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Competition and Anti-Trust Issues in the Pharmaceutical Industry in India: An Analytical Study

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ABSTRACT

The Indian pharmaceutical industry occupies a position of singular importance in global medicine supply: it produces approximately twenty per cent of the world's generic medicines by volume and exports to more than two hundred countries. At the same time the conditions under which pharmaceutical firms compete in India raise a set of competition-law concerns that are, in important respects, more acute than those encountered in other industrial sectors. Demand for medicines is inelastic, the prescribing physician rather than the patient controls the choice of product, and intellectual property rights confer on patent-holders a period of exclusivity that is readily extendable by strategic conduct. The Competition Act, 2002 provides the principal legal instrument through which these concerns are addressed in India, and the Competition Commission of India (CCI) has, since 2009, developed a body of decisional material spanning horizontal cartels among trade associations, abuse of dominance by originator firms, and the review of pharmaceutical combinations. This paper undertakes a systematic analytical study of that body of material, identifies its doctrinal strengths and weaknesses, and advances a set of recommendations directed at the legislator, the regulator and the industry. The paper argues that while the CCI's enforcement record against trade-association cartels is substantial, the abuse-of-dominance jurisprudence remains underdeveloped owing partly to inconsistent judicial supervision, and that the unresolved interface between the Patents Act, 1970 and the Competition Act, 2002 constitutes the most significant structural gap in the Indian framework.

Keywords: *Competition Law, Anti-Trust, Pharmaceutical Industry, CCI, Abuse of Dominance, Trade Associations, Combination Review, Patents Act, Reverse-Payment Settlements, India.*

I. INTRODUCTION

Competition regulation in India has, over the past decade and a half, traversed a path from the

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relatively rudimentary framework of the Monopolies and Restrictive Trade Practices Act, 1969[3] to the more modern and analytically sophisticated Competition Act, 2002, which was conceived on the recommendations of the Raghavan Committee[4] and brought into force in stages between 2009 and 2011. The pharmaceutical industry has been, from the outset, among the most heavily litigated sectors under the new statute, and for good reason.

The structural features of pharmaceutical markets make them unusually susceptible to anti-competitive conduct. The demand for medicines is, within clinically relevant ranges, largely price-inelastic[5]: a patient who requires a particular molecule cannot, in any practical sense, elect to do without it in response to a price increase. The prescribing physician decides which molecule a patient receives, but the physician is insulated from the price and responds instead to manufacturer promotion and therapeutic preference. The retail chemist, who stands between manufacturer and patient, has historically organised himself into trade associations that have exercised gatekeeping functions of considerable economic significance. And patent law, as applied to pharmaceutical products in the post-2005 product-patent regime, confers on originator firms a period of market exclusivity whose duration may be strategically extended through a range of conduct that competition law is, in principle, well placed to address.

Against this background the present paper makes four contributions. First, it provides a systematic account of the legal framework within which pharmaceutical competition issues are addressed in India, with particular attention to the relationship between the Competition Act and the surrounding sector-specific regulation. Second, it analyses the principal categories of substantive concern that have arisen in the pharmaceutical sector, from trade-association cartels to abuse of dominance to merger control. Third, it examines the leading decisions of the CCI, the Competition Appellate Tribunal (COMPAT), the National Company Law Appellate Tribunal (NCLAT) and the higher courts, identifying the doctrinal positions that have been settled and the questions that remain open. Fourth, it makes a set of concrete recommendations. The paper is doctrinal in method and draws on primary sources, including the CCI's own decisional material and the relevant statutes, as well as the secondary academic literature.

[3]Monopolies and Restrictive Trade Practices Act, 1969 (Act No. 54 of 1969), repealed with effect from 1 September 2009 by the Competition Act, 2002.

[4]Government of India, Report of the High Level Committee on Competition Policy and Law (S.V.S. Raghavan Committee) (Ministry of Law and Justice, New Delhi, May 2000).

[5]Patricia M. Danzon, "Pricing and Reimbursement of Pharmaceuticals," in Patricia M. Danzon and Sean Nicholson (eds.), The Oxford Handbook of the Economics of the Biopharmaceutical Industry 311 (Oxford University Press, New York, 2012).

