

THE INSCRIPTION OF LAW IN LIFE

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ABSTRACT

With innovation in the genetic engineering now being rewarded in the form of intellectual property rights, there are new things that are beginning to count as property and as objects of human invention – plant varieties, seeds, germplasm, genetic sequences, DNA and so on. To bring the realm of “biology” within the ambit of intellectual property, to juridify aspects of the biological as products of human invention is to bring new epistemic objects into visibility. While these are revealed through practices of biotechnology, law translates it into a capacity for monopolistic appropriation for biotech innovators. The new correlatives of innovation and intellectual property re-engineer not just the biology of an organism, but the very categories that organized property and intellectual property. What instrumentalities of technology and law co-produce biotic property? I examine these instrumentalities in a two paper series: while the first paper sought to lay out the work of technology in the creation of new biological artefacts, and consequently new economic spaces and property claims, the second paper seeks to examine the role of law in translating inventive claims as property claims.

Key words: farmer’s rights; plant patents; generic engineering, biotechnology

INTRODUCTION

To claim inventing rights over a domain that is biological and naturally regenerative, legal doctrine has had to reinvent the motifs that have traditionally explained or justified the attribution of rights.¹ It has not only had to reformat the grounds of claim making in intellectual property generally, but has also had to invert the very instrumentality that created property rights in intellectual labour, in order to effect a third order of reification of biological property, a point I make in Research Paper 1. As an assemblage, “invention” in the biological domain is a complex configuration of material factors and meaningful expressions.² While the expressive component of the assemblage could be arguments and

¹ See also, Pottage, Alain, “The Inscription of Life in Law: Genes, Patents, and Bio-Politics”, *The Modern Law Review*, Vol. 61, No. 5, at p.740 as referred in Brownsword, Roger, Cornish, W.R. and Llewelyn, Margaret (Eds.), “Human Genetics and the Law: Regulating a Revolution”, (Hart Publishing: 1998)., at p.744.

² Components in an assemblage play two roles: material and expressive (and a mix of the two). For some assemblages, the material components might be natural resources located within their spatial boundaries; these might include mineral deposits, agricultural land, etc. Or, to use the present context they may include the government, the WTO, CBD and so on – Material components are those that are capable of displaying causal interactions. Expressive components on the other hand, usually involve catalysis. Expressive component, which links to and is implicated in the material component, use expressions of identities. A good example of the expressive components of an assemblage can be for instance national

rhetoric relating to the construction and innovation of biological domain (for example how they are needed to mitigate conditions of malnutrition or disease, for instance; or, how IP rights are just reward for long, arduous, capital intensive process of research) these “expressions” operate through actual material structures of law and legal regimes. Expressive frames infiltrate the material structures, oversee the words, the syntax, the speech of law and prepare the grounds for legitimation that universalize regulatory frameworks and legal provisions.

Law has always in a sense been an instrument of enforcing and stabilizing new ideas, new relations of productions, new productive capacities. However, in an uncanny sense, something new is happening here. A big part of this novelty derives from *how* Law goes about “doing” the biogenetic. It does so not by adhering to doctrinal principles of the patent regime, but by *shifting the doctrinal scape of patent law itself*. IP law, as I seek to analyse in this paper, is able to expand its domain precisely because it annuls its doctrinal core and adherence to doctrinal norms, demonstrating, as Michel Fischer notes, that ‘life is outrunning the pedagogies in which we were trained.’³ There is, as Pottage and Sherman draw our attention to, an interesting, conflictual play of instrumentality in biotechnological patent / breeders’ rights claims.⁴ While on the one hand, patent law still works with a theory of instrumentality that is premised on a distinction between the grown and the made (the criteria of “novelty” and “non-obviousness” as patent qualification, outlined in TRIPS, reflect this distinction), on the other hand, the very same instrumentality pushes that patent law to dissolve this distinction. ‘If biotechnology is a figure of radical instrumentality (as Habermas proposes), then it is so radically instrumental that it deconstructs the logical form of instrumentality’.⁵ Intellectual property in aspects of “life” seeks to transmute these pedagogies and their conceptual and doctrinal inheritances and infiltrate, reorder, or even discard the inherited property infrastructures.⁶

Rather than see biological patents as “exceptions” to the patent rule, I suggest that we see such inversions and transposals as features of the IP assemblage in which assorted instrumentalities of property rights are thrown together in contingent (although in some cases quite durable) co-relationships. And also, where heterogeneous, diverse institutions like the World Trade Organisation

allegiance expressed through flags, parades, and symbols. Delanda, Manuel, “A New Philosophy of Society: Assemblage Theory and Social Complexity”, (Bloomsbury Academic, 2006), at p.263.

See further Deleuze, Gilles & Guattari (1987) for helpful, concrete examples of material and expressive components. Deleuze, Gilles & Guattari, Felix, “A Thousand Plateaus: Capitalism and Schizophrenia”, (University of Minnesota, 1987).

³ Fischer, Michael M.J., “Emergent Forms of Life and the Anthropological Voice”, (Durham, NC: Duke University Press, 2003), at p. 37. [Emphasis mine]

⁴ Pottage, Alain and Sherman, Brad, “Organisms and Manufactures: On the History of Plant Inventions” *Melbourne University Law Review*, Vol. 31 (2), 2007, at pp. 539-568.

⁵ Alain Pottage, “The Socio-Legal Implications of the New Biotechnologies”, *Annual Review of Law and Social Science* (2007), at p.324.

⁶ See generally, Rajan, Sunder Kaushik, “Biocapital: The Constitution of Postgenomic Life”, (Duke University Press Books: 2006), at p 284.

