
PAYING FOR SILENCE: EVALUATING REVERSE PAYMENT SETTLEMENTS UNDER MODERN ANTITRUST FRAMEWORKS

Harsh Chawla, National Law Institute University, Bhopal

Vardhman Jothe, National Law Institute University, Bhopal

ABSTRACT

A reverse payment settlement resolves patent litigation between an originator pharmaceutical company and a generic challenger in an inversion of the ordinary logic of settlement: the patentee, not the alleged infringer, pays, and in return the generic agrees to stay out of the market until a date it might otherwise have entered earlier. The practice has produced three distinct regulatory answers, each considered in turn in this article. Part II sets out the economic logic underlying such settlements, explaining why a payment exceeding the payor's own anticipated litigation costs, unexplained by any independently verifiable service, functions as a reliable signal of an anticompetitive purpose rather than a genuine litigation compromise. Part III surveys the doctrinal path taken by three jurisdictions: the Supreme Court of the United States, in *FTC v Actavis*, subjected such settlements to the ordinary antitrust rule of reason, an indeterminate standard that a decade of subsequent litigation has struggled to operationalise; the Court of Justice of the European Union, in *Lundbeck* and, more decisively, in the *Servier* judgments, has instead treated sufficiently large and unexplained value transfers as restrictions of competition by object, trading doctrinal certainty for a risk of over-inclusiveness; and India has adopted neither position, since no reported order has ever resolved whether Section 3 of the Competition Act, 2002, read with the intellectual property exemption in Section 3(5), even reaches such settlements at all. Part IV evaluates the comparative costs of each framework, and Part V proposes a structured presumption, anchored to payment size rather than patent validity, that the Competition Commission of India could adopt within its existing statutory text. The article concludes that India, as the jurisdiction with the world's largest generic pharmaceutical industry, can no longer afford the doctrinal silence its competition authority has maintained for over a decade.

I. Introduction

A patent gives its holder the exclusive right to exclude others from making, using or selling the patented invention for a fixed term. When a generic pharmaceutical manufacturer seeks to enter the market before that term expires, ordinarily by challenging the patent's validity or arguing that its own product does not infringe, the resulting litigation follows the pattern of any other infringement dispute: the patentee sues, and if the parties settle, the alleged infringer typically pays something, or agrees to stop the challenged conduct, in exchange for peace. A reverse payment settlement inverts this logic. The patentee, not the generic, makes the payment; and what the patentee buys with that payment is the generic's agreement to withdraw its challenge and stay off the market for a specified period, frequently years before the patent would otherwise have expired.

The practice has proved lucrative for both sides and costly for everyone else. The originator preserves monopoly pricing on a blockbuster drug for longer than the underlying patent may actually justify; the generic receives a guaranteed payment without the expense, delay or risk of full-blown patent litigation, which it might in fact lose. The parties who bear the cost are consumers and public health systems, who continue paying brand prices for medicines that a successful patent challenge, or an unforced settlement on the merits, might have opened to generic competition years earlier.¹ Because the payment is, by construction, unrelated to any service the generic actually performs, and because its size often bears no relationship to the litigation costs it purportedly resolves, reverse payment settlements sit uneasily between two bodies of law that pull in opposite directions: patent law, which treats the right to exclude, and to settle disputes about that right on whatever terms the parties choose, as a lawful incident of the patent grant; and competition law, which treats payments to a rival in exchange for staying out of a market as close to the paradigm case of an unlawful restraint of trade.

