B1

BIOTECHNOLOGY SECTOR

Patent Disputes in Pharma & Biotech:

Section 3(d) Challenges, Compulsory Licensing, Invalidity Proceedings & High Court Strategy

BHATT & JOSHI ASSOCIATES — INDIAN BIOTECHNOLOGY & LIFE SCIENCES LEGAL SERIES

Patent Disputes in Pharma & Biotech

Section 3(d) Challenges, Compulsory Licensing, Invalidity Proceedings & High Court Strategy — The Complete Practitioner's Guide

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CHAPTER ONE

Section 3(d) and the Evergreening Challenge: Novartis, Incremental Innovation and Invalidity Proceedings

Patents Act 1970 Section 3(d), Enhanced Efficacy Standard, Novartis AG v. Union of India, Post-Grant Opposition and Revocation Before IPAB/High Court

> *Section 3(d) of the Patents Act, 1970 is India's most distinctive contribution to global patent law — a provision that has no parallel in any other major patent jurisdiction and that defines the competitive battleground on which India's generic and biosimilar pharmaceutical industry defends its right to produce low-cost versions of patented medicines. For the large Gujarat pharmaceutical*

company that has built its business model on timely generic entry, understanding the forensic application of Section 3(d) in post-grant opposition and revocation proceedings — and having counsel who can conduct the technical-legal analysis that Section 3(d) requires — is the difference between entering a market at patent expiry and facing years of blocked entry because an originator has obtained an incremental patent that Section 3(d) should never have permitted.

1.1 The Section 3(d) Standard: What Enhanced Efficacy Means in Practice

Section 3(d) provides that the mere discovery of a new form of a known substance — including salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations, and other derivatives — shall not be patentable unless the substance "differs significantly in properties with regard to efficacy." The Supreme Court in Novartis AG v. Union of India (2013) 6 SCC 1 — the most consequential patent ruling in Indian legal history — held that "efficacy" in Section 3(d) means "therapeutic efficacy" for pharmaceutical substances, and that the patentee must demonstrate a significant improvement in therapeutic efficacy (not merely physico-chemical properties like improved solubility, better stability, or reduced manufacturing cost) to overcome Section 3(d)'s bar. The Novartis ruling denied a patent for the beta-crystalline form of imatinib mesylate (Gleevec/Glivec) — a cancer drug — on the ground that the beta-crystalline polymorph did not demonstrate significantly better therapeutic efficacy compared to the known imatinib free base. For post-grant opposition proceedings and revocation petitions challenging polymorph patents, salt patents, and ester patents in the pharmaceutical sector, the Novartis framework is the analytical starting point: the challenger must demonstrate that the claimed new form is a derivative of a known substance, and the patentee bears the burden of showing enhanced therapeutic efficacy through comparative clinical or pre-clinical evidence. Practitioners conducting Section 3(d) challenges must commission expert technical analysis comparing the therapeutic profile of the claimed form against the known prior art substance — the comparison must be on efficacy metrics (response rates, dosing requirements, bioavailability leading to efficacy) not merely physico-chemical metrics.

KEY PROVISION

Section 3(d), Patents Act 1970: "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant. Explanation — For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations, and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy."

1.2 Post-Grant Opposition Under Section 25(2): Grounds, Procedure and Evidence

Strategy

A post-grant opposition to a pharmaceutical patent — filed under Section 25(2) of the Patents Act within twelve months of the patent's grant — is the primary mechanism through which a generic company challenges an originator's patent before the Patent Office. The Section 25(2) grounds available to an opposer include: anticipation by prior publication or prior use; obviousness; non-patentable subject matter (including Section 3(d)); insufficient disclosure; failure to disclose best mode; and false suggestion or misrepresentation. In pharmaceutical patent oppositions, the most productive grounds are typically non-patentable subject matter under Section 3(d), anticipation (where the claimed compound or formulation appears in prior art), and obviousness (where the claimed compound would have been obvious to a skilled formulation chemist given the prior art). The post-grant opposition proceeds before the Opposition Board — a three-member committee of Patent Office examiners — which conducts a hearing after exchanging written statements and counter-statements between the patentee and the opposer. The Opposition Board's recommendation is then considered by the Controller, who passes an order. For large generic companies facing a patent portfolio that covers a blockbuster molecule with imminent patent expiry, coordinating post-grant oppositions across the entire portfolio — filing oppositions against every polymorph, formulation, process, and combination patent in the originator's India patent family — is the standard defensive strategy, creating maximum uncertainty for the originator and maximum optionality for the generic.