(‘WTO’), Food and Agricultural Organization (‘FAO’), Universal Declaration of Human Rights (‘UDHR’), United Nations Framework Convention on Climate Change (‘UNFCCC’), Convention on Biodiversity (‘CBD’) etc., plug into this network and resonate the same ideas and logics, even as they appear to be contradictory, incongruous, and exceptional. This paper hopes to take the “making of the law”, a step further to see the practice of law as a little more vested in dominant frames of property and technoscientific epistemes than is commonly assumed. By analysing the role of law in the creation and stabilization of the discourse of intellectual property in biogenetic resources, I take a step further in unpacking the political project of technologies of law and production.

INVERTING INSTRUMENTALITY

What demarcates intellectual property from ordinary forms of property is its ability to demonstrate an inventive step. In fact, the grant of intellectual property is contingent on the demonstration of novelty and non-obviousness. A foundational demand therefore for patents is that invention is an ‘adequate distance beyond or above the state of the art.’ (John Barton, 2003). The purpose of the inventive-step requirement is to avoid granting patent to inventions which follow from “normal” product or design and development. Such (*normal*) objects are often in the public domain and/or are designated as prior art, oral tradition, common practice, commonly shared knowledges and hence cannot be claimed as original acts of individual creation.⁷ IP claims like patents, copyrights, breeders’ rights are inextricably tied to the idea of *authorship*. Traditional, indigenous knowledges fall short of this criterion as it often is orally transmitted, inter-generational, admitting natural or supernatural agency and therefore making the distinction between man-made, natural and godly indistinct for assignment of authorship.⁸

It was in this context that the enclosure of biogenetic commons seemed to pose a set of problems not commonly encountered by IP in other realms. It was one thing to demonstrate items of “manufacture” as products of human innovation; it was quite another to demonstrate “nature”, or its parts thereof, as products and projects of human invention. *How could living organisms be shown to be products of human invention when patent law remains tied to its own version of a proprietary distinction between nature and manufactures?* Indeed, the distinction itself should have been sufficient to disqualify any ethical or ecological claims to the “commodification of life”. If the criteria of novelty and non-obviousness marks innovation from ordinary manufactures, then the same criteria becomes an impediment for claiming inventive rights over the biological realm. The life-world of the “grown” is constitutively resistant to the idea of it being “made” or performed as an act of human creation, and

⁷ Elsewhere I have critiqued knowledge claims as “original” invoking Thomas Kuhn’s theory of knowledge as essentially historical and cumulative. See, Chandra, Rajshree, “Knowledge As Property Issues in the Moral Grounding of Intellectual Property Rights”, (Oxford University Press, New Delhi: 2010)

⁸ For details see Chandra, Rajshree (2010), at pp. 297-300.

therefore also impervious to the idea that it can be marked as significantly different from other objects already existent in the public domain of either knowledge or genetic resources.

As I discussed in the previous paper (RP 1), technology becomes a mode that reveals newer forms and potential. Microbiology moves away from essences, moves away from the holistic character of the organism and alters how the organism is bound to the environment. In the absence of the “essence” of an organism (which ties the parts together), gene sequences that are discovered, isolated, spliced or transcribed can now be considered as objects of human invention. This breaches the very instrumentality that underpins patent laws. Reification of the biological as intellectual property requires that patent law abandon its fetishist attachment to distinctions such as those between nature and culture, innovation and discovery, grown and manufactured. *It had to interrupt nature’s contingency and establish social contingency of biological produce.*

THE SLEIGHT OF LAW

Plant genetic resources (seeds, plant varieties, genetic codes, sequences, DNA, germplasm) presented obstacles to commodification and even greater obstacles to its claim as intellectual property. Indeed, as I have discussed, the natural characteristics of the biological realm itself presented the biggest challenge to commodification. Although seeds can be owned privately by a person – because they are freely reproducible – they defy what were once necessary criteria of property: *excludability and divisibility*.⁹ A naturally propagating species is not amenable to be apportioned in the same way as non-biological objects. Seeds are not a form of classic commodity with fixed embodiments. Each seed had the germ of the next and carries within it the propensity to reproduce its replicas. So technically, even though you could *own a* seed, it would not prevent the propagated versions of the same seed to be owned by your neighbour. One could argue that it is not the *same* seed but a similar one, but because in terms of its productive potential it may be identical, it fails to *exclude* the neighbour from enjoying the same benefits as the first owner. In other words, the exclusionary premises for the extension of “full liberal ownership” to plant genetic resources are weak.¹⁰

The natural characteristics of plant genetic resources constitute a biological barrier for its ‘full’ commodification. Jack Kloppenburg’s evocatively outlines the nature of this obstacle:

⁹*Ibid.*

¹⁰A.M. Honore gives a detailed account of the ‘full’ or the liberal concept of ownership which he says is common to all mature legal systems. The bundle of sticks that make up full, liberal ownership are: the right to *possess*; the right to *use*; the right to *manage*; the right to *income*; the right to *capital*; the right to *security*; the power of *transmissibility*; the *absence of term*; the *prohibition of harmful use*; the *liability to execution*; *residuary character*. Property rights are, according to him, proprietary rights, or ownership rights that a person exercises over corporeal or incorporeal things. *See further*, Honore, A.M., “Ownership”, in Guest, A.G. (Ed.), “Oxford Essays in Jurisprudence”, (Oxford University Press, 1961), at pp. 107-47.