This article surveys how three major jurisdictions have resolved that tension, and argues that none of the three answers is fully satisfactory. Part II sets out the anatomy of a reverse payment settlement and the economic logic that makes a sufficiently large, otherwise unexplained payment a reliable signal of an anticompetitive purpose rather than a genuine litigation compromise. Part III traces the doctrinal path each jurisdiction has taken: the FTC's

¹*FTC v Actavis, Inc* 570 US 136 (2013).

rule of reason in *FTC v Actavis*, the European Court of Justice's classification of sufficiently large payments as restrictions of competition by object in *Lundbeck* and *Servier*, and India's decade of regulatory silence despite an open inquiry by the Competition Commission of India ('CCI') and no shortage of academic warning. Part IV evaluates the costs of each approach: the indeterminacy that has made the American rule of reason difficult and expensive to apply in practice; the risk of over-inclusiveness in treating a heterogeneous set of settlements as categorically suspect; and the specific costs that regulatory silence imposes on a jurisdiction, India, whose generic pharmaceutical industry supplies a substantial share of the developing world's medicines. Part V proposes a structured presumption that borrows the size-based trigger from the European approach while preserving a genuine, if narrower, opportunity for rebuttal, and considers what institutional steps the CCI would need to take to adopt it. Part VI concludes.

II. The Anatomy of a Reverse Payment Settlement

A. *The Hatch-Waxman paradigm and the incentive to settle*

The most developed body of reverse payment litigation arises out of the particular statutory architecture the United States created for generic drug approval. Under the Hatch-Waxman Amendments, a generic manufacturer seeking approval to market a drug can certify that the relevant patent is invalid or will not be infringed by its product, a filing that itself operates as a technical act of infringement and typically triggers patent litigation by the originator.² The first generic to file such a challenge is rewarded with a period of marketing exclusivity, which gives it a strong incentive to settle on favourable terms with the originator rather than risk losing the underlying patent challenge outright, since a loss forfeits both the exclusivity period and any prospect of near-term entry.

Comparable dynamics, though without an identical statutory exclusivity reward, arise wherever a jurisdiction allows a generic manufacturer to challenge a patent's validity before a court or patent office prior to full commercial launch. In each case, both parties to the settlement have something the other wants: the originator wants the litigation, and the risk that its patent will be invalidated for every subsequent challenger, to go away; the generic wants certainty and, ideally, compensation for foregoing what may in fact have been a winning claim. Ordinary

²Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act, codified in relevant part at 21 USC s 355(j); see 35 USC s 271(e)(2)(A).

settlement doctrine treats this as an unremarkable trade, no different from any other commercial compromise reached under the shadow of litigation risk. What makes reverse payment settlements distinctive is the direction and, often, the scale of the payment: the party with the exclusionary right pays the party challenging it, and the challenger's undertaking in return is not merely to concede the specific dispute, but to stay out of an entire market for a period that can run into years.

B. The economic logic: why a large, unexplained payment signals collusion rather than compromise

The economic case against reverse payment settlements rests on a comparatively simple insight, one the Supreme Court of the United States itself adopted as the analytical core of its *Actavis* decision: an originator will only be willing to pay a generic more than the generic's own litigation costs, and more than the value of any genuine services the generic renders in return, if the payment is cheaper than the alternative of allowing the litigation to run its course.³ If the originator expects to lose the underlying patent litigation, paying the generic to abandon the challenge and delay entry can be far more profitable than litigating to a judgment that invalidates the patent altogether, because a settlement that merely delays entry preserves monopoly pricing for the settlement's duration, whereas an adverse judgment ends it immediately and, in some systems, for every subsequent generic entrant as well.

This logic yields a testable prediction: the size of the payment, considered against the litigation costs it purports to resolve and any independent value the generic is said to provide, is a reasonably reliable indicator of whether the settlement reflects a genuine litigation compromise or a division of monopoly rents between the originator and a rival it has effectively paid to stay silent. A payment that merely reimburses litigation costs, or that compensates the generic for services with an independently verifiable market value, such as manufacturing or distribution services genuinely rendered, is unremarkable. A payment that vastly exceeds any plausible litigation cost, that is not tied to any service of comparable value, and that only makes commercial sense on the assumption that both parties are sharing in monopoly profits the originator would otherwise have had to compete away, is a different matter entirely. It is this insight, not any independent judicial assessment of whether the underlying patent was valid,

³*FTC v Actavis, Inc* 570 US 136 (2013).

that ultimately came to organise the American, and later the European, doctrinal response.