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II. THE LEGAL FRAMEWORK

A. The Competition Act, 2002

The Competition Act, 2002 addresses anti-competitive conduct under three principal heads. Section 3[6] prohibits anti-competitive agreements, distinguishing between horizontal agreements, in respect of which section 3(3) creates a rebuttable presumption of appreciable adverse effect on competition (AAEC), and vertical agreements, which are assessed under a rule-of-reason standard in section 3(4). Section 4[7] prohibits abuse of dominant position, defining dominance as a position of strength that enables a firm to operate independently of competitive forces or to affect its competitors, consumers or the market in its favour. Section 6[8] prohibits combinations that cause or are likely to cause AAEC. The test for AAEC, set out in section 19(3),[9] is a structured rule-of-reason inquiry. The maximum penalty for a contravention is ten per cent of the relevant average turnover,[10] a limit whose adequacy has been questioned in the context of large pharmaceutical firms.

B. Sector-Specific Regulation and Its Intersection with Competition Law

The Competition Act does not operate in isolation. The pharmaceutical sector is governed, in addition, by the Drugs and Cosmetics Act, 1940,[11] which regulates market authorisation through the DCGI and is primarily a quality-and-safety statute whose competition relevance lies in the regulatory costs it imposes on generic entry. Price control operates under the Drugs (Prices Control) Order, 2013,[12] administered by the National Pharmaceutical Pricing Authority (NPPA), and applies only to medicines on the National List of Essential Medicines (NLEM), leaving the pricing of non-scheduled medicines entirely unregulated. The Patents Act, 1970,[13] confers on pharmaceutical patent-holders a period of exclusivity of twenty years from the date of application, subject to section 3(d)'s restriction on the patentability of incremental

[6]Competition Act, 2002, s. 3.
[7]Competition Act, 2002, s. 4, read with s. 19(4) which lists the factors for assessing dominance.
[8]Competition Act, 2002, ss. 5 and 6, read with the CCI (Procedure in regard to the transaction of business relating to combinations) Regulations, 2011.
[9]Competition Act, 2002, s. 19(3): the six factors are creation of barriers to new entrants, driving out of existing competitors, foreclosure of competition, accrual of benefits to consumers, improvements in production or distribution, and promotion of technical or economic development.
[10]Excel Crop Care Ltd. v. CCI, (2017) 8 SCC 47 (Supreme Court), in which the Court explained the computation of penalty under section 27(b) of the Competition Act.
[11]Drugs and Cosmetics Act, 1940 (Act No. 23 of 1940), read with the Drugs and Cosmetics Rules, 1945; the Drugs Controller General of India (DCGI) is the central licensing authority.
[12]Drugs (Prices Control) Order, 2013, S.O. 1221(E), 15 May 2013, issued under the Essential Commodities Act, 1955 (Act No. 10 of 1955), s. 3(2)(c). The NPPA administers the Order in respect of scheduled medicines listed in the National List of Essential Medicines, 2022.
[13]Patents Act, 1970 (Act No. 39 of 1970), as amended by the Patents (Amendment) Act, 2005 (Act No. 15 of 2005). Section 3(d) denies patentability to new forms of known substances that do not demonstrate enhanced efficacy.

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modifications. Section 84[14] provides a compulsory-licensing mechanism through which the patent system itself addresses failures of availability and affordability.

The institutional landscape is correspondingly fragmented. Four separate bodies, the CCI, the DCGI/CDSCO, the NPPA and the Controller of Patents, hold overlapping responsibilities for different aspects of pharmaceutical market regulation. The absence of any statutory coordination mechanism among these bodies is a recognised source of regulatory inefficiency and jurisdictional conflict, and is examined further below.

