COMMODIFICATION, CONTROL, AND THE CONTRACTUALISATION OF THE HUMAN BODY*

THIRUVALLORE THATTAI Arvind
Professor, Law, University of York, UK

and

Aisling MCMAHON
Lecturer, Law, Maynooth University, Ireland

Abstract :

This chapter puts the philosophical debate on commodification in the context of the legal concept of commodities. In law, commodification is intrinsically connected with contractualisation, through which contract acquires a central role in structuring social relations. This link between contractualisation and commodification has two consequences. Firstly, it gives its objects a legal value, turning them into objects capable of being traded through market transactions and placing the focus on their commodity-value rather than social perceptions of their intrinsic worth. Secondly, in a commodified conception of contracts, the standing of people in their relations with each other is understood in terms of the characteristics of the contractual transactions linking them—their conformity with the parties' agreement, their fitness for the purposes to which they are applied, etc. This excludes values and evaluative positions other than the contractual values of autonomy and self-ordering. Through an analysis of the impact of patent law on areas ranging from the patenting of isolated genes to access to medicines, we show that commodification affects more domains and has deeper effects than generally assumed. Commodification directs the legal system's focus towards facilitating the creation of contractual frameworks of self-ordering, and towards insulating law from the broader dimensions of the value of human life, well-being, and different forms of human striving. We argue that the study of commodification must evolve beyond focusing on the limits of markets, and must also focus on the limits of contracts—which are generally modelled on an exchange framework as a way of conceiving relations and on private frameworks of regulation—their aetiology, and on devising ways of ameliorating such limitations.

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INTRODUCTION: THE INSTITUTIONAL LIMITS OF MARKETS

Much of the literature examining the limits of markets has focused on their moral or normative limits: on the types of commodities that, as an ethical matter, ought not to be subject to market mechanisms. Our focus in this chapter, in contrast, is on the *institutional* limits of markets – on the things that markets are and are not capable of doing – and the implications of those institutional limits for the social role we assign to markets.

From an institutional perspective, two points stand out when we analyse the creation of novel markets in areas such as the human body and environment. The first is that markets in these areas depend on the law giving things which are not commodities a new legal identity as commodities – a process which we term "commodification-by-fiat." The second is that commodification and marketisation involve not just exchange, but also the emergence of private contracts as a key instrument of governance. To commodify something is not just to subject it to monetary exchange, but also to subject it to governance by contract – a process which we term "contractualisation." The debate around the limits of commodification and the market has traditionally been framed in terms of moral and ethical considerations – autonomy, agency, vulnerability, value, and so on – in large part because of its preoccupation with understanding the normative limits of markets. By studying the institutional limits of markets, we seek, in contrast, to place the focus on a different set of issues: namely, the problems inherent in using contract as a way of conceiving social relations and the limits of contract as a form of social organisation.

At one level, the relationship between markets and contracts is intuitive: markets function through contract, and market exchange depends on parties contracting with each other. However, contract also limits the range of social interests which receive legal protection. In both the common and civil law worlds,[1] contracts are treated as a form of private governance or private regulation which is given considerable freedom to derogate from the priorities and values established in public frameworks of regulation. Whilst *ordre public* and public policy exceptions do apply, they do little to prevent contractualist values of autonomy and self-ordering from taking priority over more relational values, such as trust, reliance, and power. Nor do they stop ordinary, default rights that are assigned a high priority in public frameworks of governance from being deprecated in private frameworks of governance.[2] The result is that contracts not only direct attention away from ethical and distributional issues, but also reduce the question of the scope, extent, and limits of one's legal entitlements to one of contractual interpretation, leave the balance between competing interests to be settled by private actors acting in their self-interest, and erect hurdles to drawing other values into consideration.

Although these dimensions of contracting have been a central feature in relational critiques of private law,[3] they also have implications for commodification. Commodification is the primary device by which a given issue passes from public frameworks of governance to private, contractual, frameworks of governance, facilitating the creation of contractual frameworks of self-ordering and towards insulating law from broader dimensions of the value of human life and well-being. The study of commodification must accordingly evolve beyond

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[1] See e.g. art. 1103 Code civil: "Les contrats légalement formés tiennent lieu de loi à ceux qui les ont faits."

[2] For a recent critical analysis of this dimension, see M. J. RADIN, *Boilerplate*, Princeton University Press, 2013.