‘Included in any compendium of "obstacles to the capitalist penetration of agriculture" should be the natural characteristics of the seed itself. Like the Phoenix of myth, the seed re-emerges from the ashes of the production process in which it is consumed. A seed is itself used up (or, rather, transformed) as the embryo it contains matures into a plant. But the end result of that process is the manifold replacement of the original seed. The seed thus possesses a dual character that links both ends of the process of crop production: *It is both means of production and, as grain, the product.*’¹¹

Commodification of the grain is as old as history. Grain displays traits of a commodity and is enabled with “property” sticks of use, exclusion, disposal and transfer. However, grain also has the capacity to become a means of production. A farmer may purchase seeds, consume it or use it as a means of production by planting it to generate a new crop. In planting the new crop, ‘farmers also reproduce a necessary part of their means of production.’¹² Unlike other means of production, seed as a mean of production does not have the propensity to create exclusionary premises. This linkage, as Kloppenburg says, ‘at once biological and social, is antagonistic to the complete subsumption of seed (as opposed to grain) under the commodity-form.’¹³ In order to circumvent this obstacle to commodification and to route the exchange of seeds through the market, somehow the act of saving seeds which had the propensity to propagate the altered genetic sequence, needed to be made contrary to law itself.

Commodification of seeds was pursued through two routes (Kloppenburger, 1988; Shiva, 1991; Berland and Lewontin, 1986).¹⁴ First, the technological route, through which plant varieties/seeds were genetically modified to display hybrid features. A large percentage of GM seeds can be saved and replanted and will regenerate its genetically modified form, albeit at times with reduced hybrid vigour.¹⁵ The second route to commodification was the legal-institutional or the *social* route. Privately developed plant varieties and genetic modification were demonstrable aspects of human intervention and innovation and therefore needed to be protected as intellectual property, i.e. as products of human invention. First UPOV and then TRIPS codified new rules and rewards of innovations. The innovators rights were to be protected as patents or a breeders’ rights granting them

¹¹ See, especially, Kloppenburg, Jack, “First the Seed: The Political Economy of Plant Biotechnology 1492–2000”, (Cambridge: Cambridge University Press, 1988), at pp. 10-11.[Emphasis mine]

¹² *Ibid.*

¹³ *Ibid.* at p. 11.

¹⁴ See Kloppenburg, (1988) *supra* n.13; Shiva, 1991; Berland, J.P. & R. Lewontin, “Breeder’s Rights and Patenting Life Forms”, *Nature*, 322 (28), at pp. 785-788.

¹⁵ Some GM seeds are known as “terminator seeds” or “suicide seeds” because their reproductive capacity has been stunted through what is known as Genetic use restriction technology (GURT). GURT is the name given to proposed methods for restricting the use of genetically modified plants by causing second generation seeds to be sterile. The technology was developed under a cooperative research and development agreement between the Agricultural Research Service of the United States Department of Agriculture and Delta and Pine Land company in the 1990s, but it is not yet commercially available.

salience over a “farmer’s privilege” to save, replant and exchange seeds outside of the market nexus. The reasons were clear and resonated in practically all international treaties and convention proceedings. Two documents - FAO and OECD - on policy concepts relating to plant varieties and plant breeders rights provides a neat summary of intent and the motivation behind IPRs:¹⁶

‘[N]ew plant varieties are afforded legal protection to encourage commercial plant breeders to invest the resources, labour and time needed to improve existing plant varieties by ensuring that breeders receive adequate remuneration when they market the propagating material of those improved varieties. In the absence of a grant of exclusive rights to breeders, the dangers of free riding by third parties would be considerable. This is because the genetic material within plants that specifies their distinctive and commercially valuable features is naturally self-replicating, for example by reproduction of seeds or other propagating material. Self-replication makes innovations incorporating biological material particularly susceptible to exploitation by parties other than the innovator.’¹⁷

‘IPRs in plant varieties [...] provide some assurance to breeders that they will be able to recoup the risks and costs of a value-added innovation that is based upon an underlying biological resource (OECD 1996).’¹⁸

While technology played a huge part in establishing social contingency (a point I make in RP 1), it was not a sufficient condition for an intellectual property claim to be established. A seed protected by a patent could regenerate its own replicas (generally speaking) and would therefore disable the exclusion and monopoly granted by the patent.

The ‘sufficiency’ condition was fulfilled through a couple of doctrinal shifts that were designed to circumvent the biological impediment to patent in “life products”. Doctrines that were foundational to the idea property – “labour theory of value” (John Locke, *Second Treatise on Government*, 1689), principles of “just acquisition” (Robert Nozick, 1974), “just transfer” (John Locke, 1689; Robert Nozick, 1974), “moral autonomy” (Kant 1991 [1797], “first occupancy” (Samuel Pufendorf, 1991 [1673] – indeed, all principles on which the edifice of legitimate property existed have had to be disowned or selectively implied and used.¹⁹

This paper looks at these doctrinal moves within legal framework of intellectual property, the “legal proceduralizations”, which have manifested themselves as *exceptions* to the prevalent doctrines. I

¹⁶ Laurence R. Helfer, “Intellectual Property Rights in Plant Varieties International Legal Regimes and Policy Options for National Governments”, FAO Legislative Study, 85 (2004), 3. *See also* W. Lesser, “Assessing the Implications of Intellectual Property Rights on Plant and Animal Agriculture”, *American Journal of Agricultural Economics*, 79 (1997), at pp. 1584–1591.

¹⁹ For a detailed discussion *see*, Chandra, R (2010), chapters 1-3

outline two doctrinal shifts here: the *product of nature doctrine* and the *patent exhaustion doctrine* that have enabled the realm of the biological to be incorporated into the social as a product of human contingency and creation.