III. Three Doctrinal Answers: A Comparative Survey

A. United States: from the scope-of-the-patent test to the rule of reason in Actavis

Before two thousand and thirteen, the United States Courts of Appeal were split on how to treat reverse payment settlements. The Second, Eleventh and Federal Circuits had converged on what became known as the 'scope of the patent' test: so long as the settlement's anticompetitive effects fell within the exclusionary potential the patent itself would have conferred had it been fully litigated and upheld, the settlement was immune from antitrust scrutiny, absent sham litigation or fraud on the patent office.⁴ The Third Circuit, by contrast, in *In re K-Dur Antitrust Litigation*, held that any payment from a patentee to a generic in exchange for delayed entry was prima facie evidence of an unreasonable restraint of trade, shifting the burden to the defendants to justify the payment.

The Supreme Court resolved this split in *FTC v Actavis, Inc*, arising out of a settlement between Solvay Pharmaceuticals, the holder of the patent on the testosterone gel AndroGel, and two generic manufacturers, Actavis and Paddock, who had filed patent challenges. Under the settlements, the generics agreed not to market their products for several years before patent expiry, in exchange for payments running into tens of millions of dollars annually, nominally characterised as compensation for promotional and manufacturing services of doubtful independent value.⁵ The FTC alleged that these payments amounted to an unlawful agreement to share in Solvay's monopoly profits, abandon a patent challenge with a real prospect of success, and keep a low-cost generic off the market for nine years.

Writing for a five-justice majority, Breyer J declined to adopt either of the two categorical positions urged upon the Court. The scope-of-the-patent test, the majority reasoned, effectively immunised reverse payment settlements from scrutiny regardless of how large or facially unjustified the payment was, so long as the settlement's restraint did not exceed the maximum exclusion the patent could theoretically have conferred, an approach the Court considered to

⁴FTC v Actavis: Supreme Court Adopts Rule of Reason for 'Reverse Payment' Settlements' (WilmerHale, 2013) <<https://www.wilmerhale.com/en/insights/client-alerts/ftc-v-actavis-supreme-court-adopts-rule-of-reason-for-reverse-payment-settlements>> accessed 21 September 2026; *In re K-Dur Antitrust Litigation*, 686 F 3d 197 (3d Cir 2012).

⁵*FTC v Actavis, Inc* 570 US 136 (2013); see also 'FTC v Actavis, Inc' (Justia US Supreme Court Center, 2013) <<https://supreme.justia.com/cases/federal/us/570/136/>> accessed 21 September 2026.

give undue weight to the likely validity of a patent that, by definition, had never actually been tested to judgment.⁶ At the same time, the Court declined to adopt the FTC's preferred position that reverse payments should be presumptively, or 'quick look', unlawful, holding that the economic complexity and industry-specific variation in these settlements meant that a full rule-of-reason inquiry, rather than a truncated or categorical one, was required.⁷

The Court did, however, give lower courts an analytical anchor: the size of the payment, judged against the payor's anticipated litigation costs, the payment's independence from any other service the generic might genuinely provide, and the absence of any other convincing justification, was, in the Court's own words, the most important indicator of whether a settlement was likely to prove anticompetitive.⁸ A settlement structured around a payment large enough that it 'lacks any other convincing justification' is, on this reasoning, suspicious not because size alone proves anticompetitive intent, but because a rational originator would not otherwise pay more than its own expected litigation costs unless it was, in substance, purchasing a delay in competition it feared it would lose the right to prevent through litigation.