[3] I. MACNEIL, *The New Social Contract*, Yale University Press, 1980.

focusing on the ethical limits of markets, and also focus on the limits of contracts – specifically, of traditional theories of contract grounded in exchange as a way of conceiving of relations and of private frameworks of regulation as a way of structuring them, and the impact they cumulatively have on the ability of the law to respond to broader interests.

We illustrate our argument through an extended case study of patent law. Although they have rarely been discussed in the literature on commodification, patents and patent licensing self-evidently commodify their subject matter by making them subject to market transactions. They thus provide a classic example of how commodification and contractualisation mask their impact on rights that are of foundational importance to the legal system in other contexts – specifically, the right to health, life, and culture – and of the role of contractualisation in perpetuating existing inequalities. And although public policy provisions exist in the form of exclusions against granting patents if the exploitation of an invention is against morality/*ordre public*, such provisions tend in practice to be marginalised and are rarely successfully used to challenge private legal entitlements. These issues are deeply embedded in modern markets, and flow directly from the specific, reductionist understanding of social relations on which both commodification-by-fiat and contractualisation rest. As such, they cannot easily be addressed by regulatory intervention, and instead require a fundamental re-conceptualisation of the role of commodification and contractualisation in governance.

Part I of this chapter puts the philosophical literature on commodification and marketisation in the context of the role of contract in markets. We argue that commodification is closely linked with broader tendencies in the modern state – and, specifically, the role that markets and contracts play in modern forms of regulatory governance. Whilst this gives them an attractive – and alluring – philosophical foundation, it also means that they are built on a reductionist understanding of social interaction, of human culture, and of the human relationship with the environment. This has non-trivial implications for the types of interests of which they can take cognisance, as well as the relative priorities of the interests they protect.

Part II builds our case study of the patent system. We use the examples of the commodification of isolated genes and medicines through the patent system to demonstrate the way patents and licences mask the underlying and integral relationship between medicines or health technologies and the human body. Rather than focus on the intrinsic value of humans and loss of life caused by limitations on access to genetic testing or medicines, a commodified, property-based representation emphasises the importance of intellectual property rights as a key driver of innovation, and focuses on the risks of creating exceptions to intellectual property rights. The result is a second-order commodification of the human body and its well-being, whose effect is to insulate patents from considerations of the costs to human life, whilst also having a propensity to direct productive effort away from developing medicines or diagnostic testing which make greater contributions to human wellbeing.

Part III turns to the broader implications of this commodified approach and the ways in which we might mitigate its impact. We argue that the limits of contracts have serious implications for how we study the limits of markets as mechanisms of social governance and social ordering. The standard solutions, which call for greater regulatory intervention without fundamentally altering the legal framework within which commodification occurs, can even in the best case only address a part of the underlying issues. Breaking out of the fetters set by the traditional contractualised frameworks, and moving towards a system which better encapsulates or at least acknowledges the broader interests and dimensions of human interaction that are left out of a contractualised account, requires a more fundamental re-evaluation of the current approach. Marketisation, in particular, must be viewed not as a tool of unique efficacy or as a natural consequence of a commitment to autonomy. Instead, it should be seen as simply one regulatory tool amongst many, with its own institutional weaknesses and limits.

PART I: CONTRACTUALISATION, COMMODIFICATION, AND THE SOCIAL WORLD

A. – *The growth of commodification*

The starting point for the argument we set out in this chapter is the relationship between markets, commodification, and contracts, and the role they play in modern governance. At the heart of the modern approach to regulatory governance is a reliance on market-oriented legal mechanisms to deal with regulatory and allocative issues, and an expansion of those mechanisms to cover an ever-broadening swathe of social and cultural life.

Although commodification is a complex phenomenon shaped by a range of cultural and economic factors,[4] the expansion of markets is not an organic social development. To be viable, markets require supportive legal and governmental institutions. The expansion of markets into new areas has been underpinned by state action and, specifically, by "commodification-by-fiat": the use of law to transform objects and phenomena that are not natural commodities – in that they are not produced for consumption on the market – into juristic commodities – objects of law that can be bought, sold, and dealt with via market mechanisms. Simultaneously, state policy creates and upholds the perception that the underlying social issues of allocation, regulation, and mediation between conflicting interests are best dealt with through market mechanisms, which have an efficacy and legitimacy that other regulatory and allocative mechanisms lack.