> **PRACTITIONER NOTE**
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> The twelve-month post-grant opposition window runs from the date of the patent's publication in the official journal, not from the grant date. Companies monitoring competitor patent grants must implement a systematic watch on Patent Office official journal publications, with an automatic trigger for opposition analysis when any patent covering a product of commercial interest is published. Missing the twelve-month window forces the generic company to pursue revocation under Section 64 — a more expensive and time-consuming route requiring a High Court petition — rather than the administrative post-grant opposition, which is significantly more efficient for routine invalidity challenges.

1.3 Revocation Before the High Court: Section 64 and the Commercial Context

Following the abolition of the Intellectual Property Appellate Board (IPAB) under the Tribunals Reforms Act 2021, jurisdiction to hear patent revocation petitions (previously before the IPAB) has vested in the High Courts under Section 64 of the Patents Act. The High Court of Gujarat — along with the other High Courts with original jurisdiction over intellectual property matters — now hears patent revocation petitions filed by any person who is interested in the revocation of a patent. The "person interested" threshold for revocation standing is broad: any person who manufactures, imports, or intends to manufacture or import a product claimed in the patent is a person interested in its revocation. For a Gujarat generic manufacturer preparing to launch a product at patent expiry, the Section 64 revocation petition — which can be filed at any time

during the patent's life, unlike the twelve-month-limited post-grant opposition — is the preferred route for challenging patents that have survived the post-grant opposition process or that were not opposed within the twelve-month window. Section 64 revocation grounds are identical to the post-grant opposition grounds, and the Section 3(d), anticipation, and obviousness analyses applicable to post-grant oppositions apply equally to revocation proceedings. The key procedural difference is that Section 64 revocation before the High Court is a formal civil proceeding with full discovery, cross-examination of expert witnesses, and the possibility of declaratory relief — the High Court's revocation order is a binding determination of invalidity, enforceable against the patentee and all persons claiming through the patent.

LEADING CASE

Novartis AG v. Union of India (2013) 6 SCC 1: The Supreme Court dismissed Novartis's challenge to Section 3(d)'s constitutionality and upheld the Patent Office's rejection of the patent for the beta-crystalline polymorph of imatinib mesylate. The Court held that Section 3(d) was a deliberate legislative policy choice to prevent "evergreening" — the strategy of obtaining patents on incremental modifications of known drugs to extend effective market exclusivity beyond the original compound patent's expiry — and that this policy choice was constitutionally valid as a reasonable restriction on patent rights in the public interest. The ruling confirmed that India's patent law deliberately creates a higher threshold for pharmaceutical patents than the international standard, and that this higher threshold is a legitimate exercise of the TRIPS Agreement's flexibilities.

1.4 Quia Timet Actions and Pre-Launch Injunctions: The Originator's Counter-Strategy

When a generic company announces its intention to launch a product covered by a subsisting patent — either through a public announcement, a regulatory submission to the DCGI, or a market communication to distributors — the originator's immediate legal response is typically a quia timet injunction application: an injunction restraining the anticipated, not yet occurred, infringement. The quia timet doctrine in Indian patent law — derived from English equity and applied by the Delhi High Court and other High Courts in pharmaceutical patent matters — allows the patentee to seek an injunction before the infringing act occurs, where there is a sufficiently imminent and credible threat of infringement. The standard three-part test for a patent injunction — prima facie case of infringement; balance of convenience favouring the patentee; irreparable harm — is particularly contentious in pharmaceutical patent matters because: the balance of convenience analysis must weigh the patentee's commercial loss against the public interest in access to more affordable generic medicines; and the irreparable harm analysis in pharmaceutical cases frequently favours the generic (whose first-mover advantage in a competitive generic market is lost if it is enjoined at launch), not the originator. For Gujarat's large generic companies — which have sophisticated legal teams that prepare revocation petitions and invalidity defences in advance of launch — the quia timet injunction defence strategy must be prepared and ready before the launch decision is made: the revocation petition or post-grant opposition, if filed before the originator's injunction application, gives the generic a

counterclaim that significantly affects the balance of convenience analysis in the injunction hearing.