This is the “*sleight of law*” that I refer to, and one that is instrumental in reifying plant genetic resources as intellectual property and embedding it with all the distributive and residential connotations of property. Law alters not just the instrumentality of conventional property law but also mandates an alteration of the foundational principles of traditional (industrial) patent law itself. It is important to look at them as they lie at the heart of the paradigmatic shift that law makes in order that technology can claim the intervened biogenetic realm as intellectual property and erase the commons/public goods character of plant genetic resources.

THE PRODUCT-OF-NATURE DOCTRINE

The “product of nature doctrine” has gained recent salience in context of patent claims over human genetic codes and sequences, most recently in the United States Supreme Court ruling in *Myriad Genetics v. Association for Molecular Pathology*.²⁰ Reference to this doctrine is not meant to derive ontological normativity of plant genetic resources from human genomics and related ethical issues related to, but to focus on the instrumentality of gene isolation and manipulation and the traction it has for plant genetic IP claims.

Conventionally, patents were granted for tangible, usually mechanical devices and processes, such as hydroplanes, radio navigation and so on.²¹ The patent system expanded to keep pace with developments in technology, and patents have been granted for less tangible inventions, and increasingly for inventions related to or incorporating fragments of genetic code. Numerous patents have been granted to biotechnological innovations make IP claims on genetic material in various form, isolated , purified, mutated and so on.²²

A critical aspect of difference between the two patent kinds – industrial and biogenetic – was the distinction industrial patents made between products of nature and manufactures and, impliedly, between discovery and human invention. As far back as 1889 in *Ex Parte Latimer*, the first product of nature decision and was issued as an opinion of the Commissioner of Patents, rejecting a patent

²⁰ 569 U.S. 12-398 (2013). The product of nature doctrine finds its earliest articulation in American jurisprudence; hence a large number of cases referred here are from American jurisprudential history. See also http://www.supremecourt.gov/opinions/12pdf/12-398_1b7d.pdf ass accessed on 04-08-2014.

²¹ For a list of mechanical and industrial patents see Bieberich, Jim, “Historical Patents of the United States”, as available at <http://www.uspat.com/historical/>, last accessed on 21-07- 2013.

²² For details see, Jensen, K. & Murray, F., “Intellectual Property Landscape of the Human Genome”, 310 *Science* (2005), at pp. 239-240; MM Hopkins et. al., “The Patenting of Human DNA: Global Trends in Public and Private Sector Activity”, (*The PATGEN Project*) (Brighton: SPRU, Science and Technology Policy Research, University of Sussex, 2006).

for ‘purified pine needle fibre’ and stating that fibre extracted from pine-tree needles ‘can no more be the subject of a patent in its natural state when freed from its surroundings than wheat which has been cut by a reaper.’²³ The US Patent Office recognized that it would be wrong ‘for an element or a principle to be secured by patent’, lest patents might ‘be obtained upon the trees of the forest and the plants of the earth.’²⁴

Patent law follows this intuition up to a point, at least prior to the *Diamond v. Chakrabarty*²⁵, which breached earlier agreed upon thresholds of human inventiveness. But before that, in a number of cases the US Courts rejected patents for natural artefacts. Two Supreme Court decisions are noteworthy – *American Fruit Growers v. Brogdex*,²⁶ where the Supreme Court rejected a patent for fruit treated with mould-resistant coating; and *Funk Brothers v. Kalo Inoculant Co.*,²⁷ where the SC invalidated a patent for a combination of natural bacteria. In both cases the Court invalidated claims for extracted plant material or for new combinations of bacteria. The arguments presented by the Supreme Court in the case of *Funk Bros*, is an instructive elucidation of the reasons why the inventive criterion does not withstand the challenges presented by products of nature, such as isolated bacteria. It states that the mixed cultures of root nodule bacteria, for which a patent was being claimed ‘are the work of nature’...‘patents cannot [be issued] for the discovery of the phenomena of nature.’²⁸ The judgement makes some very pertinent points:

Each of the species of root nodule bacteria contained in the package infects the same group of leguminous plants which it always infected. No species acquires a different use. The combination of species produces no new bacteria, no change in the six species of bacteria, and no enlargement of the range of their utility. Each species has the same effect it always had. The bacteria perform in their natural way. Their use in combination does not improve in any way their natural functioning. *They serve the ends nature originally provided, and act quite independently of any effort of the patentee.*²⁹ [Emphasis mine]

Intuitively powerful, these rationales formed the conventional wisdom that formed the loosely formed the “product of nature doctrine”, that excluded naturally occurring biological artefacts from the patentability. Interestingly, and perhaps significantly, there is no explicit articulation of the product of nature doctrine. In each case, the Federal Circuit judges relied on a different rationale in applying the “product of nature” doctrine to the claimed invention. In the *Funk Bros*. Case, the judgement stated that no new *utility* was created – the bacteria, in combination continued to perform the same

²³ *Ex parte Latimer*, 1889 Dec. Com. Pat. at p. 123, 127.

²⁴ *Ibid.* at p. 123.

²⁵ 447 U.S. 303 (1980)

²⁶ 283 U.S. 1 (1931).

²⁷ *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, S.Ct. 440, 92 L.Ed. 588 (1948).

²⁸ *Ibid.* at p. 130.

