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THE INDIAN LEGISLATIVE FRAMEWORK AND BIOPIRACY: A CRITICAL ANALYSIS

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ABSTRACT

This paper undertakes a rigorous doctrinal and analytical examination of two foundational dimensions of traditional knowledge protection under Indian law. Chapter III furnishes a critical audit of the principal legislative instruments through which India seeks to guard the intellectual heritage of its indigenous and local communities – encompassing the Patents Act 1970 (as amended), the Geographical Indications of Goods (Registration and Protection) Act 1999, the Protection of Plant Varieties and Farmers' Rights Act 2001, and the Biological Diversity Act 2002. Chapter IV then subjects three landmark biopiracy controversies – the turmeric, neem, and basmati disputes – to granular legal scrutiny, tracing the manner in which each case exposed structural deficiencies in both domestic and international intellectual property frameworks and catalysed subsequent legislative and diplomatic responses.

The analysis reveals that India's existing patchwork of legislative instruments, while individually innovative in certain respects, collectively fails to constitute a coherent or comprehensive system of traditional knowledge protection. The Patents Act's defensive mechanisms prevent the wrongful grant of patents on traditional knowledge but confer no positive rights on knowledge-holding communities. The Biological Diversity Act's access and benefit sharing framework is undermined by inadequate institutional capacity and fragmented enforcement. Geographical indications and plant variety protection offer narrowly circumscribed relief. Meanwhile, the biopiracy case studies demonstrate that successful challenges have been extraordinarily resource-intensive and structurally dependent on prior documentation – advantages that marginalised indigenous communities rarely possess.

The paper concludes by affirming that genuine protection for India's traditional knowledge heritage demands the enactment of a sui generis legislative framework that accords positive collective rights to knowledge-holding communities, mandates genuine free prior informed consent, and institutes robust benefit-sharing mechanisms enforceable both domestically and in foreign jurisdictions.

Keywords: Traditional Knowledge; Biopiracy; Patents Act; Biological Diversity Act; TKDL; Geographical Indications; PPVFR Act; Access and Benefit Sharing; Turmeric Case; Neem Case; Sui Generis Protection; India.

CHAPTER III

THE INDIAN LEGISLATIVE FRAMEWORK FOR TRADITIONAL KNOWLEDGE PROTECTION

I. OVERVIEW OF THE REGULATORY ARCHITECTURE

India's legislative engagement with the challenge of protecting traditional knowledge has developed unevenly over three decades, propelled in substantial part by the international embarrassment generated by high-profile biopiracy controversies and by India's increasingly assertive role in international negotiations on the subject. The resulting statutory landscape is characterised by plurality rather than coherence: a collection of instruments, each addressing one dimension of the problem but none offering a comprehensive or rights-based solution.

Four principal legislative instruments currently intersect with traditional knowledge protection: the Patents Act 1970 (as amended in 2002 and 2005), the Geographical Indications of Goods (Registration and Protection) Act 1999, the Protection of Plant Varieties and Farmers' Rights Act 2001, and the Biological Diversity Act 2002. Taken together, these instruments occupy distinct but overlapping legal spaces, and their interaction has not been governed by any overarching policy framework oriented towards the genuine empowerment of traditional knowledge communities.

II. THE PATENTS ACT, 1970: DEFENSIVE PROTECTION THROUGH PRIOR ART

A. Foundational Provisions and Their Inherent Inadequacies

The Patents Act 1970 was conceived to construct a domestic patent system calibrated to India's developmental imperatives at the time of its enactment. The original legislation already contained exclusions from patentability that carried some relevance for traditional knowledge

– notably, the prohibition on granting patents for methods of agriculture and processes for the medical treatment of human beings.¹ However, these exclusions operated exclusively within India's own jurisdiction and offered no mechanism to prevent foreign patent offices from granting monopoly rights over knowledge derived from Indian traditional practice.

The fundamental problem was structural: Indian traditional knowledge, however extensively documented in classical Sanskrit, Urdu, or Tamil texts, was not rendered accessible to patent examiners in Washington or Munich who were conducting prior art searches. The absence of a systematic, multilingual, electronically searchable database of Indian traditional medicinal knowledge meant that examiners in foreign jurisdictions were routinely unaware of prior art that would have been fatal to the applications before them. This informational asymmetry – rather than any deficiency in the underlying concept of prior art – accounted for the spate of wrongful patents granted on traditional Indian knowledge in the 1990s.