CHAPTER TWO

Compulsory Licensing: Natco v. Bayer, Section 84 Grounds, Controller Proceedings and High Court Appeals

Patents Act 1970 Sections 84–92, Compulsory Licence Grounds, Natco Pharma v. Bayer Corporation, Reasonable Requirements Test, Royalty Determination and IPAB/High Court Review

> *India's compulsory licensing regime — Sections 84 through 92 of the Patents Act — is the most commercially significant exception to patent exclusivity available to a generic manufacturer seeking to produce a patented pharmaceutical product without the originator's consent. The Natco Pharma v. Bayer Corporation compulsory licence (2012) — the first compulsory licence granted in India under the amended Patents Act — established that the compulsory licensing mechanism is a live, operational tool that generic companies can deploy against high-priced patented drugs where the three Section 84 grounds are demonstrably satisfied, and that the Controller of Patents will exercise the power if the statutory conditions are met.*

2.1 Section 84 Grounds: The Three-Limbed Test and Evidence Requirements

Section 84(1) of the Patents Act provides that any person interested may, three years after the grant of a patent, apply to the Controller for a compulsory licence on any of three grounds: (a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied; (b) that the patented invention is not available to the public at a reasonably affordable price; or (c) that the patented invention is not worked in the territory of India. The Natco v. Bayer case — involving Sorafenib Tosylate (Nexavar), a liver and kidney cancer drug priced at approximately Rs. 2.8 lakh per month by Bayer — succeeded on grounds (a) and (b): the Controller found that Bayer's sales of Nexavar reached only approximately 2 per cent of the patient population requiring the drug, and that the price was not reasonably affordable to the vast majority of Indian patients. The royalty fixed by the Controller — 6 per cent of net sales — was subsequently affirmed by the IPAB and the Bombay High Court. For a generic manufacturer considering a compulsory licence application, the evidence-building exercise must precede the filing: public health data on patient population and unmet need (from ICMR, NACO, NPPA, and published epidemiological studies); the patentee's import and sales data (available from NPPA's drug pricing database and DGCI import records); pricing data comparing the Indian price to prices in other jurisdictions and to per-capita income benchmarks; and evidence that the applicant is capable of manufacturing the product in India at a scale sufficient to meet public need.

2.2 Section 92 Government Use: Emergency Compulsory Licences

Section 92 of the Patents Act enables the Central Government — by notification — to authorise the use of a patented invention for government purposes or to address a national emergency, extreme urgency, or public non-commercial use without requiring the three-year waiting period applicable to Section 84 applications. The COVID-19 pandemic renewed interest in Section 92 as a mechanism for government-authorised production of patented vaccines and antiviral drugs — the Government of India's deliberations on whether to invoke Section 92 for COVID-19 vaccines were widely discussed in the pharma policy community, though ultimately not invoked for the leading vaccines due to the Serum Institute of India's voluntary licence arrangements. For practitioners advising biotech and pharma companies that hold government supply contracts for patented medicines — or companies seeking government authorisation to supply patented products — the Section 92 mechanism is a route to supply that does not require the patentee's consent and that overrides any injunction the patentee might otherwise obtain. The royalty for Section 92 use is determined by the Controller based on the economic value of the authorisation, subject to the patentee's right to be heard and to challenge the royalty determination before the High Court.

2.3 Royalty Determination: The TRIPS Article 31 Standard and Indian Practice

The Patents Act's compulsory licensing provisions require that the royalty paid to the patentee be "reasonable" — a standard that Section 90 of the Patents Act and TRIPS Article 31(h) specify must be determined having regard to the economic value of the licence. The Controller's royalty determination in the Natco v. Bayer case — 6 per cent of net sales — drew on a comparative analysis of royalties in comparable compulsory licence situations in other jurisdictions and on economic analysis of the reasonable return to the patentee given the R&D investment in the drug. Practitioners challenging a Controller's royalty determination (on behalf of either patentee or licensee) must deploy an expert economic analysis: the patentee's R&D cost attributable to the Indian market; the patentee's reasonable expected return on Indian sales; the public health impact of the licence; and international comparators for royalty rates in compulsory licence situations. The High Court's standard of review of the Controller's royalty determination — which is an exercise of regulatory discretion within a statutory framework — is the reasonableness standard applicable to quasi-judicial economic determinations, and the Court will interfere with the royalty only if it is so unreasonable as to be arbitrary or if the Controller has committed an error of principle in the royalty computation methodology.