III. HORIZONTAL RESTRAINTS AMONG TRADE ASSOCIATIONS

The most extensively litigated area of Indian pharmaceutical competition law concerns the conduct of chemists' and druggists' associations. The All India Organisation of Chemists and Druggists (AIOCD) and its state and district-level affiliates have, over several decades, exercised a gatekeeping role in pharmaceutical distribution through three principal instruments: the requirement of a no-objection certificate (NOC) before a manufacturer may appoint a new stockist; the imposition of a mandatory Product Information Service (PIS) charge on the introduction of any new product; and the collective fixing of trade margins. Each of these practices has been examined and condemned by the CCI in a long series of decisions commencing with the foundational order in Santuka Associates.[15]

In Santuka Associates the Commission held that the NOC requirement amounts to a horizontal agreement among the members of the association to limit and control the supply of medicines, contravening section 3(3)(b) of the Act. The defence that the NOC is a legitimate quality-control mechanism designed to exclude dealers in spurious drugs was rejected on the ground that the prevention of spurious drugs is a statutory function of the DCGI and cannot be relied upon to justify a private restriction on entry. The mandatory PIS charge was condemned as a toll on market access, anti-competitive regardless of any notional service rendered in return. The fixing of trade margins was characterised as resale price maintenance in its horizontal form, contravening section 3(3)(a). These findings have been replicated in decisions against the Bengal Chemists and Druggists Association, the Chemists and Druggists Associations of Goa, Baroda, Punjab, Assam and many other states.

[14]Patents Act, 1970, s. 84: any person interested may, after three years from grant of a patent, apply to the Controller for a compulsory licence on the grounds that the reasonable requirements of the public have not been satisfied, that the invention is not available at a reasonably affordable price, or that the invention is not worked in India.

[15]Santuka Associates Pvt. Ltd. v. All India Organisation of Chemists and Druggists (AIOCD) & Ors., Case No. 20 of 2011, order of the Competition Commission of India dated 19 February 2013; penalty of approximately INR 4.7 million imposed on AIOCD.

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The Bengal Chemists case represents the high-water mark of this enforcement effort.[16] The Commission imposed a total penalty of INR 18.38 crore on the association and held seventy-eight individual office-bearers personally liable under section 48 of the Act. The graded penalty structure, ten per cent of average income for principal office-bearers and seven per cent for executive committee members, has become the template for subsequent personal-liability assessments. The pattern of enforcement has extended across the country,[17] with the most recent significant decision, the Sriganganagar Chemists Associations case of 2023,[18] demonstrating the continuing relevance of the framework established in Santuka Associates.

The enforcement record is, however, not without significant qualifications. The Competition Appellate Tribunal set aside the principal AIOCD penalties in December 2016 on evidentiary grounds, holding that the Director General's findings did not adequately support the imputation of personal liability under section 48. In a 2022 decision concerning the Chhattisgarh Chemists and Druggists Association the Commission exonerated the association after a Director General investigation, accepting the pharmaceutical companies' submissions that the PIS charges they paid were voluntary. The Baroda association, penalised in an earlier case, was found by the Commission in 2018 to have continued the same conduct under a slightly different label.[19] The repeat-offender character of the conduct underscores the structural limitation of a case-by-case enforcement model in addressing practices that are sustained by the collective economic interest of a large and organised professional body.

IV. ABUSE OF DOMINANT POSITION BY PHARMACEUTICAL FIRMS

A. The Biocon / Roche Episode

The single most important pharmaceutical abuse-of-dominance order in the Indian decisional record is the Commission's prima-facie order in Biocon.[20] The order arose from a complaint by Biocon Ltd. and Mylan Pharmaceuticals against F. Hoffmann-La Roche AG, which had been the sole supplier of Trastuzumab (marketed as Herceptin) for the treatment of HER2-positive breast cancer in India since 2002. Following the marketing approval granted to Biocon and

[16]In re: Bengal Chemist and Druggist Association, Reference Case No. 01 of 2013 & Suo Motu Case No. 02 of 2012, order of the Competition Commission of India dated 11 March 2014; total penalty of INR 18.38 crore imposed on the association and 78 individual office-bearers under section 48 of the Competition Act.

[17]Varca Druggist & Chemist & Ors. v. Chemists and Druggists Association, Goa, MRTP C-127/2009/DGIR, order of the Competition Commission of India dated 11 June 2012; Vedant Bio Sciences v. Chemists and Druggists Association of Baroda, Case C-87/2009/DGIR, order dated 5 September 2012 (CCI).