²⁹ *Ibid.* at p. 131.

function as they did in their natural state. In the *American Fruit Growers, Case* there was a clearer articulation of the product of nature doctrine and its distinction with items of *manufacture*. The *Century Dictionary* definition of “manufacture” was used – ‘anything made for use from raw or prepared materials.... [which gave] these materials new forms, qualities, properties, or combinations whether by hand or by machinery’ – to rule that the borax coating on the orange rind did not “*change in the name, appearance, or general character of the fruit*” [emphasis mine].³⁰ Similarly, in the *Hartranft v. Wiegmann*³¹ the ruling stated that ‘[t]here must be transformation; a new and different article must emerge 'having a distinctive name, character, or use.’³²

It is interesting to note that there is no distinct attribution of the product of nature doctrine separate from the patentability criteria of Title 35³³ (United States Code) of utility, novelty and non-obviousness, codified in the US patent statute of 1952. Cobbled together from dicta in older cases, the product of nature doctrine has increasingly been rendered vacuous. As technology expanded the realm of manufacture to incorporate the realm of “*physis*” as “*techne*” (a point I make in RP 1), law interpreted the meaning of invention as distinct statutory requirements of novelty, utility, and non-obviousness. The product of nature doctrine thus co-mingled with the statutory requirements of inventiveness, distancing itself from questions of ‘subject matter’ and earlier held distinctions between nature and culture.³⁴

The subsumption of the product of nature doctrine to the criteria of novelty and non-obviousness began its definitive journey from three landmark cases – *In Re: Bergy*,³⁵ *In Re: Chakrabarty*³⁶ and *In Re: J.E.M.*³⁷ Judgements in all three cases demonstrate the intent to rescind the product of nature doctrine and inscribe “life” within the domain of human inventiveness. In *Bergy*, the Court of Customs and Patent Appeals (predecessor of the modern Federal Circuit) upheld a patent directed toward a purified version of an antibiotic producing strain of streptomycin, a substance that appears in nature in an unpurified state. In *Chakrabarty*, the Supreme Court held that newly created bacteria were included within the term “manufacture” or the term “composition of matter” in section 101 and that genetically modified micro-organisms not found in nature can be patented.³⁸ In *J.E.M. Ag. Supply*

³⁰ 283 U.S. 1 (1931), at p. 10.

³¹ 121 U.S. 609 (1887).

³² *Ibid.* at p. 12.

³³ Title 35 U.S.C. 101, 102, 103.

³⁴ The distinction between nature and culture (natural and manufactured) lends itself to the doctrinal distinction upheld by patent law between invention and discovery. See generally Brownsword, Roger, Cornish, W. William Rodolph & Llewellyn, Margaret (Eds.), “Law and Human Genetics: Regulating a Revolution”, (Oregon: Hart, 2000).

³⁵ 596 F.2d 952 (C.C.P.A. 1979).

³⁶ 571 F.2d 40, 42 (C.C.P.A. 1978).

³⁷ 20 Kan. App. 2d 596 (1995).

³⁸ “United States: Summary of Court of Customs and Patent Appeals Decisions *In Re Bergy* and *In Re Chakrabarty* (Biological Research: Genetic Engineering; Patentability of Microorganisms)”, *International Legal Materials*, Vol. 18, No. 4 (JULY 1979), at pp. 983-985.

v. Pioneer Hi-Bred International, the Supreme Court held that newly developed plant breeds are also patentable.³⁹

IP law has had to alter the logical form of its instrumentality by selectively relinquishing the distinctions between two types of causal genealogies – the natural/biological mechanism and human intervention. A “bioethicist” quoted in a RAFI (Rural Advancement Foundation International) text, says that “[t]he product of nature doctrine has been rendered vacuous by allowing the isolation, purification, or alteration of an entity or substance from its natural state [and turning] it into something ‘not found in nature.’⁴⁰ Once a gene is removed from its natural state, is isolated and “purified” from a mixed ensemble of genetic profusion, it can be claimed as no longer existing in its natural state or can be claimed as “substantially altered” from its natural condition, and therefore as an act of social contingency. Biotechnologists who alter, modify, isolate, and purify naturally occurring micro-organisms become eligible for patent claims precisely because of the claim that the purified gene exists in a “novel” or a “non-obvious” state, detached from its nature given matrix and telos.

The significance and meaning of a doctrine is always a relational one, especially where the term (doctrine) and its signifiers are controlled and performed. I use the word ‘performed’ to suggest that there is nothing ‘self evident’ about doctrinal coherence. Till a point that they cohere with ‘civic epistemologies’ and appear as ‘normal’ utterances or practices, they prevail. Civic epistemology is a term introduced by Sheila Jasanoff to mark out the relations between science, publics and state, in which the ‘public is seldom so devoid of agency with respect to the production and application of scientific knowledge ...as in Foucauldian regimes of biopower.’⁴¹ It refers to shared, patterned understandings or ‘public knowledge’ - ways through which they assess the rationality and robustness of claims that seek to order their lives; demonstrations and arguments that fail to meet the test may be dismissed as illegitimate or irrational.⁴² How people know things in common, how they perceive certain S&T projects to be reliable or credible, and others as not, cannot be a priori assumptions about how publics relate to or understand science. These are ‘culturally specific, historically and politically grounded.’⁴³ Public knowledge-ways play an important part in co-productions of legal rules and regulations in a complex matrix of technology, state and globalized capital. Coherence with prevalent civic epistemologies allows the creation of authorship or inventorship over detached genetic codes.

³⁹ 534 U.S. 124.

⁴⁰ Ned Hettinger, cited in RAFI Communique, Jan - Feb 1994, “The Patenting of Human Genetic Material”, Available at: <http://www.etcgroup.org/sites/www.etcgroup.org/files/publication/492/02/raficom36humangenetic.pdf> . Last visited 25 Aug, 2014

⁴¹ Jasanoff, Sheila, “Designs on Nature: Science and Democracy in Europe and United States,” (Princeton University Press: 2005), at p. 248. Defining the term on p. 255, she says, “*civic epistemology refers to the institutionalized practices by which members of a given society test and deploy knowledge claims used as a basis for making collective choices.*”

⁴² *Ibid.* at p. 255.

⁴³ *Ibid.* at pp. 249, 255.

