct and attached instead to the continuation of a favorable regulatory pattern. In a field as dynamic as pharmaceutical patent governance, that broader formulation becomes analytically unstable [12].

A more defensible approach is to separate expectation into three forms. The first is expectation grounded in individualized commitments. This includes explicit promises, negotiated undertakings, stabilization clauses, or authoritative representations directed at a particular investor. The second is expectation grounded in procedural regularity. Investors may reasonably expect decisions to be taken through intelligible procedures, with notice, reasons where appropriate, and avenues for review. The third is expectation grounded in the persistence of substantive policy. This last category should receive the weakest protection, because it is closest to an implied guarantee that regulation will not change.

In the pharmaceutical sector, tribunals should require strong evidence before treating substantive policy continuity as a protected expectation. Patent validity standards, evidentiary thresholds, and licensing tools are not peripheral matters. They are part of the

ongoing design of the patent system. A foreign investor that chooses to enter such a sector knows, or should know, that legal doctrines may evolve in response to judicial interpretation, scientific reassessment, competitive conditions, or public health emergencies. To assume otherwise is to mistake participation in a regulated market for acquisition of a stabilized legal enclave.

This does not mean that all regulatory change is immune from scrutiny. A state may still violate fair and equitable treatment if it acts opportunistically, disguises discrimination behind technical reform, or applies new standards in a grossly inconsistent manner designed to target particular firms. Likewise, sudden policy shifts adopted without transitional reasoning, adequate notice, or institutional coherence may give rise to legitimate concerns. But the vice in such cases lies in the manner and context of the state's conduct, not in the mere fact that substantive regulation changed.

The distinction between commitment and framework is especially important where an investor points to reliance on pre-existing patent doctrine. Domestic patent law generates expectations of legal argument, not guarantees of doctrinal permanence. Judicial systems reinterpret standards. Administrative agencies revise examination guidance. Legislatures alter the balance between exclusivity and access. None of this is extraordinary. If investment law were to treat these developments as presumptively suspect whenever foreign investors suffer concentrated losses, it would selectively constitutionalize one side of pharmaceutical policy while leaving the public burdens of the sector to domestic institutions [13, 14].

The preferable view is narrower. Fair and equitable treatment protects the conditions under which legal change is made and applied, rather than the investor's preference that change not occur. That approach preserves a meaningful role for the standard while avoiding the false alternative between total deference and expansive investor entitlement. It also aligns more closely with the public-law intuition that government must act fairly, but need not immobilize itself in order to remain fair.

5. Systemic Context: Public Health, Intellectual Property, and Treaty Interpretation

Interpretation of fair and equitable treatment in pharmaceutical disputes cannot proceed as if investment law were isolated from related fields. Pharmaceutical patents are simultaneously embedded in international intellectual property obligations, domestic constitutional or administrative principles, and global public health frameworks. Although investment tribunals are not general courts of public policy, they interpret treaty standards against a broader legal background. Ignoring that background can produce decisions that appear formally plausible yet systemically distorted [15].

International intellectual property law does not mandate a single maximal model of pharmaceutical patent protection. Even within the framework established by the Agreement on Trade-Related Aspects of Intellectual Property Rights, states retain discretion in defining patentability criteria, structuring exceptions, and using public interest safeguards subject to treaty limits. Public health instruments and state practice further reinforce the legitimacy of measures designed to improve access to medicines or respond to health emergencies. This broader normative environment should matter when tribunals evaluate whether an investor's claimed expectation was reasonable in the first place [16, 17].

A contextual approach does not dissolve the specificity of investment obligations. It does not mean that any measure labeled public health is automatically fair, or that investment tribunals must defer whenever intellectual property is politically sensitive. Rather, it means that reasonableness under fair and equitable treatment should be assessed with awareness of the regulatory ecology in which pharmaceutical patents operate. If that ecology is characterized by express legal flexibility, recurrent policy revision, and strong public welfare functions, investor expectations of immobility become correspondingly weaker.

Comparative public law offers a useful analogue. Domestic courts reviewing complex social regulation often distinguish between the legitimacy of regulatory

objectives and the lawfulness of regulatory administration. They are generally more willing to address irrationality, procedural unfairness, and discriminatory treatment than to second-guess the substantive merits of contested policy choices in technically complex areas. Investment law need not copy domestic administrative law, but the analogy is instructive. It suggests that treaty review is most defensible when it focuses on abuse and institutional failure rather than on whether patent policy struck the optimal balance between innovation and access.

This contextual method also helps explain why public health emergencies should not be treated as exceptional only in the narrow temporal sense. The pharmaceutical field is permanently shaped by the possibility of shortage, epidemic risk, budgetary stress, and unequal access. Emergency powers are part of the legal architecture not because crisis is constant, but because vulnerability is structurally present. Investors operating in this sector benefit from large markets created and stabilized by public institutions. It is therefore difficult to justify a doctrinal framework that treats the state's health responsibilities as external shocks rather than intrinsic features of the investment environment.