[18]In re: Alleged anti-competitive practices in the Sriganganagar district, Suo Motu Case No. 04 of 2022, order of the Competition Commission of India dated 23 August 2023.

[19]Reliance Agency v. Chemists & Druggists Association of Baroda & Ors., Case No. 97 of 2013, order of the Competition Commission of India dated 23 November 2018.

[20]Biocon Limited & Mylan Pharmaceuticals Private Limited v. F. Hoffmann-La Roche AG & Ors., Case No. 68 of 2016, order of the Competition Commission of India dated 21 April 2017.

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Mylan for their biosimilar versions in 2014, Roche filed civil suits in the Delhi High Court and communicated to the Drugs Controller General of India (DCGI), the NPPA, and several hospitals, raising safety and efficacy concerns about the biosimilars.

The Commission defined the relevant market narrowly as the market for biological drugs based on Trastuzumab and its biosimilars for the treatment of HER2-positive breast cancer in India. The narrowness of the definition reflected the clinical reality that no other molecule shares the same mechanism of action. On this definition Roche held an eighty-three point nine per cent market share by value in 2014, rendering it clearly dominant. The Commission declined to find a prima-facie case of unfair pricing under section 4(2)(a)(ii), accepting that the high initial price of an originator biologic reflects its research-and-development investment. The Commission also declined to find abusive litigation per se. It did, however, find a prima-facie case of denial of market access under section 4(2)(c) on the basis of the communications to the DCGI, the NPPA and the hospitals, characterising those communications as abusive denigration designed to impede the biosimilars' market penetration, and directed the Director General to investigate.

Within one month of the Commission's order, Roche filed a writ petition before the Delhi High Court.[21] The single judge made oral observations characterising the Commission's order as "anti-competition and anti-legal," on the ground that it would prevent any dominant firm from exercising its right to sue a competitor or to make representations to a regulator. Although no formal restraint was issued in writing, the Commission undertook not to proceed pending the Court's final hearing, and the investigation has in substance remained stayed since 2017. The episode has produced a chilling effect on the Commission's willingness to issue section 4 orders against pharmaceutical patent-holders. An earlier decision concerning anti-retroviral and anti-tuberculosis drugs[22] shows a similar pattern of dismissal at the threshold dominance stage without rigorous market-definition reasoning, suggesting a systemic caution that predates Biocon and that has persisted since.

B. Analytical Deficiencies in the Abuse-of-Dominance Jurisprudence

Three analytical deficiencies are apparent in the Commission's section 4 jurisprudence in the pharmaceutical sector. The first is the inconsistency between the molecule-level market definition applied in Biocon and the combination-review cases on the one hand, and the looser approach adopted in the threshold dismissals on the other. If the relevant market is consistently

[21]Roche Products (India) Pvt. Ltd. v. Competition Commission of India, 2017 SCC OnLine Del 11196. The writ petition was admitted and the Commission's investigation was in practice stayed pending the Court's final hearing.
[22]Manoj Hira Singh Pardeshi v. Gilead Sciences Inc., USA & Ors., Case No. 41 of 2012, order of the Competition Commission of India dated 5 March 2013, in which the Commission declined to find dominance in markets for anti-retroviral and anti-tuberculosis drugs without explicit market-definition reasoning.

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defined at the ATC4 (molecular) level in combination cases because clinical substitution across molecules is impossible, the same logic must apply in section 4 cases. Applying a broader market definition in abuse-of-dominance cases, without stated reasons for the departure, creates an unjustified asymmetry that advantages respondents without analytical justification.

The second deficiency is the Commission's reluctance to engage with the category of excessive pricing as an abuse. The academic literature on pharmaceutical antitrust is in broad agreement that the refusal to engage with excessive pricing arguments reflects not the absence of analytical tools, the SSNIP test adapted to a cost-plus framework has been applied by competition authorities in the Netherlands, South Africa and other jurisdictions, but a policy choice to defer to the NPPA's price-control function. That policy choice is defensible in respect of NLEM medicines where NPPA control is active, but leaves entirely unaddressed the very large segment of the market where no price control operates.