Law stabilizes this interruption by abandoning the product of nature doctrine and creating conditions for the continued reproduction of genetic engineering.

PATENT EXHAUSTION DOCTRINE

Biogenetic resources (and I take the example of seeds here to illustrate my point) present a conundrum for the patent exhaustion doctrine. Under the doctrine, again derived largely from US patent law,⁴⁴ once an *unrestricted*, authorized sale of a patented item occurs, the patent holder's exclusive right to control the use of *that* article is exhausted and the purchaser is free to use, sell that item without further restraint from patent law.

The term "unrestricted" serves as an important proviso. An unrestricted sale refers to sale without qualifications or restrictions imposed by the seller on the buyer. A restricted sale, impliedly, is one where restrictions or conditions are imposed on the buyer for the use or sale of the patented article. For example, it can exclude purchasers of that article from making the patented invention anew. In *Monsanto Co. v. Scruggs*⁴⁵ the court ruled that the initial sale of seeds by Monsanto to Scruggs was not an "unrestricted sale"; the sale required Scruggs to sign Monsanto's "Technology Agreement", which places conditions of a technology fee or a royalty bag of seed containing the Roundup Ready seeds sold by the seed company.⁴⁶

"Restrictions" play an important role in curbing the implications of naturally propagating resources. In the absence of restrictions, patent exhaustion terms would render the seed patent meaningless. The Court of Appeals for the Federal Circuit ('CAFC') ruled that '[a]pplying the first sale doctrine to subsequent generations of self-replicating technology would eviscerate the rights of the patent holder.'⁴⁷ Pertinently, this is not the first time that Monsanto has sued an individual farmer for patent infringement.⁴⁸ In another example, *McFarling v. Monsanto*,⁴⁹ the CAFC held that rights to second-generation seeds are lost by unencumbered sale of first generation seeds.

"Don't Blame-the-bean ": Monsanto v. Bowman

In a recent case⁵⁰, (a case I want to take up in some detail because the debate between the parties is one that probes the heart of the patent exhaustion doctrine) Monsanto, a producer of herbicide

⁴⁴ First enunciated by the Supreme Court more than 130 years ago in *Adams v Burke*, 84 US (17 Wall) 453 (1873), and subsequently in *US v Universal Lens Co.*, 316 US 241, 250 (1942).

⁴⁵ Fed. Cir. 2006, 459 F.3d at 1328, Nos. 04-1532, 05-1120, -1121 (Fed. Cir. Aug. 16, 2006).

⁴⁶ See *Monsanto Co. v. Scruggs*, 459 F.3d 1328, at p. 1336 (Fed. Cir. 2006). For details of Monsanto Technology Agreement see http://thefarmerslife.files.wordpress.com/2012/02/scan_doc0004.pdf, last accessed on 25-07-2013.

⁴⁷ *Ibid.* at p.12.

⁴⁸ Two other prominent cases concerning Monsanto have been *Homan McFarling v. Monsanto* [April 9, 2004] (CAFC [US] Nos. 03-1177, 03-1228); and *Monsanto Canada Inc. v. Schmeiser*, Canada, 1 S.C.R. 902, 2004 SCC 34.

⁴⁹ *Ibid.*

⁵⁰ *Bowman v. Monsanto Co.*, 657 F. 3d 1341.

resistant soybean seeds and technology, sued Vernon Hugh Bowman, a soybean farmer, for patent infringement.⁵¹ Monsanto argued that by planting the product of Monsanto's herbicide resistant seeds instead of purchasing new ones, Bowman was in violation of the Technology Agreement for the seeds.⁵²

Bowman's defense invoked the "patent exhaustion" doctrine of US patent law as per which, 'the initial authorized sale of a patented item terminates all patent rights to that item.'⁵³ Bowman argued that Monsanto's patent rights were exhausted once he bought the seeds and that use of progeny seeds is an expected use of the product. Monsanto responded arguing that in case of self-replicating technologies, the patent extends to the technology, here the trait of herbicide resistance, rather than the seed itself.⁵⁴

The District Court rejected Bowman's invocation of the patent exhaustion doctrine and awarded damages to Monsanto. On appeal, the Federal Circuit held that patent exhaustion did not protect Bowman because he had "created a newly infringing article" rather than use an article sold by Monsanto. In May, 2013 The Supreme Court granted *certiorari* on the issue of patent exhaustion. The patent exhaustion doctrine, as the Court explained, 'restricts a patentee's rights only as to the 'particular article sold; it leaves untouched the patentee's ability to prevent a buyer from making new

⁵¹ Two patents, of importance here, protect aspects of Monsanto's Roundup Ready technology that involves different parts of the herbicide resistance technology. First, Patent No. 5,352,605 ("605 ") which covers a process by which Monsanto combined two different sequences of DNA to create a new gene called a chimeric gene.

The second was Monsanto's US Patent No. RE39, 247 ("247E "). The '247E patent uses the process in '605 patent to create chimeric genes in soybean plants that makes them compatible with herbicides.

⁵² Monsanto distributes the patented seeds by authorizing various companies to produce the seeds and sell them to farmers. It required those seed companies to obtain a signed Technology Agreement from purchasers. Monsanto licenses its proprietary Roundup Ready technology through two interrelated licensing schemes. First, it licenses the patented gene to seed companies that manufacture the glyphosate tolerant seeds that are sold to farmers. Under this license, seed companies gain the right to insert the genetic trait into the germplasm of their own seeds (which can differ from one seed company to another), and Monsanto receives the right to a royalty or 'technology fee' of US 6.50 dollars for every 50-pound bag of seed containing the Roundup Ready sold by the seed company. Monsanto also owns several subsidiary seed companies that comprise approximately 20 per cent of the market for Roundup Ready soybeans. See Chandra, Rajshree, "Knowledge as Property: Issues in Moral Grounding of Intellectual Property Rights", (Oxford University Publishing, 2012).