B. The 2002 and 2005 Amendments: Section 3(p) and Enhanced Defences

The Patents (Amendment) Act 2002 introduced the most significant structural change to the defensive protection of traditional knowledge: the insertion of Section 3(p), which explicitly excludes from patentability any invention that, in effect, constitutes traditional knowledge or that merely aggregates or duplicates known properties of traditionally known components. This provision translates into statutory language a legislative judgment that traditional knowledge should not be susceptible to monopolisation through the patent system, regardless of the jurisdiction in which the application is filed.²

Complementing Section 3(p), the same amendment expanded the concept of prior art under Section 13 to encompass traditional

knowledge, and created specific grounds for both pre-grant opposition under Section 25(1)(j) and post-grant opposition under Section 25(2)(k) where the claimed invention appropriates traditional knowledge.³ These provisions theoretically enable indigenous community representatives to intervene directly in patent proceedings to protect their knowledge – though the practical accessibility of such proceedings remains severely limited by resource constraints and procedural complexity.

C. The Traditional Knowledge Digital Library: Architecture and Appraisal

The most internationally recognised innovation in India's defensive protection strategy is the Traditional Knowledge Digital Library (TKDL), a collaborative initiative of the Council of Scientific and Industrial Research (CSIR) and the Ministry of AYUSH. The TKDL is a structured digital repository containing transcriptions of traditional medicinal knowledge drawn from classical Ayurvedic, Unani, Siddha, and Yoga texts, translated into five

international languages and classified according to the International Patent Classification system to enable patent examiners worldwide to conduct effective prior art searches.⁴

Through access agreements concluded with major patent offices – including the European Patent Office and the United States Patent and Trademark Office – the TKDL has enabled India to challenge, and in many cases cause the withdrawal of, numerous patent applications grounded in traditional knowledge.⁵ Measured by this criterion alone, it represents a significant policy success. Yet the TKDL's acknowledged limitations are equally important. Access to the database is restricted to participating patent offices under confidentiality protocols; the indigenous communities whose knowledge it documents cannot access it to verify accuracy or assert rights. More fundamentally, the TKDL is a

defensive instrument – it blocks others from obtaining patents but creates no positive entitlement in knowledge-holding communities.

Critics have also observed that the TKDL's focus on classically codified knowledge – Ayurveda, Unani, Siddha, and Yoga – leaves entirely unprotected the vast body of orally transmitted, uncoded knowledge held by tribal and forest-dwelling communities.⁶ These communities, whose knowledge is in many respects the most ecologically specific and the most commercially valuable, are precisely those who remain beyond the reach of the current documentation apparatus.

III. GEOGRAPHICAL INDICATIONS LAW AS A VEHICLE FOR TRADITIONAL KNOWLEDGE PROTECTION

The Geographical Indications of Goods (Registration and Protection) Act 1999, enacted to fulfil India's obligations under Article 22 of the TRIPS Agreement, offers an alternative legal vehicle for protecting a subset of traditional knowledge – specifically, knowledge whose distinctive character is inseparable from a particular geographical origin.⁷ GI registration confers on producers from the relevant region the right to use the geographical name and to prevent misrepresentation in trade, thereby offering economic protection for products whose quality or reputation derives substantially from traditional knowledge and practice.

The Darjeeling Tea GI, granted in 2004, is widely cited as India's most commercially effective registration. Through sustained enforcement in the European Union, the United States, Japan, and other major markets, the Tea Board of India has successfully defended the exclusivity of the 'Darjeeling' denomination against misuse, maintaining price premiums and delivering economic benefits to tea-growing communities whose traditional cultivation and processing methods are integral to the product's character.⁸

However, geographical indications are a structurally limited tool for the broader project of traditional knowledge protection. Many forms of traditional knowledge possess no specific or exclusive geographical nexus – medicinal knowledge regarding a plant species found across a wide region may be shared among communities in multiple states. Moreover, GI protection attaches to the geographical denomination rather than to the underlying knowledge, processes, or innovations. It does not prevent a third party from adopting the same traditional formulations or cultivation methods under a different name.

A further limitation is institutional. GI protection vests in registered producers' associations; communities lacking the capacity to organise and maintain such associations – as is frequently the case with tribal communities – are effectively excluded from the framework's benefits.⁹ This asymmetry is particularly acute given that tribal communities are often the custodians of the most endangered and commercially valuable forms of traditional knowledge.