The third deficiency is the failure to distinguish between the legitimate exercise of regulatory rights, making submissions to the DCGI or filing a patent infringement suit, and the strategic use of those rights as instruments of competitive exclusion. The Commission made that distinction in Biocon, correctly in the present writer's submission, when it found the communications anti-competitive while declining to impugn the civil litigation as such. The Delhi High Court's characterisation of even that measured finding as "anti-competition and anti-legal" illustrates the doctrinal difficulty of maintaining the distinction under judicial scrutiny.

V. THE PATENT-COMPETITION INTERFACE

A. Evergreening and Section 3(d)

The most direct competition concern associated with pharmaceutical intellectual property is evergreening: the strategy of extending effective patent protection through successive patents on incremental modifications of a known molecule, such as new polymorphs, enantiomers, salts, esters or new formulations. The Indian Patents Act, in section 3(d), addresses this concern ex ante, at the patent-grant stage, by denying patentability to the discovery of a new form of a known substance that does not result in enhanced efficacy. The Supreme Court's construction of this provision in Novartis AG v. Union of India[23] confirmed that the threshold of enhanced efficacy is a meaningful one and that the provision applies to the full range of incremental modifications that originator firms typically seek to patent. Section 3(d) is accordingly a

[23]Novartis AG v. Union of India, (2013) 6 SCC 1 (Supreme Court). The Court held that the beta-crystalline form of imatinib mesylate did not qualify for a patent under section 3(d) because the applicant had not demonstrated enhanced therapeutic efficacy over the known free base form.

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significant constraint on evergreening in the Indian context, though it is limited to patentability objections and has nothing to say about the strategic use of a validly granted incremental patent.

B. Compulsory Licensing

Compulsory licensing under section 84 of the Patents Act provides the patent system's internal mechanism for addressing the failure of a patent-holder to make a patented invention available to the public on reasonable terms. The leading instance, Natco Pharma's application for a compulsory licence in respect of Bayer's sorafenib (Nexavar),[24] resulted in India's first section 84 licence and demonstrated that the mechanism is operational. The Controller's decision, upheld all the way to the Supreme Court, established that the criteria of reasonable public requirements, reasonably affordable price and working in India are to be assessed by reference to the actual conditions of patient access rather than the patent-holder's commercial choices.

The doctrinal proximity between the grounds on which a compulsory licence may be granted under section 84 and the categories of abuse under section 4 of the Competition Act is evident. An originator firm's refusal to supply its patented drug at a reasonably affordable price is both a potential ground for a compulsory licence and a potential abuse of its dominant position in the relevant market. The two remedies differ: a compulsory licence alters the terms of access while leaving the dominant position in place; a competition-law finding orders the cessation of abusive conduct and may impose a penalty. There is no principled reason why the two regimes cannot operate in parallel, each addressing its particular concern through its particular remedy.

C. The Ericsson Litigation and Jurisdictional Controversy

The jurisdictional relationship between section 84 of the Patents Act and section 4 of the Competition Act has been the subject of conflicting judicial pronouncements in the Ericsson litigation.[25] The dispute concerned standard-essential telecommunications patents, but its doctrinal holdings extend across the patent system. The single judge of the Delhi High Court held in 2016 that the two statutes confer different remedies and may operate in parallel, permitting the CCI's investigation to proceed. The Division Bench, in its decision of 13 July 2023, reversed this, holding that the Patents Act is a special and self-contained statute exhaustive of the regulation of patent-holder conduct, and that section 3(5) of the Competition

[24]Natco Pharma Ltd. v. Bayer Corporation, Application No. C.L.A. 1 of 2011, decision of the Controller of Patents dated 9 March 2012; affirmed by the Intellectual Property Appellate Board and, on writ, by the Bombay High Court: Bayer Corporation v. Union of India, 2014 SCC OnLine Bom 963; appeal dismissed, (2019) 4 SCC 250 (Supreme Court).