In the decade since *Actavis*, commentators and courts alike have struggled to convert this size-based heuristic into a workable litigation standard. Because the rule of reason requires plaintiffs to prove market definition, anticompetitive effect, and the absence of offsetting procompetitive justifications, all before a jury or judge untrained in pharmaceutical economics, reverse payment cases post-*Actavis* have become notoriously expensive and slow to litigate, with outcomes that vary considerably across circuits in how much weight is given to the size of the payment as opposed to a full accounting of the litigation's expected value to each side.⁹ An American Bar Association retrospective similarly notes that, although the number of reverse payment claims rose sharply in the two years immediately following the decision, the subsequent decade has produced no settled consensus on how the rule of reason should actually be operationalised at trial.¹⁰

⁶FTC v Actavis, Inc' (Justia US Supreme Court Center, 2013)
<<https://supreme.justia.com/cases/federal/us/570/136/>> accessed 21 September 2026.

⁷*California Dental Association v FTC*, 526 US 756 (1999).

⁸Justia (n 6).

⁹A Decade of FTC v Actavis: The Reverse Payment Framework Is Older, but Are Courts Wiser in Applying It' (White & Case LLP, 2025) <<https://www.whitecase.com/insight-our-thinking/decade-ftc-v-actavis-reverse-payment-framework-older-are-courts-wiser-applying>> accessed 21 September 2026.

¹⁰A Decade of FTC v Actavis: The Reverse Payment Framework Is Older, but Are Courts Wiser in Applying It' (American Bar Association Antitrust Journal, 2023)
<<https://www.americanbar.org/content/dam/aba/publications/antitrust/journal/86/issue-2/decade-of-ftc-v->

B. European Union: restriction 'by object' in Lundbeck and Servier

The European Commission's first pay-for-delay enforcement action targeted settlements between the Danish pharmaceutical company Lundbeck and several generic manufacturers over citalopram, an antidepressant, under which Lundbeck made substantial payments to generic companies in exchange for their agreement not to enter the citalopram market for a defined period. The Commission fined Lundbeck and the generic companies a combined total exceeding one hundred million euros, characterising the agreements as restrictions of competition 'by object' under Article 101 of the Treaty on the Functioning of the European Union ('TFEU'), meaning that they were treated as inherently anticompetitive without the need for the Commission to demonstrate actual anticompetitive effects in the market.¹¹

The General Court upheld the Commission's decision, and on the twenty-fifth of March, two thousand and twenty-one, the Court of Justice of the European Union ('CJEU') dismissed the final appeals by Lundbeck and the generic manufacturers.¹² The Court held that the existence of a patent could not, by itself, mean that a generic manufacturer was not a potential competitor of the originator, since potential competition existed wherever the generic had a genuine and demonstrable intention and ability to enter the market and had shown a readiness to challenge the patent's validity, irrespective of whether that patent was later found to be valid in separate proceedings.¹³ Crucially, the Court did not hold that every pay-for-delay agreement was automatically unlawful; it held that where a value transfer to the generic could not be explained by anything other than the commercial interest of both parties in avoiding competition on the merits, the agreement would constitute a restriction by object, though the parties retained an opportunity, on the facts, to demonstrate genuine procompetitive justifications.¹⁴

The Court's approach was substantially reinforced, and its application clarified, in the long-

actavis.pdf> accessed 21 September 2026.

¹¹"Pay-For-Delay': conviction for delaying the release of a generic drug' (Cuatrecasas, 2022) <<https://www.cuatrecasas.com/en/global/competition-eu-law/art/pay-for-delay-the-cjeu-confirms-e146-million-in-fines-against-four-pharmaceutical-companies-for-delaying-the-market-entry-of-a-g>> accessed 21 September 2026.

¹²Case C-591/16 P *Lundbeck v Commission*, judgment of the Court of Justice of 25 March 2021, ECLI:EU:C:2021:243 (and related appeals, Cases C-586/16 P to C-614/16 P).

¹³'CJEU confirms pay-for-delay approach and upholds decision in Lundbeck cases' (Herbert Smith Freehills Kramer, 2021) <<https://www.hsfkramer.com/notes/crt/2021-03/cjeu-confirms-pay-for-delay-approach-and-upholds-decision-in-lundbeck-cases>> accessed 21 September 2026.