CHAPTER THREE

Patent Infringement in Pharma: Quia Timet Injunctions, Springboard Injunctions and Balance of Convenience

Patent Infringement Under Section 48, Interim Injunction Standards, Balance of Convenience in Pharmaceutical Matters, Springboard Doctrine and Damages Assessment

3.1 Infringement Analysis: Claim Construction and Equivalence Doctrine

A patent infringement analysis in a pharmaceutical matter begins with claim construction — the determination of what the patent actually claims, based on the language of the claims read in light of the specification and the prosecution history. Indian patent claim construction applies the "purposive construction" approach — claims are construed not literally but in light of the invention's essential features, as a person skilled in the relevant art would understand them. The doctrine of equivalents — which extends infringement to variants that perform substantially the same function in substantially the same way to achieve substantially the same result — has been applied cautiously by Indian courts in pharmaceutical patent matters: the Delhi High Court has applied the doctrine but has emphasised that a variant that falls outside the literal scope of the claims must be "insubstantially different" from the claimed invention to infringe under the equivalents doctrine, and that the prosecution history estoppel principle bars a patentee from claiming equivalents to subject matter that was disclaimed or narrowed during prosecution to overcome prior art rejections. For Gujarat generic manufacturers defending infringement suits, the prosecution history of the patent — available from the Patent Office file wrapper — is a critical source of equivalents estoppel arguments: where the originator narrowed its claims during prosecution to avoid prior art, it cannot recapture the disclaimed scope through the equivalents doctrine in an infringement suit.

3.2 Springboard Injunctions: Restraining Regulatory Submissions

A springboard injunction — restraining a generic company not merely from launching a product but from making regulatory submissions (ANDA filings, bioequivalence study applications, DCGI import licences) that would give it an "unlawful springboard" advantage during the patent term — has been granted by Indian courts in a small number of pharma patent matters, drawing on the English precedent of Cephalon v. Orchid (UK). The springboard injunction theory is that a generic company which uses a patented product or process to conduct regulatory studies — bioequivalence tests, stability studies, and the manufacturing process optimisation that is necessarily done using the patented product — derives an unjust competitive advantage from the patented product's use during the regulatory submission phase, even though the actual

generic product will only be marketed after patent expiry. Indian courts' approach to springboard injunctions has been mixed: some courts have restrained regulatory submissions where the generic has used the patented product in an infringing manner to generate regulatory data; others have declined, on the ground that Section 107A of the Patents Act — India's Bolar provision — expressly exempts acts done "for the purpose of development and submission of information required under any law" from infringement. Practitioners advising large Gujarat generics on pre-launch patent strategy must assess, for each product, whether the bioequivalence and regulatory studies have been conducted in a manner that triggers Section 107A protection — if the Bolar exemption applies, the springboard injunction theory is defeated at threshold.

3.3 Damages in Pharmaceutical Patent Infringement: Section 108 and the Gujarat High Court's Approach

Section 108 of the Patents Act provides that in infringement proceedings, the Court may award either damages (the patentee's actual loss caused by the infringement) or an account of profits (the infringer's gain from the infringing activity) — the patentee elects which remedy to pursue after liability is established. In pharmaceutical patent infringement, damages quantification is a complex expert exercise: the patentee's "but for" sales volume and price (what it would have sold if the generic had not infringed); the price erosion caused by the generic's presence in the market; and the consequential losses on the patentee's entire product portfolio (where the generic's market entry triggers price reductions across the product family). An account of profits — which requires the infringer to disgorge its net profit from the infringing sales — is frequently more commercially significant for the patentee than damages in pharmaceutical matters: a large generic company that has sold an infringing product at high volume for several years before the injunction issues will have accumulated significant profits, and the account of profits can exceed the patentee's own lost sales figure. For practitioners handling the damages or profits inquiry phase of pharmaceutical patent litigation, the appointment of an independent forensic accountant — jointly by both parties or by the Court — to analyse the financial records and quantify the relevant figure is standard practice at the High Court level.