[25]Telefonaktiebolaget LM Ericsson (Publ) v. Competition Commission of India & Anr., 2016 SCC OnLine Del 1951 (Single Judge, Delhi HC); LPA 150/2020, decision of the Division Bench of the Delhi High Court dated 13 July 2023. The matter is pending before the Supreme Court of India.

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Act[26] expresses a legislative intention that the reasonable exercise of intellectual property rights should not be subject to competition law scrutiny. The appropriate forum for grievances about patent-holder conduct is accordingly the Controller of Patents, not the Commission.

The Division Bench decision is, in the present writer's submission, both analytically and institutionally unsatisfactory. Analytically, it conflates the scope of patent rights with the scope of competition law: the existence of a patent does not, and cannot, immunise the patent-holder against the application of general competition law, any more than the existence of a labour agreement immunises the parties to it against the application of general contract law. The Competition Act is a statute of general application; section 3(5) carves out only the "reasonable conditions necessary for protecting" the intellectual property rights in question, not all conduct by an intellectual property owner. The Division Bench's reading effectively converts section 3(5) from a narrow carve-out into a broad immunity, a construction the text will not support. Institutionally, confirming the Division Bench's approach would leave unaddressed a significant range of pharmaceutical conduct, including the kind of regulatory-communications strategy at issue in Biocon, that is not amenable to redress under section 84. The Supreme Court's judgment, when it comes, will be the most consequential single decision for the future of pharmaceutical competition law in India.

VI. Reverse-payment settlements: an emerging concern

A reverse-payment settlement, sometimes called a pay-for-delay agreement, is an agreement between a pharmaceutical patent-holder and a generic competitor, in settlement of patent litigation, under which the patent-holder makes a payment (or provides equivalent value) to the generic in return for the generic's agreement to delay market entry for a defined period. The competitive harm is straightforward: the consumer is deprived of the benefit of generic entry, which might have followed promptly had the patent been tested and found invalid or not infringed, and continues to pay monopoly prices for the duration of the agreed delay. The parties share the rents that would otherwise have flowed to the public.

The American approach, settled by the Supreme Court in FTC v. Actavis[27] after two decades of doctrinal controversy, applies a rule-of-reason analysis in which the size and justification of the reverse payment are material factors; a large and unjustifiable payment is treated as evidence

[26]Competition Act, 2002, s. 3(5): the section does not restrict the right of any person to restrain any infringement of, or to impose reasonable conditions, as may be necessary for protecting any of his rights under intellectual property statutes listed therein, including the Patents Act, 1970.

[27]Federal Trade Commission v. Actavis Inc., 570 U.S. 136 (2013). The Supreme Court held that a reverse-payment settlement is not per se lawful by reason of the patent, and is subject to rule-of-reason antitrust scrutiny; a large and unjustified reverse payment is itself evidence of anti-competitive purpose.

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of the patent-holder's own assessment of its patent's weakness and of an anti-competitive purpose. The European Commission has gone further, characterising reverse-payment settlements in Lundbeck[28] and Servier as restrictions of competition by object, attracting substantial fines. The Court of Justice has upheld this characterisation, making the European approach structurally more aggressive than the American one.

The Indian position is undeveloped. The CCI has not, to the present writer's knowledge, issued any substantive order on a pharmaceutical reverse-payment settlement. The absence of decisional output is not evidence that the practice does not occur; it is more plausibly evidence that the practice has not yet attracted regulatory attention and that the Commission has not yet developed the analytical framework necessary to address it. As the post-2005 product-patent regime matures and pharmaceutical patent litigation between originator and generic firms becomes more common, the probability of reverse-payment arrangements increases. A settlement under which an originator pharmaceutical firm pays a generic competitor to delay entry would, in principle, be amenable to scrutiny under section 3(3)(b) of the Competition Act as a horizontal agreement to limit supply, or under section 3(4) as a vertical restraint on distribution, with the Actavis approach informing the rule-of-reason analysis under section 19(3). The doctrinal tools are available; the institutional will has not yet been demonstrated.