IV. THE PROTECTION OF PLANT VARIETIES AND FARMERS' RIGHTS ACT, 2001

The PPVFR Act represents India's most ambitious attempt to balance the competing interests of commercial plant breeders and traditional farming communities. The Act departs significantly from the standard international model established under the UPOV Convention by incorporating a parallel regime of Farmers' Rights alongside the conventional system of plant breeders' rights. Section 39 of the Act recognises farmers' entitlements to save, use, exchange, and sell farm produce of registered varieties, subject to restrictions on the commercial sale of branded seed.¹⁰

The Act also provides for the registration of 'extant varieties' – including traditional farmers' varieties cultivated and conserved over generations – thereby theoretically enabling

communities to secure formal legal recognition for varieties that would otherwise remain unprotected. The National Gene Fund established under Section 45 is intended to act as a repository for benefit-sharing payments from commercial breeders who have utilised farmers' varieties in developing protected plant varieties.¹¹

In practice, however, the PPVFR Act's community-oriented provisions have been imperfectly realised. Registration of farmers' varieties remains disproportionately low relative to India's enormous agricultural biodiversity. The Protection of Plant Varieties and Farmers' Rights Authority has instituted awareness programmes and procedural simplifications, but fundamental barriers – including literacy requirements, administrative complexity, and geographic inaccessibility – have not been surmounted.¹² The National Gene Fund has similarly underperformed: collections have been modest and disbursements to farming communities have been constrained by the absence of operationally effective guidelines for identifying, valuing, and distributing benefits at the community level.

V. THE BIOLOGICAL DIVERSITY ACT, 2002: ACCESS, BENEFIT SHARING, AND COMMUNITY REGISTERS

A. Institutional Architecture and Access and Benefit Sharing Provisions

The Biological Diversity Act 2002 constitutes the most structurally comprehensive of India's traditional knowledge protection instruments. Enacted to implement the Convention on Biological Diversity, the Act establishes a three-tiered institutional framework – the National Biodiversity Authority (NBA), State Biodiversity Boards (SBBs), and Local Biodiversity Management Committees (BMCs) – and creates an integrated system of access and benefit sharing obligations governing the use of biological resources and associated traditional knowledge.¹³

Section 6 of the Act requires any person seeking an intellectual property right over an invention derived from or based on information pertaining to a biological resource obtained from India to obtain prior approval from the NBA, which may impose benefit-sharing conditions. These provisions were intended to institutionalise the principle of equitable benefit

sharing at the level of patent law – requiring that those who commercially exploit biological resources and associated knowledge make adequate returns to the originating communities.¹⁴

In practice, however, the Act's implementation has fallen significantly short of this aspiration. The number of formalised access and benefit sharing arrangements concluded by the NBA remains modest; many commercial actors have simply not engaged with the approval process. The 2023 amendment to the Biological Diversity Act attracted substantial criticism for removing several categories of domestic users – including Ayurvedic practitioners and Indian companies – from prior approval requirements, a change that critics contended weakened community rights protections while proponents argued was necessary to facilitate AYUSH sector growth.¹⁵

B. People's Biodiversity Registers: Promise and Practice

One of the more innovative features of the Biological Diversity Act is its provision for the preparation of People's Biodiversity Registers (PBRs) by Local Biodiversity Management Committees. PBRs are intended to document local biological diversity and associated traditional knowledge, serving simultaneously as conservation records and as prior art databases that can prevent the wrongful patenting of community knowledge.¹⁶

The PBR programme has, however, encountered persistent implementation difficulties. Documentation quality varies markedly across states. Kerala, which has

invested substantially in biodiversity governance, presents a relatively positive record of comprehensive PBR coverage; many other states have registers that are incomplete, outdated, or limited to bare species lists without the associated knowledge and practices that give those lists legal significance.

A more fundamental concern is the paradox of documentation: by making traditional knowledge publicly available in written registers, PBRs may inadvertently facilitate the very commercial exploitation they are designed to prevent. Knowledge recorded in a PBR that is accessible to researchers and commercial entities, without simultaneously conferring any positive intellectual property right on the originating community, may aggravate the problem

of appropriation rather than ameliorate it. The legal status of PBR information – who owns it, who may access it, and what remedies are available if it is misused – remains inadequately resolved in the legislation and its implementing rules.