CHAPTER FOUR

Patent Linkage and Pre-Grant Opposition: Section 25, Form 7A and the DCGI-Patent Office Interface

Pre-Grant Opposition Under Section 25(1), Form 7A, Third Party Observation Mechanism, Patent Linkage Debate and Regulatory Data Protection Proposals

4.1 Pre-Grant Opposition: Strategic Use and Procedural Mechanics

Section 25(1) of the Patents Act permits any person to file a representation opposing the grant of a patent application, at any time after the application's publication under Section 11A and before the grant of the patent. The pre-grant opposition — filed as a Form 7A representation with the Patent Office — is the first line of defence available to a generic company that identifies a competitor's patent application covering a molecule or formulation of commercial interest. Unlike the post-grant opposition (which is limited to twelve months after grant), the pre-grant opposition can be filed at any time during the application's pendency — which for pharmaceutical patents can span several years from filing to grant. The grounds available for pre-grant opposition are the same as for post-grant opposition, and the Section 3(d) analysis — applied to polymorph, salt, and formulation applications — is equally applicable in the pre-grant context. The pre-grant opposition's strategic value lies in its timing: a successful pre-grant opposition prevents the grant of the patent entirely, eliminating the need for a subsequent post-grant opposition or revocation proceeding and preserving the generic's freedom to operate without any patent obstacle. For a large generic company with a pipeline monitoring programme, systematic pre-grant oppositions against competitor applications covering pipeline products — filed by in-house counsel or by external patent agents with technical expertise — is a cost-effective way to maintain freedom to operate across the generic product pipeline.

4.2 Patent Linkage: The DCGI's Position and Its Practical Implications

Patent linkage — the practice of linking the grant of regulatory approval (drug manufacturing or marketing approval) by the drug regulator to the patent status of the product — is not formally mandated in India. The DCGI does not conduct patent searches or condition approval on patent clearance: a generic company can obtain a manufacturing licence under the Drugs and Cosmetics Act for a product that is the subject of a subsisting patent, and the patent dispute is resolved in civil court proceedings independently of the regulatory approval process. This absence of formal patent linkage is a significant departure from the US framework (where the FDA's paragraph IV certification and 30-month stay create a formal patent-regulatory interface) and is a deliberate policy choice that India has defended in WTO TRIPS Council deliberations. For practitioners, the absence of patent linkage means that the generic company's regulatory

approval pathway is not blocked by the originator's patent, and that the originator's only remedy to prevent a generic launch is a civil court interim injunction — not a regulatory hold. The practical implication is that the race between the generic's regulatory approval process (which can proceed while patent disputes are pending) and the originator's injunction application (which must be filed before launch to be effective) defines the strategic timeline that large generic companies manage in parallel regulatory and IP proceedings.

CHAPTER FIVE

Technology Transfer Agreements: Licensing Structures, Royalty Enforcement, Sublicensing Rights and Dispute Resolution

Licensing Agreement Drafting, Royalty Audit Rights, Milestone Payment Disputes, Sublicensing Restrictions, Termination Clauses and International Arbitration in Pharma Licensing

5.1 Licence Agreement Architecture: Field of Use, Territory and Exclusivity

A pharmaceutical or biotech technology transfer agreement — whether a patent licence, a know-how licence, or a combined technology licence — is the commercial instrument through which an innovator company monetises its intellectual property in a new territory or for a new application without directly manufacturing or marketing the product itself. The fundamental commercial parameters of any licence — the field of use (the specific product, indication, or technology covered); the territory (the geographic scope of the licence); the exclusivity (whether the licensee receives exclusive, co-exclusive, or non-exclusive rights); and the consideration structure (upfront fees, milestone payments, royalties, and minimum guaranteed royalties) — must be defined with the same precision as any other major commercial contract. Field of use definitions in pharmaceutical licensing are a recurring source of dispute: an agreement that licences "the manufacture and sale of imatinib mesylate in India" is narrower than one licensing "the manufacture and sale of imatinib and its salts and pharmaceutical compositions thereof in India" — the distinction may determine whether the licensee can manufacture the mesylate salt formulation that is clinically preferred, or whether it is limited to the free base. Practitioners drafting or reviewing pharmaceutical licence agreements must ensure that the field of use definition is aligned with the licensee's actual product development plans, the claims of the licensed patents, and the regulatory submissions the licensee intends to make — a misalignment between the licensed field and the regulatory submission can expose the licensee to infringement claims for activity that it assumed was within the licence scope.