The spread of markets, in other words, is predicated on the ability of the law to create fictitious commodities[5] out of natural phenomena and objects. Much of the modern economy is underpinned by precisely such processes. The approach to the regulation of financial markets that has dominated the western world for the past three decades, for example, is also dependent on the law treating "risk" as a commodity capable of being bought, sold, divided, combined, and traded on the market even though the actual empirical phenomenon underlying it – the uncertainty produced by our having only an imperfect and limited ability to predict the range of possible future positions of the market – is obviously not a commodity. Much the same could be said of the insurance market which, notwithstanding the traditional private law view of insurance as a means of loss spreading,[6] in practice functions through complex, structured transactions involving commodified risk (as a study of the balance sheet of any large insurance company shows).[7]

In both these instances, the mechanism through which commodification takes place, and through which the commodity is subsequently dealt with on the market, is contract. This is also true of commodification more generally. Commodification, in this sense, is ubiquitous in contemporary social and intellectual life, and it exercises a considerable hold over political and philosophical debate. This also applies in relation to nature, where the use of the law to create fictitious commodities is frequently uncontroversial. Spectrum auctions, for example,

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[4] N. CASTREE, "Commodifying what nature?", *Progress in Human Geography* 2003, p. 273-297.

[5] The terminology of fictitious commodities is taken from the work of Karl Polanyi, although we use the term in a broader sense than Polanyi (who, in this respect, was primarily concerned with the traditional socialist investigation of land, labour, and capital). K. POLANYI, *The Great Transformation*, Farrar & Rinehar, 1944, p. 44, where he saw land, labour and capital as "fictitious commodities" as they were "not produced for sale on the market."

[6] See e.g. J. STAPLETON, "Tort, insurance and ideology," *Modern Law Review* 1995, p. 820. Contrast F. EWALD, *L'État providence*, Grasset, 1986, which notes the commodificatory basis of insurance societies, and the need for a way of thinking not based in private law to deal adequately with the challenges it poses for states.

[7] But see R. MERKIN and J. STEELE, *Insurance and the Law of Obligations*, Oxford University Press, 2013.

require the law to commodify the natural ability of the atmosphere to act as a medium for propagating waveforms in the electromagnetic spectrum, by treating this ability as if it were a commodity ("spectrum") owned by the state, which can be bought, sold, and licensed in precisely the same way as a ship or a building, and whose purchasers or licensees can agree to share, combine, and divide it much as with any commodity.[8] Nevertheless, this form of commodification causes little theoretical controversy.

B. – *Contract and the allure of commodification*

The role of law in supporting novel markets highlights the importance of analysing the limits of markets with reference not just to their political and philosophical limits,[9] but also the limits of the legal mechanisms used to translate moral and ethical considerations into practical policy. From an institutional perspective, this requires us, in the first instance, to understand their general success. What explains this trend? What is the logic underlying this peculiar allure of commodification and markets as ways of responding to social problems? The answer lies in the utility of a resort to markets as a way of resolving complex social problems, and the strong philosophical resonances markets and contractual autonomy have. In her work on legal change, Professor Jenny Steele has argued that certain legal concepts have an allure, in that:

> For example, they may very neatly capture a way of approaching a complex problem; or they may carry inherent normative appeal […] An alluring concept is not only a good representation of what is needed; it also appeals in some other way. Perhaps it carries its own explanation implicitly with it, possibly even by making an appeal to common or shared morality. Or perhaps it is simply "neat": a distillation of what needs to be thought about, considered, or calculated in order to reach a conclusion.[10]

Commodification through contract is alluring in both these senses. Linking commodification to contract grounds it in the moral principle of autonomy, which has strong resonances in western political thought. It also embodies a form of "neatness." Entrusting an aspect of social governance to a market constituted by contract is an alluring way of resolving a social issue because it shifts legal responsibility to processes instead of outcomes, significantly lightening both the regulatory burden and the culpability of the law for producing particular outcomes.

C. – *The consequences and limits of contractualisation*

Where, then, do the downsides of markets come from? The answer lies in the very factors that make contractualisation and marketisation so alluring. In the paper cited above, Professor Steele points to an important danger of the allure of concepts:

> Particularly with the most appealing of concepts, it may appear that the linguistic structures provided by the concept genuinely provide the route to decision-making; and there is the temptation to neglect the underlying interests and outcomes that are

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[8] See discussion of spectrum auctions *in* P. CRAMTON *et al.*, "Using spectrum auctions to enhance competition in wireless services," *Journal of Law and Economics* 2011, p. 167-188.