¹⁴Cuatrecasas (n 11).

running *Servier* litigation concerning perindopril, a cardiovascular medicine. The European Commission's decision found that Servier's settlements with five generic manufacturers, Niche/Unichem, Matrix, Teva, Lupin and Krka, together with an alleged abuse of dominant position, infringed Articles 101 and 102 TFEU. The General Court, in a set of judgments delivered in two thousand and eighteen, upheld the Commission's findings as to four of the five generic settlements but annulled the finding against the settlement with Krka, along with the Commission's abuse-of-dominance finding, holding among other things that the Commission had defined the relevant product market too narrowly by confining it to a single molecule rather than the broader class of angiotensin-converting-enzyme inhibitors.¹⁵

On the twenty-seventh of June, two thousand and twenty-four, the CJEU, largely following Advocate General Kokott's opinion, allowed the Commission's appeal and held that all of Servier's settlement and licence agreements, including the Krka settlement the General Court had cleared, constituted restrictions of competition by object.¹⁶ The Court's judgments refine the analytical framework first set out in its earlier preliminary ruling in *Generics (UK) and Others v Competition and Markets Authority*, confirming that pay-for-delay agreements will be treated as restrictions by object where the parties are at least potential competitors, where the originator makes a payment or comparable value transfer to the generic, and where that transfer is sufficiently significant to induce the generic to refrain, even temporarily, from independent entry, without a countervailing, independently verifiable justification for the payment.¹⁷ The judgment, delivered after sixteen years of investigation and litigation stretching back to a two-thousand-and-eight dawn raid, left one element of the abuse-of-dominance finding remitted to the General Court, but on the central question, whether large, otherwise unexplained payments to generic rivals in exchange for delayed entry are categorically anticompetitive, the Court's answer was unambiguous.¹⁸

¹⁵'Competition and Regulatory Newsletter: European Court of Justice hands down judgment in Servier, siding with Commission in 'pay for delay' appeals' (Slaughter and May, 2024) <<https://www.slaughterandmay.com/insights/new-insights/competition-and-regulatory-newsletter-european-court-of-justice-hands-down-judgment-in-servier-siding-with-commission-in-pay-for-delay-appeals/>> accessed 21 September 2026.

¹⁶'ECJs Servier judgments clarify the analytical framework in pay for delay cases' (A&O Shearman, 2025) <<https://www.aoshearman.com/en/insights/ao-shearman-on-life-sciences/ecjs-servier-judgments-clarify-the-analytical-framework-in-pay-for-delay-cases>> accessed 21 September 2026.

¹⁷'The One that Almost Got Away – The CJEU's Judgments in Servier' (Kluwer Competition Law Blog, 2024) <<https://legalblogs.wolterskluwer.com/competition-blog/the-one-that-almost-got-away-the-cjeu-judgments-in-servier/>> accessed 21 September 2026; Case C-307/18 *Generics (UK) and Others v Competition and Markets Authority*, ECLI:EU:C:2020:52.

¹⁸*ibid.*

C. India: absence by default

India presents a striking contrast to both the American and European positions, not because its competition authority has considered and rejected the case for intervention, but because it has never definitively decided the question at all. A study commissioned by the Competition Commission of India ('CCI') as early as two thousand and ten flagged reverse payment settlements in the pharmaceutical sector as a potential anticompetitive practice, but cautioned that their treatment under Indian competition law remained ambiguous.¹⁹ In two thousand and fourteen, reports emerged that the CCI had opened an investigation into pharmaceutical patent settlement agreements between brand and generic firms, drawing an explicit comparison to the FTC's decades-long enforcement programme in the United States.²⁰ No reported order or public decision resolving that inquiry has followed. As one recent academic assessment observes, although reports of the Commission opening inquiries into pay-for-delay settlements circulated at the time, there has been no subsequent public follow-up or final ruling on the question.²¹