CHAPTER IV

BIOPIRACY AND THE INDIAN RESPONSE – CASE STUDIES

I. INTRODUCTION

The inadequacy of India's intellectual property framework in protecting traditional knowledge is rendered most vividly apparent through the lens of specific biopiracy controversies. Three cases in particular – involving turmeric, neem, and basmati rice – galvanised both domestic legislative action and India's increasingly assertive international advocacy during the 1990s and 2000s. Each case followed a characteristic pattern: a foreign entity obtained a patent on knowledge long embedded in Indian traditional practice; India mounted a challenge, ultimately with some success; and the outcome underscored both the possibilities and the severe limitations of the existing legal architecture.

These cases are not merely historical curiosities. They established the procedural and evidential templates for subsequent defensive action, directly informed the TKDL's design philosophy, and furnished India with the moral authority and empirical foundation for its advocacy in international forums including the WIPO Intergovernmental Committee and the WTO's TRIPS Council. They also revealed the structural asymmetries that continue to disadvantage traditional knowledge communities: the resource-intensive nature of patent challenges, the burden of documenting knowledge that communities never intended to publish, and the absence of mechanisms for communities to derive positive benefit from their knowledge even where biopiracy is prevented.

II. THE TURMERIC CASE: ESTABLISHING THE PRIOR ART CHALLENGE

In 1995, the United States Patent and Trademark Office granted Patent No. 5,401,504 to the University of Mississippi Medical Center, claiming the use of turmeric powder for healing wounds. The patent covered a practice that had been integral to Indian domestic medicine and household healing for centuries – a practice documented in Sanskrit texts, described in published Indian scientific papers, and known to virtually every household on the subcontinent.¹⁷

The Council of Scientific and Industrial Research (CSIR) mounted a formal re-examination challenge before the USPTO, submitting over thirty references establishing prior art, including an article published in the Indian Journal of Medical Research in 1953 explicitly describing the wound-healing properties of turmeric. The USPTO cancelled the patent in 1997, concluding that the claimed use lacked novelty in light of the submitted prior art – a decisive vindication of the principle that ancient knowledge cannot be monopolised through a patent system that presupposes novelty.

The turmeric case established several significant precedents. It demonstrated that classical Indian texts and published scientific papers – properly translated and organised – could constitute legally cognisable prior art before foreign patent offices. It revealed the viability of the prior art challenge as an instrument of defensive protection. And it directly motivated the TKDL project: if the existence of a single prior art article could defeat a patent, what could a systematically organised, IPC-classified digital library of 0.9 million traditional formulations achieve?¹⁸

However, the case also exposed a structural injustice that the prior art challenge cannot remedy: the burden of preventing biopiracy fell entirely upon India and its institutional resources, not upon the patent applicant. The applicant made no disclosure of traditional knowledge origins; CSIR was required to invest substantial resources in identifying, compiling, and presenting the counter-evidence. The asymmetry of this process – in which the knowledge holder must actively prove prior art rather than the applicant being required to disclose known origins – remains a fundamental flaw in the international patent system.¹⁹

III. THE NEEM CASE: COLLECTIVE ADVOCACY AND EUROPEAN JURISPRUDENCE

The neem controversy illustrates both the cross-jurisdictional dimensions of biopiracy and the indispensable role of civil society coalitions in mounting effective challenges. In 1994, the European Patent Office granted Patent EP 0436257 B1 to the W.R. Grace Company and the United States Department of Agriculture, claiming a method of controlling plant fungi using a stable, oil-based extract derived from neem seeds. The neem tree (*Azadirachta indica*) had been used in Indian agriculture, medicine, and cosmetics for millennia; its biopesticide properties were documented in ancient texts and had been practised in Indian farming communities

without interruption.²⁰

A coalition led by Dr Vandana Shiva and the International Federation of Organic Agriculture Movements filed an opposition before the EPO's Opposition Division. The challenge succeeded in 2000: the Opposition Division revoked the patent on the ground that the claimed method lacked novelty, having been publicly disclosed in India prior to the patent application date. The revocation was upheld on appeal by the EPO's Technical Board of Appeal in 2005.²¹

The neem case carries several layers of doctrinal and institutional significance. In terms of evidentiary law, the EPO proceedings established that traditional knowledge could constitute prior art in the form of 'prior public use' even where the relevant use was predominantly oral and practical in character rather than recorded in published technical literature. Expert witness testimony regarding long-standing agricultural practices was accepted as adequate evidence – an important precedent for knowledge systems that are inherently oral.