[9] D. SATZ, *Why Some Things Should not be for Sale: The Moral Limits of Markets*, Oxford University Press, 2010; M. TREBILCOCK, *The Limits of Freedom of Contract*, Harvard University Press, 1997.

[10] J. STEELE, "Alluring concepts," Paper presented at the Symposium on Fossilization and Innovation in Law, Newcastle University, July 11-12, 2016, available at https://pure.york.ac.uk/portal/files/58892586/Alluring_Concepts_july.docx.

> inevitably involved. Thus, the "allure" of concepts may be as dazzling and as dangerous as it is attractive […] We tend to think that the forms of words we use actually are what is being developed or decided by the law: the general begins to rule over the factual and particular.[11]

Underlying this point is the position that all legal structures and concepts are reductionist,[12] and based on a deliberately narrow understanding of the pattern of human interaction. Legal concepts embed evaluative criteria which direct legal officials to consider certain factors but not others. The effect is to create representations of real-world phenomena, which are substituted for the phenomena themselves within the law's reasoning.[13] The drawbacks of commodification follow from the character of the representations of social interaction implicit in contractualisation, and the dimensions of empirical interaction which they leave out of the picture.

The work of Karl Polanyi provides a useful starting point in exploring what these are, because this very issue was his primary concern. The central plank of Polanyi's work was his analysis of the growing divergence in modern polities between economic relations as they actually are, and the same relations as represented in political accounts. In the empirical world, economic relations are naturally "submerged" or "embedded" in social relations.[14] The governance of modern societies is, however, characterised by representations which "disembed" the economy and economic relations from the social relations of which they are part, by conceptualising the economy as a system of self-regulating markets which automatically set prices and allocate resources independently. Polanyi argued that these representations are false. In the empirical world, markets depend for their existence and functioning on a range of social institutions, including many created by the state, which makes dis-embedding impossible.

Polanyi derived from this that the mode of transacting which is the focus of classical contract theory – market-based exchange – is neither the only nor the primary form of transaction. As relevant are two other patterns of behaviour – reciprocity and redistribution.[15] Reciprocity as a mode of transacting entails doing acts not because they are part of an exchange contingent upon the rendering of performance by each party, but because actions of that type are institutionalised, as a result of which the person in question will benefit from the fact that others, too, act similarly.[16] Redistributive institutions are characterised by having, as a key purpose, the appropriation for the benefit of others of a portion of the surplus that is generated by or accrues to one party.[17] Unlike reciprocity, there is no expectation of mutual benefit in redistribution, and it is therefore typically implemented through a centralised mechanism. Centralised food stores in hunter-gatherer societies are the classic example, but the same

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[11] *Ibid*.

[12] See F. SCHAUER, "Formalism," *Yale Law Journal* 1988, p. 509.

[13] A. HÄGERSTRÖM, *Filosofi och vetenskap*, Stockholm, 1957, p. 126-128, 171-179.

[14] K. POLANYI, *op. cit*., chap. 4.

[15] In describing these classes, Polanyi was characterising not only interpersonal interaction as such, but also the ways in which such interaction could be integrated into an institutional form. Polanyi was, specifically, interested in the integration of individual exchanges into an economic system, and the institutional conditions under which that could happen. See K. POLANYI, "The economy as instituted process," *in Trade and Market in the Early Empires*, Henry Regnery, 1957, p. 243.

[16] As Elinor Ostrom has pointed out, institutionalising reciprocal action is one of the primary means by which the problem of free-riders is dealt with. E. OSTROM, *Governing the Commons: The Evolution of Institutions for Collective Action*, Cambridge University Press, 1990.

[17] Unlike reciprocity, where a person who confers a benefit in one round of interaction is also likely to herself benefit in a future round, the person giving up the surplus in a redistributive institution does not necessarily ever expect to benefit from redistribution. K POLANYI, "The economy as instituted process," *loc. cit.*, p. 253-256.

principle has been recognised as applying in a broad range of economic transactions, including the modern welfare state.

In the empirical world, all systems of interaction contain all three types of forms in integration. An ideal representation which treats economic relations as being dis-embedded, in contrast, treats market exchange as the most natural type of transaction, and de-emphasises the role of the other systems of interaction. This is particularly true of large-scale institutions by which individual transactions and individual instances of social interaction are integrated into a broader system. Structuring formal institutions as if society were ordered exclusively on the basis of exchange does not banish or diminish the elements of reciprocity and redistribution. Instead, it creates a mismatch between the formal institutions of governance, and the reality of the polity to which they apply.