The doctrinal difficulty is compounded by the structure of Section 3 of the Competition Act, 2002. Section 3(1) prohibits agreements likely to cause an appreciable adverse effect on competition in India, but Section 3(5) carves out a specific exemption, providing that nothing in Section 3 shall restrict the right of any person to restrain infringement of, or to impose reasonable conditions necessary for protecting, rights conferred under the Patents Act, 1970, and other listed intellectual property statutes.²² A reverse payment settlement can plausibly be framed, by the originator, as nothing more than a reasonable exercise of the patentee's right to restrain infringement, the very right Section 3(5) exists to protect, which raises a structural question closely analogous to the scope-of-the-patent defence the Supreme Court of the United States rejected in *Actavis*: does an agreement that merely enforces a delay in market entry consistent with the patent's nominal term fall outside Section 3 altogether, or does the size and structure of the payment itself take the agreement outside the protection Section 3(5) was

¹⁹'Proscribe pay for delay' (CUTS International (CCIER), 2019) <<https://cuts-ccier.org/proscribe-pay-for-delay/>> accessed 21 September 2026.

²⁰'India Enters 'Pay-for-Delay' Fray: CCI Investigating Pharmaceutical Patent Settlements' (Wilson Sonsini Goodrich & Rosati, 2014) <<https://www.jdsupra.com/legalnews/india-enters-pay-for-delay-fray-cci-i-33325/>> accessed 21 September 2026.

²¹'Devising Antitrust Responses to Pharmaceutical Pay-for-Delay Settlements' (The Contemporary Competition Law Review, 2025) <<https://www.tcclr.com/post/devising-antitrust-responses-to-pharmaceutical-pay-for-delay-settlements>> accessed 21 September 2026.

²²Competition Act 2002, s 3(5)(i), as reproduced in 'Section 3 in The Competition Act, 2002' (Indian Kanoon, 2002) <<https://indiankanoon.org/doc/1153878/>> accessed 21 September 2026.

designed to offer?

The CCI has, in other contexts, read Section 3(5) narrowly, holding that the exemption does not apply to unregistered intellectual property rights and that any restriction imposed by an IP holder must independently satisfy a 'reasonableness' inquiry rather than being presumptively protected merely because it flows from an underlying IP right.²³ Nothing in the Commission's reported jurisprudence, however, addresses the specific question a reverse payment settlement poses, namely whether a payment structured around delayed market entry, rather than a conventional licence restriction or exclusive distribution term, can ever be a 'reasonable condition' within the meaning of Section 3(5) at all, still less what evidentiary threshold, size-based or otherwise, would displace that characterisation.

This silence carries particular weight given India's position in the global pharmaceutical supply chain. India is frequently described, including in the Commission's own commissioned research, as central to the availability of affordable generic medicines both domestically and across the developing world, a position the Supreme Court of India's own jurisprudence on patent evergreening, most notably its decision rejecting Novartis's patent claim over a beta-crystalline form of imatinib, has explicitly sought to protect.²⁴ A regulatory gap that leaves reverse payment settlements effectively unreviewable, whether because Section 3(5) is read expansively or because the Commission simply declines to resolve pending inquiries, therefore carries costs in India that are, if anything, more acute than in either the United States or the European Union.

IV. Evaluating the Three Frameworks

A. The indeterminacy of Actavis's rule of reason

The principal virtue claimed for the American approach is flexibility: by declining to adopt a categorical rule in either direction, the Supreme Court preserved the ability of courts to distinguish reverse payment settlements that genuinely reflect litigation risk from those that merely divide monopoly rents. The principal cost of that same flexibility is that a full rule-of-

²³Q&A: IP rights in competition in India' (Lexology, 2020) <<https://www.lexology.com/library/detail.aspx?g=f646a285-65aa-4352-ad54-0e8591af3616>> accessed 21 September 2026; *Samsher Kataria v Honda Sael Cars India Ltd*, Case No 03 of 2011, Competition Commission of India.