VII. MERGER CONTROL IN THE PHARMACEUTICAL SECTOR

Pharmaceutical combinations have, since the notification of sections 5 and 6 of the Competition Act in June 2011, been subject to a pre-merger notification and clearance regime. The Commission's combination review in the pharmaceutical sector has centred on the Anatomical Therapeutic Chemical (ATC) classification system, using overlaps at the ATC4 (molecular substance) level as the primary screen for competitive concern. The leading decision, Sun Pharma / Ranbaxy[29] established the principal methodological precedents: molecular-level market definition, a preference for structural over behavioural remedies, and the approved-purchaser condition designed to ensure that divested products are transferred to a buyer with the capacity and incentive to maintain them as a competitive force. The transaction, the largest pharmaceutical combination reviewed by the Commission to that point, was cleared subject to

[28]European Commission Decision of 19 June 2013 in Case AT.39226 (Lundbeck), upheld in relevant part by the General Court: Lundbeck A/S v. European Commission, Case T-472/13, judgment of 8 September 2016 (EU:T:2016:449); further appeal dismissed by the Court of Justice: Case C-591/16 P, judgment of 25 March 2021 (EU:C:2021:243).

[29]Sun Pharmaceutical Industries Limited / Ranbaxy Laboratories Limited, Combination Case No. C-2014/05/170, order of the Competition Commission of India dated 5 December 2014; divestiture of seven products to Emcure Pharmaceuticals approved March 2015. The transaction valued at approximately USD 4 billion was the first pharmaceutical combination to proceed to CCI Phase II review.

the divestiture of seven products in markets where the combined share exceeded levels consistent with effective competition.

Subsequent pharmaceutical combinations have, in the main, been cleared unconditionally. The GlaxoSmithKline / Pfizer consumer health combination[30] and the Mankind Pharma / Bharat Serums and Vaccines combination of 2024 were each cleared after examination of ATC-level overlaps, with the Commission concluding in each case that combined shares in individual markets were insufficiently high to raise serious competitive concerns. The methodological framework of pharmaceutical combination review is, by comparison with the other areas of pharmaceutical competition law examined in this paper, relatively mature and internationally orthodox.

Two areas of doctrinal underdevelopment remain. The first is the treatment of pipeline-product overlaps, namely the situation where both parties to a combination have products under clinical development for the same indication. The competitive concern in such cases is forward-looking: the combination may remove a potential future competitor from the market for the pipeline product, and the merged entity may have weaker incentives to bring the product to market than the parties would have had separately. The Commission has touched on pipeline concerns in passing in Sun Pharma / Ranbaxy but has not yet developed a systematic methodology for their assessment, in contrast to the European Commission which has addressed pipeline overlaps in several pharmaceutical combination decisions. The second area of underdevelopment is the analysis of innovation-loss concerns in a broader sense, including the risk that a combination between research-intensive firms may reduce the overall level of pharmaceutical innovation. As the Indian industry moves towards the production of more sophisticated originator and biosimilar products, these concerns will become increasingly relevant.

VIII. CRITICAL ASSESSMENT AND RECOMMENDATIONS

A. Overall Assessment

The foregoing analysis supports the following overall assessment. The Indian pharmaceutical competition jurisprudence has, over the decade and a half since the Competition Act came into substantive force, produced a body of decisional material that is substantial in volume but uneven in doctrinal development. The section 3(3) jurisprudence on trade-association conduct is by far the most developed component: the doctrine is settled, the analytical framework is consistently applied, and the body of decisions is geographically extensive. The section 6

[30]GlaxoSmithKline plc / Pfizer Inc., Combination Case No. C-2019/03/654, order of the Competition Commission of India dated 22 May 2019; cleared unconditionally after examination of overlaps at ATC3 and ATC4 levels.

combination jurisprudence is procedurally robust and methodologically orthodox, though it remains substantively cautious and has not yet grappled seriously with pipeline-overlap or innovation-loss concerns. The section 4 jurisprudence on abuse of dominance is the weakest component: a single significant prima-facie order has been produced, and that order has been in practice stayed by judicial intervention for nearly a decade. The reverse-payment settlement area is entirely uninvestigated. The patent-competition interface remains the subject of irreconcilable judicial pronouncements whose ultimate resolution by the Supreme Court is awaited.

B. Recommendations

The following recommendations are advanced.