⁵³ Patent exhaustion is a fundamental doctrine of US patent law, first enunciated by the Supreme Court more than 130 years ago in *Adams v Burke*, 84 US (17 Wall) 453 (1873). According to this doctrine, a patent's monopoly ends with the first sale or disposition of an article embodying the claimed invention by the patentee, or by a licensee of the patentee acting within the scope of the licence. As the court later noted in *US v Universal Lens Co.*, 316 US 241, 250 (1942): "*The patentee may surrender his monopoly in whole by the sale of his patent or in part by the sale of an article embodying the invention... But sale of it exhausts the monopoly in that article and the patentee may not thereafter, by virtue of his patent, control the use or disposition of the article.*" Quoted from Lennon, Michael J & Kenyon & Kenyon LLP, "The Growing Global Impact of the US Patent Exhaustion Doctrine", as available at <http://www.iam-magazine.com/issues/article.ashx?g=52a5e001-e3e5-4353-abe3-9f1f8ef48a3c> last visited on 17-07-2013.

⁵⁴ *Monsanto Co. v. Vernon Bowman*, Appeal from the United States District Court for the Southern District of Indiana in 657 F.3d 1341 (Fed. Cir. 2011).

copies of the patented item.’⁵⁵ Explaining that the patents are a system of reward that extend not just to the particular article sold but to the idea and technology behind it, the Court stated, ‘If the purchaser of that article could make and sell endless copies, the patent would effectively protect the invention for just a single sale.’⁵⁶ The doctrine of patent exhaustion thus does not allow the purchaser to make new copies of the patented invention.⁵⁷

The Bowman case represents the dilemma that seeds (or naturally propagating plant varieties) present for patent claims. On the one hand, the Supreme Court held that the harvested soybeans did not constitute the actual article sold by Monsanto, and rejected Bowman's arguments of patent exhaustion. Only the *actual* soybeans purchased by Bowman – which he could resell, consume, feed to his animals – came under the terms of patent exhaustion. ‘[T]he exhaustion doctrine does not enable Bowman to make additional patented soybeans without Monsanto's permission (either express or implied).’⁵⁸ The Court also held that this conclusion applied irrespective of how Bowman had acquired the seeds.

As a counter, Bowman's reply was interesting and gestures towards the conundrum that self-replicating biological materials pose not only for patent exhaustion term but to a conflict between the foundational principles of property and intellectual property. Bowman asserted that because the seeds naturally self-replicate or "sprout" unless stored in a controlled manner, it was the planted soybean, and not Bowman ‘*that made replicas of Monsanto's patented invention.*’⁵⁹ The Court found the "blame-the-bean" defence was "tough to credit,"⁶⁰ because Bowman was not a passive observer. However, the Court recognized that self-replicating inventions were becoming ‘ever more prevalent, complex, and diverse.’⁶¹

The ‘complexity’ of plant genetic materials does pose a challenge for patent law. The fundamental challenge for IP rights in plant genetic materials is how to create intellectual property beyond the “first-sale” in biological materials that replicate themselves? Does the fact of a patented technology's ability to replicate itself, give a purchaser the right to use replicated copies of the technology? Applying the first sale doctrine to subsequent generations of self-replicating technology would deprive the patent holder of his rights. And denying a farmer his right to use saved seeds, eviscerates his property rights.

⁵⁵ Supreme Court of United States, 569 U. S. (May 13, 2013), 5 As available at http://www.supremecourt.gov/opinions/12pdf/11-796_c07d.pdf.

⁵⁶ *Ibid.*

⁵⁷ *Ibid.* at p. 1.

⁵⁸ *Ibid.* at p. 5.

⁵⁹ *Ibid.* at p. 9.

⁶⁰ *Ibid.* [Emphasis mine]

⁶¹ *Ibid.* at p. 10..

The patent exhaustion doctrine represents a classic tussle between property rights and intellectual property rights. The TRIPS regime largely relies on the Union for the Protection of New Plant Varieties ('UPOV' – one of the earliest supranational agreements on IPRs in plant varieties). The UPOV was first adopted in 1960, and subsequently revised in 1972, 1978 and 1991, each time curtailing a "farmer's privilege" to reuse propagating material from the previous year's harvest and to freely exchange seeds. The use of the nomenclature "privilege" – to describe farmers' claim to save, reuse and sell propagating material – is not accidental, for unlike the term "right", a privilege is more of a *grant* of benefit rather than an entitlement. UPOV made farmers' privilege optional for member countries, while widening the ambit of what was ownable (as a property right) of "essentially derived varieties". When a legal regime chooses between a customary claim that a farmer has had over centuries – to save, reuse seeds (derived from a concomitant outcome of self replication of plant genetic resources) – and between intellectual property rights of the breeders, it is not just an innocent, apolitical extension of law to a new domain of life sciences. As Sunder Rajan puts it, 'life becomes a business plan,'⁶² where the very grammar of law and of life sciences are co-constituted.

CONCLUSION

Biotechnological artefacts coalesce very uneasily with both traditional property law and with conventional (industrial) patent doctrines and for this reason 'law' has had to renege on both the "product of nature doctrine" and on the "patent exhaustion doctrine". Intellectual property in biotechnological artefacts is a troubling idea from the perspective of conventional property law because conditions of scarcity are not operative in the biological realm in the same sense as with tangible (non-biological) objects of value. To allow patents in biological objects that owe their primary causation and instrumentality to nature, is to rescind the foundational principles of patenting and its connections with novelty. To dissolve the invention-discovery/nature-culture distinctions is also to dilute the foundational premise that instrumentalizes intellectual property. But most importantly, to prevent a farmer – who may be the rightful legal, purchaser and owner of GM seeds – from replanting or exchanging his seeds, is to curtail the domain of his property rights and consequently, his livelihood claims.⁶³ This is the political and the business end of things.