²⁴CUTS International (n 19); *Novartis AG v Union of India* (2013) 6 SCC 1.

reason inquiry, requiring proof of relevant market, anticompetitive effect, and the absence of offsetting justifications, is exceptionally expensive to litigate, and the size-based heuristic the Court offered as an anchor has not, in a decade of subsequent litigation, hardened into a predictable standard that originators and generics can rely on when structuring a settlement in advance.²⁵ A regime that a sophisticated pharmaceutical company cannot confidently predict in advance, and that a smaller competition authority without the litigation resources of the FTC may struggle to enforce at all, offers less practical protection to consumers than its doctrinal generosity might suggest.

B. The EU's 'by object' shortcut and its own costs

The European approach trades this indeterminacy for administrability: once a payment is shown to be large relative to litigation costs and unexplained by any independently verifiable service, the agreement is treated as anticompetitive by object, without the Commission needing to prove actual market effects. This considerably lowers the Commission's evidentiary burden and, as the sixteen-year duration of the *Servier* litigation itself demonstrates, still leaves ample room for years of appellate contest over whether the underlying facts, principally the existence of genuine potential competition and the absence of any convincing alternative explanation for the payment, are made out.²⁶ The categorical character of the 'by object' finding also carries a real cost of its own: it risks treating a heterogeneous category of settlements, some of which may reflect genuine, good-faith assessments of litigation risk rather than any agreement to divide monopoly rents, under a single, largely irrebuttable label, with only a narrow and, on the Commission's own evidentiary practice, rarely successful opportunity for the parties to establish a procompetitive justification.²⁷

C. What India's silence actually costs: the pharmacy-of-the-world problem

Whatever their respective costs, both the American and European approaches share one feature India's position lacks entirely: a settled answer. A generic manufacturer weighing whether to challenge a pharmaceutical patent in the United States or the European Union at least knows the legal framework, indeterminate as its practical application in the American case may be, under which any eventual settlement will be assessed. In India, by contrast, neither

²⁵White & Case (n 9).

²⁶Kluwer Competition Law Blog (n 17).

²⁷Herbert Smith Freehills (n 13).

originators nor generics know whether Section 3(5) shields a reverse payment settlement from scrutiny altogether, whether the CCI would apply anything resembling the American size-based heuristic or the European 'by object' standard if it were ever to rule, or indeed whether the Commission's decade-old inquiry will ever produce a public decision at all.

This uncertainty does not operate neutrally. An originator contemplating a reverse payment settlement in India faces, at worst, the prospect of an investigation with no clear enforcement track record and an uncertain legal standard; a generic contemplating whether to litigate a patent challenge to judgment, rather than accept a payment to settle, faces the same uncertainty in reverse, with considerably less capacity to absorb the downside of an adverse and immediately binding outcome. Given the size of India's domestic generic manufacturing base and its role in supplying affordable medicines well beyond its own borders, a regulatory vacuum of this kind allows exactly the practice competition authorities elsewhere have spent over a decade litigating against to persist here by default, not because Indian competition law has been shown incapable of reaching it, but because the CCI has, in over a decade, never definitively said either way.²⁸

V. Towards a Coherent Standard

A. A presumption anchored to payment size, not motive

The most defensible position available to any competition authority addressing reverse payment settlements for the first time is neither the full, open-ended rule of reason the Supreme Court of the United States adopted nor the near-categorical 'by object' presumption the CJEU has developed, but a structured presumption that borrows the evidentiary trigger of the European approach while preserving a genuine, evidence-based opportunity for rebuttal along the lines the American size-based heuristic already implies in substance, even if American courts have struggled to apply it with the Commission's own comparative administrability. Concretely: where a settlement involves a payment or other value transfer from an originator to a generic that exceeds the originator's reasonably anticipated litigation costs, and where that transfer is not independently justified by services of demonstrable, comparable market value, the settlement should be presumed to have the object or effect of restricting competition, with the burden shifting to the parties to establish a genuine, independently verifiable justification

²⁸Contemporary Competition Law Review (n 21).

for the payment's size.