The case also illustrates the collective action problems inherent in biopiracy challenges. The farming communities most directly affected – those who had used neem-based preparations for generations – were structurally incapable of conducting patent opposition proceedings before an international patent office. It was the intervention of NGOs, academic institutions, and civil society organisations that rendered the challenge possible. This dependence on external intermediaries, while effective in this instance, is a precarious foundation for a systematic protective regime. Any reformed framework must provide institutional support that makes the challenge process accessible to communities themselves.

IV. THE BASMATI CASE: THE INTERSECTION OF PATENTS AND GEOGRAPHICAL IDENTITY

In 1997, the American company RiceTec Inc. obtained a patent from the USPTO claiming novel rice varieties characterised as 'basmati-like' lines, novel cultivation and breeding methods, and – most controversially – the right to use the term 'basmati'

cultivated in South Asia. Basmati rice had been grown in the Himalayan foothills for centuries by farming communities with deep traditional knowledge of its distinctive aromatic properties and cultivation requirements.²²

The Indian government mounted a formal challenge before the USPTO, successfully securing the cancellation of a significant portion of the contested claims. The surviving claims were narrowed to specific hybrid varieties developed by RiceTec itself, rather than the traditional varieties or the 'basmati' denomination as a generic descriptor for South Asian aromatic rice. While this outcome was widely reported as a victory, it was at best a partial one: RiceTec retained intellectual property protection for its hybrid varieties, and the 'basmati' geographical denomination remained contested in certain markets.

The basmati controversy illuminated the critical intersection between the patent system and the geographical indications framework. Had a recognised international GI for basmati rice been in place at the time of the RiceTec application, the use of the term 'basmati' for non-South Asian rice would have been legally precluded in GI-recognising jurisdictions. The dispute thus strengthened India's resolve to pursue GI protection for basmati and contributed to subsequent advocacy for stronger international GI protection for agricultural products originating in developing countries.²³

The basmati case also exposed the fragility of traditional agricultural variety protection in the international legal framework. The UPOV

Convention, which governs plant variety protection in most developed countries, does not recognise farmers' traditional cultivars as subject matter deserving protection, thereby enabling commercial breeders to present derivative hybrid varieties as entirely novel without confronting the traditional varietal heritage upon which they draw. India's subsequent decision to include extant varieties within the scope of the PPVFR Act can be read in part as a legislative response designed to close this precise gap.

V. EMERGING BIOPIRACY CHALLENGES IN THE DIGITAL AGE

The three landmark cases examined above were fought in an era when bioprospecting required physical access to communities and biological resources. The digital revolution has fundamentally altered this landscape. Ethnobotanical data, traditional formulations, and indigenous ecological knowledge are increasingly available in digitised form through academic publications, open-access databases, and online repositories. Artificial intelligence systems capable of mining these datasets to identify novel therapeutic applications or commercially valuable patterns represent a qualitatively new form of bioprospecting – one that requires no physical access to communities or biological resources and that generates no paper trail that could trigger existing regulatory frameworks.²⁴

If an AI system identifies a novel therapeutic application by recombining knowledge elements from two traditional medicinal plants, the critical question for Indian patent law is whether Section 3(p) of the Patents Act would exclude the resulting invention from patentability. The answer is not straightforward: Section 3(p) targets inventions that 'in effect' constitute traditional knowledge or aggregate known properties of traditionally known components, but the AI-generated synthesis may involve sufficient abstraction or recombination to present itself

as a genuinely novel contribution. The existing legislative framework has no mechanism to interrogate AI-assisted bioprospecting, and this gap is likely to become increasingly significant as these technologies mature.

Conversely, digital technologies also create opportunities to strengthen traditional knowledge protection. Blockchain-based systems have been proposed as mechanisms for generating tamper-proof, timestamped records of community knowledge – records that could supplement the TKDL as prior art evidence in foreign patent offices while maintaining community control over access and use. Smart contract architectures could, in principle, automate benefit-sharing obligations, ensuring that royalty flows are transparent, verifiable, and disbursed directly to knowledge-holding communities without dependence on state administrative intermediaries.²⁵ Whether these technological complements are integrated into a reformed legislative framework will be an important test of India's policy responsiveness in the years ahead.

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