5.2 Royalty Disputes: Audit Rights, Royalty Base Computation and Withholding Tax

Royalty payment disputes — whether the royalty has been correctly computed, whether the royalty base includes all required net sales, and whether the licensee has improperly deducted items from the royalty base — are the most common category of pharmaceutical licence dispute requiring legal intervention. The royalty base definition (typically "net sales" — gross invoiced sales less specified deductions for discounts, returns, and government-mandated price reductions) is the source of most computational disputes: licensees with manufacturing-oriented distribution structures frequently have internal transfer pricing arrangements between group

companies that reduce the effective royalty base below the arms-length market value of sales, while licensors contend that the royalty base should reflect the arms-length market price regardless of internal pricing. The licensor's audit right — the contractual right to examine the licensee's books and records to verify royalty computations — is the primary enforcement tool for royalty disputes, and the scope of the audit right (what records can be examined, by whom, and over what period) is a critical drafting variable. An audit right that is limited to the licensee's royalty calculation spreadsheet is far narrower than one that extends to the licensee's complete sales records, tax returns, and intercompany pricing documentation. Practitioners conducting royalty audits on behalf of licensors must obtain access to: sales invoices; net sales reconciliation worksheets; deduction calculation support; and intercompany pricing agreements for products sold through affiliated distribution entities.

CHAPTER SIX

Data Exclusivity, Trade Secrets and Regulatory Data Protection in Indian Pharma Litigation

TRIPS Article 39.3 Obligations, India's Data Protection Debate, Know-How Misappropriation, Confidentiality Agreement Enforcement and Trade Secret Litigation

6.1 India's Data Exclusivity Gap and Its Commercial Implications

TRIPS Article 39.3 requires WTO members to protect undisclosed test data submitted to regulatory authorities against unfair commercial use — the provision that forms the international legal basis for data exclusivity regimes. India has not implemented a standalone data exclusivity regime — the Indian legal framework does not provide a defined period of exclusivity during which a generic company cannot rely on the originator's regulatory submission data for its own approval. This absence of data exclusivity is commercially significant for originator pharma and biotech companies that invest in clinical trial data generation for new drug applications before the DCGI: a generic company can, under the current framework, obtain marketing approval from the DCGI by relying on published bioequivalence studies and publicly available safety data without conducting its own independent trials, even if the originator's unpublished clinical data was the basis for the original NDA. For originator companies, the practical protection available in India in the absence of statutory data exclusivity is contractual: non-disclosure agreements with clinical research organisations (CROs), ethics committees, and investigators; trade secret protection for proprietary analytical methods and clinical protocols; and regulatory submission confidentiality provisions in engagement contracts. The litigation route for enforcing these contractual protections — whether as breach of contract claims or trade secret misappropriation claims — is the High Court's original civil jurisdiction, and injunctive relief for trade secret misappropriation is available under the broad equitable jurisdiction of the High Court.

6.2 Trade Secret Misappropriation: The Indian Legal Framework

India does not have a standalone trade secrets statute — trade secret protection is provided through the common law of confidential information (the equitable duty of confidence derived from English law and consistently applied by Indian courts), breach of contract (non-disclosure and non-compete agreements), and in some cases, criminal law (breach of trust under the Indian Penal Code for employees who steal confidential business information). The High Court's injunctive jurisdiction in trade secret cases — available under Section 37 of the Specific Relief Act, 1963 for the mandatory injunction to deliver up or destroy confidential material, and under the court's inherent equitable jurisdiction for restraining disclosure or use — is the primary

remedy for a biotech company whose confidential manufacturing process, cell line data, fermentation protocol, or clinical study design has been misappropriated by a departing employee or a former contract research partner. The three-element trade secret test applied by Indian courts — the information must be confidential in character; it must have been communicated in circumstances importing an obligation of confidence; and it must be used or threatened to be used without authority — closely follows the English Coco v. A.N. Clark (Engineers) Ltd. standard, and practitioners advising biotech companies on trade secret protection and litigation must demonstrate all three elements through documentary and testimonial evidence at the interim injunction stage.

Booklet I Complete Summary: Patent strategy in the pharmaceutical and biotech sector — from Section 3(d) challenges to compulsory licensing, from pre-grant oppositions to springboard injunction defence — is the highest-value IP practice in India's life sciences sector. The Novartis ruling defines the Section 3(d) analytical framework; the Natco v. Bayer compulsory licence establishes the Section 84 evidentiary requirements; and the absence of formal patent linkage and data exclusivity shapes the generic industry's regulatory freedom of action. Technology transfer agreement disputes — royalty computation, field of use interpretation, and audit right enforcement — are the transactional litigation that accompanies India's position as the world's largest generic medicine supplier and a growing biosimilar developer. For Gujarat's large pharma companies, these are not academic questions — they are the commercial battles that determine product launch timelines, market exclusivity periods, and licensing revenue streams worth hundreds of crores.