This formulation deliberately does not ask a competition authority to determine, as a threshold matter, whether the underlying patent was likely to be held valid, a question competition regulators are poorly placed to resolve and that both the *Actavis* Court and the CJEU have each, in their own ways, declined to make central to the analysis.²⁹ It instead asks the far more tractable question the size-based heuristic was always meant to answer: does the payment make commercial sense on any explanation other than a division of monopoly rents the parties would otherwise have had to compete away? A payment that does not, whatever the parties call it, should not escape scrutiny merely because it is dressed in the language of a patent settlement.

B. Institutional design: why the CCI needs sector-specific guidance

A structured presumption of this kind is only useful if market participants know it exists in advance of, rather than discovering it through, years of contested litigation. The CCI has, in the past, issued sector-specific guidance and market studies, including the very study that first flagged reverse payment settlements as a concern, without translating that research into a binding enforcement position.³⁰ The Commission could close this gap considerably more cheaply than either full-scale litigation or legislative amendment would require, by issuing formal guidance under its existing advocacy and regulation-making powers, setting out the size-based presumption described above, and, critically, resolving the pending inquiry that has sat unresolved since two thousand and fourteen so that both originators and generic manufacturers have a concrete decision, rather than a decade-old, unresolved investigation, to calibrate their conduct against.³¹

C. Reconciling Section 3(5) with an effects-based inquiry

The remaining structural question is how a size-based presumption of this kind interacts with Section 3(5)'s exemption for reasonable conditions necessary to protect an IP right. The answer, consistent with the Commission's own narrow reading of the exemption in other contexts, is that Section 3(5) should be understood to protect an IP holder's right to enforce the

²⁹Justia (n 6).

³⁰CUTS International (n 19).

³¹Wilson Sonsini (n 20).

actual scope of its right, not to purchase a rival's silence at a price the underlying right does not itself justify.³² A settlement in which a generic simply withdraws a weak challenge in exchange for reimbursement of its litigation costs falls comfortably within the patentee's right to restrain infringement and should remain outside Section 3 altogether. A settlement in which the originator pays a multiple of those costs, untethered to any independently verifiable service, is no longer merely restraining infringement; it is purchasing an outcome the underlying patent right, standing alone, could not guarantee, since a patent that might well have been struck down confers no entitlement to the market exclusivity the payment is functionally buying. On this reading, the 'reasonableness' the Commission already requires of conditions claiming the Section 3(5) exemption supplies exactly the doctrinal hook needed to bring reverse payment settlements within the Competition Act's reach, without requiring Parliament to amend the statute at all.

VI. Conclusion

Reverse payment settlements present competition law with an unusually clean test of its own coherence, because the economic logic that makes them suspicious is not contested: a payment from a patentee to a rival, in exchange for that rival's agreement to delay entering a market it might otherwise have entered sooner, makes commercial sense to the payor only if it is buying something the underlying legal right could not itself guarantee. The Supreme Court of the United States recognised this logic in *Actavis* but declined to give it categorical force, producing a decade of litigation whose outcomes remain difficult to predict. The CJEU, across *Lundbeck* and, decisively, *Servier*, has given the same logic categorical force, producing greater administrability at the cost of treating a genuinely heterogeneous set of settlements under a single, largely irrebuttable label.

India has, for over a decade, done neither. A study conducted in two thousand and ten flagged the risk, an inquiry opened in two thousand and fourteen promised to investigate it, and no public decision has followed either. That silence is not a neutral middle position between the American and European approaches; it is a default that favours precisely the arrangements both of those jurisdictions have spent a combined three decades of litigation working to restrain. Given the scale of India's generic pharmaceutical industry, and the corresponding stake its own consumers and the broader developing world have in the timely arrival of generic

³²Lexology (n 23).

competition, that silence is now the least defensible position of the three. A structured presumption, anchored to payment size rather than to an unresolvable inquiry into patent validity, and grounded in the Commission's own existing, narrow reading of the Section 3(5) exemption, would allow India to resolve the question the CCI has left open since two thousand and fourteen, without waiting for a Parliament that has, on the pattern of comparable reform elsewhere in Indian law, shown little appetite for moving first.