For treaty interpretation, the practical implication is clear. Tribunals should read fair and equitable treatment in a manner that preserves protection against arbitrariness and bad faith while recognizing that pharmaceutical patent regulation carries an irreducibly public dimension [18]. That dimension does not erase investor rights, but it does narrow the circumstances in which disappointed commercial assumptions can be translated into successful treaty claims.

6. Toward a More Disciplined Arbitral Approach

If fair and equitable treatment is to remain credible in disputes over pharmaceutical patents, arbitral reasoning must become more explicit about institutional competence. Tribunals are often asked to decide whether a domestic patent decision was so inconsistent, abrupt, or unreasonable that it crossed the treaty line. The temptation is to answer that question by reconstructing the substantive merits of patent policy. Yet such reconstruction invites overreach, particularly where tribunals lack the democratic mandate and technical embeddedness of domestic institutions.

A more disciplined approach would proceed through a sequence of focused inquiries. First, the tribunal should identify whether the investor points to a specific commitment, a procedural entitlement, or only a general expectation of legal continuity. Second, it should examine the nature of the impugned measure: adjudicative reversal, legislative reform, administrative reinterpretation, licensing decision, pricing intervention, or emergency action. Third, it should ask whether the measure was adopted and applied through procedures consistent with transparency, reason-giving, and non-discrimination. Fourth, it should assess whether the investor has shown conduct approaching arbitrariness, bad faith, targeted prejudice, or manifest institutional incoherence.

This sequence matters because it prevents the analysis from collapsing into a simple comparison between past and present regulatory outcomes. A patent invalidated under a revised interpretation is not, without more, evidence of unfair treatment. A compulsory license issued pursuant to domestic law in response to health needs is not, without more, evidence of arbitrariness. A price control that reduces profitability is not, without more, an assault on legal security. The burden should remain on the claimant to show why the state's conduct departed from standards of fairness that investment law can legitimately enforce.

There are also reasons to adopt a relatively high threshold where the investor seeks to transform domestic legal disagreement into treaty breach. Patent law is interpretive and often contested even within mature legal systems. Reasonable decision makers can differ on utility standards, claim scope, or the balance between exclusivity and competition. If every significant departure from prior administrative or judicial practice were framed as a fair and equitable treatment problem, the treaty system would become an appellate layer

over national regulatory development [19]. That outcome would be difficult to defend either doctrinally or institutionally.

At the same time, discipline should not be confused with indifference [20]. The pharmaceutical sector creates opportunities for subtle forms of favoritism, politicized enforcement, and strategic ambiguity. Tribunals should remain attentive to evidence that a government manipulated technical criteria to disadvantage foreign firms, withheld procedural protections available to domestic actors, or used public health rhetoric to conceal industrial protectionism. The argument of this paper is not that states always regulate well. It is that investment law should target genuinely unfair modes of regulation, rather than the ordinary burdens of living under a mutable patent regime.

Such an approach would also produce better systemic incentives. Investors would remain protected against abuse, but they would have weaker incentives to treat investment arbitration as a means of preserving commercially advantageous interpretations of patent law. States, for their part, would retain room to adjust pharmaceutical regulation while knowing that opaque, erratic, or bad-faith conduct could still attract liability [9]. The resulting balance is imperfect, but it is more consistent with both the function of fair and equitable treatment and the public significance of pharmaceutical governance.

7. Conclusion

The tension between fair and equitable treatment and pharmaceutical patent regulation should not be understood as a collision between legal certainty and sovereignty in the abstract. The deeper issue is whether investment law will treat pharmaceutical patents as static proprietary holdings or as rights embedded in a dense and evolving public regulatory order. This paper has argued for the latter view. Pharmaceutical patent governance is shaped by scientific change, distributive conflict, and persistent public health responsibility. Those characteristics make broad claims to regulatory stability especially difficult to justify.

A coherent interpretation of fair and equitable treatment in this setting must therefore remain anchored in the core concerns of the standard: good faith, procedural fairness, transparency, rational administration, and protection against arbitrariness or discrimination. What it should not do is convert disappointment with lawful regulatory evolution into a treaty violation. The doctrine of legitimate expectations is useful only if it is disciplined by attention to specific commitments and to the known mutability of the legal environment in which the investor operates.

The practical consequence is not a denial of protection to pharmaceutical investors. It is a refusal to let investment law become an indirect instrument for entrenching the most investor-favorable version of patent policy. States remain accountable for how they regulate, but not for every reduction in the value of a patent-dependent business model. In an area where access to medicines, innovation policy, and public welfare are tightly connected, that distinction is essential. A more context-sensitive and institutionally modest understanding of fair and equitable treatment offers the best prospect for preserving both treaty credibility and regulatory legitimacy.

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