⁶² Rajan, S. (2006), *supra* n.7 at p. 283.

⁶³This can be called the techniques of *appropriationism* and *substitutionism* which displaces a farmer from his original location by substituting and appropriating both his processes and products. David Goodman, Bernardo Sorj, and John Wilkinson developed the parallel concepts of appropriationism and substitutionism in their theory of agro-industrial development described in *From Farming to Biotechnology*. Together, these concepts explain the industrialization of agriculture through the application of science and capital investments to discrete segments of the rural labor and biological processes in agricultural production. For details of the thesis see Goodman, D. & Sorj, B. et. al., "From Farming to Biotechnology", (UK: Blackwell, 1987).

This paper has tried to understand the manner in which alterations in the doctrinal landscape of intellectual property law sustains new technoscientific cultures that stabilize new ideas and new objects of intellectual property. Doctrinal shifts in property and patent law are conceptual moves that underpin a particular and encultured political rationality. These are moves which dramatically alter the character of technology, transforming it into property, and loading it with all the residential connotations of property and the “active” or performative ones of power. The interruption of the “product of nature doctrine” and the “patent exhaustion doctrine”, I have suggested, is a necessary manoeuvre to establish social contingency and, correspondingly, authorship over invention. The consequent conflation of discovery and invention, product of nature and product of manufacture, and the subordination of property to intellectual property, not only reproduce the process of genetic engineering, but also the labels and hierarchies that accompany epistemes through their mandated conformity with novelty, non-obviousness, utility, capability of industrial application.

What is important is the way in which the specific forms of life and population are posed within technology and law. The history of intellectual property, its institutions, its form, its objects and subjects is a history of the law accompanying economic and technological developments and stabilizing meanings and terms of appropriation and distribution. The rupture with earlier meanings of intellectual property and novelty is critical to the creation of property in biogenetic artefacts. Stepping out of an earlier doctrinal position becomes a necessary and a politically imbued manoeuvre to enable the propertization and monopolization of a realm that was earlier outside of the frames of intellectual property.

Clearly there are two mutually constitutive moves here, each underwriting the other's existence. The first move is a technological one that enabled the reification of the sub-cellular structure of plants into distinct commodities with distinct properties. The second move allows this to be commoditized and claimed as a product of human invention, as property. The legal cultural resources, with which biotechnologists bring biogenetic artefacts into view, often pre-exist the “discovery” of the objects themselves. As techniques of molecular biology become central to research and development efforts in biologically related fields, law serves to institutionalize the emergent economic space and devise property rules that facilitate the entry of organic, biological things in the taxonomic precincts of ‘property’. Law claims these newer forms, classifies them as biotechnological inventions and grants protection as patents or breeders’ rights, helping to reproduce intended outcomes. While technology creates new artefacts that can be claimed as property, law, in a joint enterprise with biotechnology, co-produces the reification of biological property as intellectual property.

The importance of this argument does not lie in the rather broad reflections on social constructionism of science and technology projects in general, or biotechnology in particular. Rather, it draws attention to science and technology projects as exercises in production of power (Jasanoff 2006, 2005;

Latour 1999, 1988, 1987; Pickering 1995; Hacking 1999), just as race, gender, class, caste function as modes through which power is exercised and reproduced. This it does primarily via two routes. The first has to do with dissolution of fundamental distinctions between social norms (technological, economic and juridical) and organic (natural) norms, such that the cultural practice of science and technology appear as naturalized practices, capable of universal application and ‘*portability* across time, place and institutional contexts.’⁶⁴ Simultaneously, other epistemic practices – that vary across cultures – are rendered either less or non-credible, making biotechnology productions a specific instance of a larger claim for cultural domination.

From what may be property, to who may own, to articulations of use, the struggles over intellectual property relate, fundamentally, to a struggle over contesting meanings of nature, culture, knowledge, ownership etc. The very process of defining what constitutes intellectual property effectively reinforces particular perspectives that may benefit some at the expense of others, rendering some things as property while others remain 'freely' available.⁶⁵ Institutionalization of IP law serves not just to draw lines, delineating realms of property but to construct and secure social arrangements. Law in fact formulates the discourse that lends meaning, conceptions and a vocabulary for the participants in the legal system relating to claims of rights. The field of science or biotechnology, and its attendant legal paraphernalia, is ideologically imbued with the particularistic epistemic footprints. Science and technology projects become, like other cultural practices, socially contingent and ideologically infused. As it lends the vocabulary of modern property law to forms of biological species, property law also serves another purpose. It helps society to determine who has what rights to these biological materials.

⁶⁴ For recurrent and partially overlapping themes in S&T scholarship – of which intelligibility and portability are one – see Jasanoff, 2006, *supra* n. 69, at pp. 5-6.

⁶⁵ See, Cutler, A. C., Haufler, V. and Porter, T. (Eds.), “Private Authority and International Affairs”, (Albany: State University Press of New York, 1999), at p. 347. Indeed, asymmetrical economic power goes a long way toward explaining why semiconductor chips are identified as intellectual property, whereas indigenous folklore is not. See, Drahos, P., “Indigenous Knowledge and the Duties of Intellectual Property Owners”, *Intellectual Property Journal*, 11: 179-201.