First, the legislature should enact a statutory provision expressly affirming that the jurisdiction of the CCI to investigate conduct under the Competition Act is not excluded or curtailed by reason only that the conduct involves the exercise of rights conferred by the Patents Act or any other intellectual property statute. Such a provision would legislatively resolve the Ericsson conflict in favour of the parallel-jurisdiction approach, which is doctrinally correct and which the CCI's market study on pharmaceuticals has itself implied is necessary for effective enforcement.[31] The provision should be modelled closely on section 60 of the Competition Act, 2002, which declares the Act to have effect notwithstanding anything inconsistent therewith contained in any other law.

Second, the legislature should amend the Competition Act to require the notification to the CCI of pharmaceutical patent settlement agreements above a threshold reverse payment, along lines analogous to the merger notification requirement. This would enable the Commission to develop a working analytical framework for pay-for-delay arrangements before the first major contested case arises, and would signal to the industry that such arrangements will be subjected to regulatory scrutiny.

Third, the CCI should publish a pharmaceutical-sector guidance document setting out its approach to market definition, dominance assessment and the categories of conduct it regards as prima-facie abusive in the pharmaceutical context. The purpose of such a document would be to counteract the chilling effect of the Roche Products litigation and to provide the industry with predictable guidance on the scope of the Commission's authority. The guidance should

[31]Competition Commission of India, Market Study on the Pharmaceutical Sector in India (CCI, New Delhi, 2021). The study noted declining prevalence of mandatory NOC and PIS charges following the principal enforcement actions.

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make clear that molecular-level market definition is the Commission's default approach in pharmaceutical section 4 cases, consistent with the methodology applied in combination review.

Fourth, the CCI, the DCGI/CDSCO, the NPPA and the Controller of Patents should establish, by formal inter-agency protocol, a mechanism for the regular exchange of information about regulatory proceedings with potential competition implications. The mechanism should include a requirement that each agency formally notify the CCI when it receives communications from a dominant pharmaceutical firm about the safety, quality or regulatory status of a competitor's product. This would address directly the information asymmetry that enabled the Biocon situation to develop without the CCI's awareness until a complaint was filed.

Fifth, the CCI should develop, in advance of the first major case, a systematic methodology for the assessment of pipeline-product overlaps and innovation-loss concerns in pharmaceutical combination review. The methodology should draw on the approaches adopted by the European Commission in its recent pharmaceutical combination decisions, adapted to the specific features of the Indian pharmaceutical market. The methodology should be published in the form of guidance and applied consistently in future cases.

IX. Conclusion

The Indian pharmaceutical industry and the competition law that regulates it are both, in different senses, at an inflection point. The industry is moving from its historical base as a generic producer towards the production of more sophisticated patented and biosimilar products, a transition that will generate a new set of competition concerns relating to the strategic use of intellectual property, the suppression of generic and biosimilar entry through regulatory and litigation strategies, and the concentration of research-and-development capability through mergers and acquisitions. Competition law is itself at the threshold of a Supreme Court judgment, in the Ericsson appeal, that will determine whether the CCI has the jurisdictional reach necessary to address the most commercially significant category of those concerns.

The gap between the doctrinal adequacy of the Competition Act, which is, on its face, well-equipped to address the full range of pharmaceutical competition concerns, and the effectiveness of enforcement, which has been limited and uneven, is the central finding of this paper. Closing that gap requires, as this paper has argued, legislative clarification of the patent-competition interface, regulatory action to address the structural conditions that enable trade-association conduct to persist despite repeated enforcement, analytical development of the tools needed to address reverse-payment settlements and pipeline-overlap concerns, and inter-agency

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coordination sufficient to give the CCI the information base it needs to act effectively.

Competition law does not, by itself, guarantee access to affordable medicines or the maintenance of pharmaceutical innovation. What it can do, when coherently applied, is ensure that the conditions of rivalry in pharmaceutical markets are maintained against the most damaging forms of anti-competitive conduct. The recommendations advanced in this paper are directed towards that more modest but still significant objective, and it is in pursuit of that objective that the analysis herein has been undertaken.

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