Polanyi's insights on this issue apply equally to contracts as a form of social organisation and provide us with a framework for identifying the dimensions of interaction a contractualised regime ignores. As a system of self-regulation, contracts encompass all types of social interaction including reciprocity and redistribution. The primary failing of marketised approaches to contract, thus, lies in their reduction of contracts to an exchange theory of interaction. Contracts, particularly in the complex settings that are the subject of novel markets, are not mere exchanges. They incorporate significant elements of reciprocity and redistribution. Commodification-by-fiat and contractualisation, in contrast, are principally focused on exchange, narrowly understood, and have little room for reciprocity and redistribution.

Table 1 sets out an overview of the impact this has on governance and society. As the table demonstrates, its implications go beyond the legal paradigm used to regulate a particular type of social phenomenon (set out in the second column). It also creates a new understanding of the ideal-type of social interaction, which eliminates dimensions of interaction that are not commensurable with the market-based account. The consequence, as the final column of the table documents, is to reshape and alter actual human relations. The primacy of exchange-oriented contracts as a social structure creates a derelationalised understanding of social interaction, a commodified representation of community, and a dejurified approach to governance.

Each of these affects both how relations are perceived and how they are regulated. Exchangeability, for example, refers to the view that all things are commensurable, so that anything can replace anything else, because everything is capable of being measured in monetary terms. Derelationalisation survives as a way of understanding a social phenomenon because it is based on a social vision where exchange and exchangeability form the relational underpinning of social interaction. Fungibility, similarly, refers to the view that no commodity is unique: one peppercorn is the same as another, and so are all commodified things including inventions under patent, whether they are medicines, components of a machine, isolated genes etc. This gives them a colourless quality: the commodity is divorced from the purposes that might have prompted its acquisition or desire for its acquisition (i.e., the underlying human wants or needs) simply because the law is never concerned about why commodities are being acquired or what the person acquiring them intends to do with them.

Table 1 The impact of commodification on social relations

Social phenomenon	Legal understanding of the phenomenon	Effect on relations
Structure	Contractualisation	Alienation
Interaction	Derelationalisation	Exchangeability

Community	Commodification	Fungibility
Governance	Dejuridification	Managerialism

By far the most significant consequence, however, is the dejuridification that accompanies marketisation. Contractualisation creates an alienated[18] understanding of human relations both at the level of the parties themselves, and at the level of their relationship with non-parties. It is fundamental to institutional structures based on exchange (as distinct from reciprocity and redistribution) that an individual who desires access to a commodity must contract for it on the market: exchange is the primary means of acquiring access to a thing. For the parties themselves, the consequence is to entrench the priority of exchange and exchangeability as the primary yardstick of value, and of exchange-based self-regulation as the primary mechanism of governance. In either case, the consequence is to dejuridify the transaction by assigning primacy to the system of rights and obligations created by the exchange, at the expense of those to which the legal system would otherwise assign priority.

Critically, every one of these legal incidents of commodification and contractualisation makes perfect sense when one *is* dealing with real commodities. A peppercorn is in fact fungible and near-infinitely exchangeable, and parties to such a transaction are typically dealing with each other in an alienated way in which their social relations, and the broader system of rights and entitlements set out by law, are of relatively little relevance to their specific transaction. Their primary concern, instead, will almost invariably be the effective management of the risks and potential problems that could arise in the course of the transaction. It is only as the characteristics of a given transaction begin to recede from a transaction involving real commodities – as the fictitious character of the commodities that are the subject of the market become ever more apparent – that these incidents begin to assume a more problematic character. In the next section, we explore this in more detail with reference to an important, but less studied, instance of the modern trend to commodification and contractualisation in the area of the body, namely, the modern patent system.

PART II: CONTRACTUALISATION, PATENTS, AND THE HUMAN BODY

In many ways, the patent system instantiates the issues we have discussed in Part I. Although intellectual property is not often considered in the literature on the limits of commodification,[19] as a legal device it is closely connected with commodification,

[18] The term "alienation" is today associated with Marxist critiques of capitalist production, but is used here in the sense it has in the work of Georg Simmel. Alienation, in Simmel's theory, does not refer to the relationship between workers and the products of their labour. It refers, instead, to the transformation of social relations between people, in consequence of the dematerialisation of relations, which makes it possible to relate to them as if they were a commodity, rather than as person to person. G. SIMMEL, *The Philosophy of Money*, Routledge, 1978.

[19] For an exception to this, albeit not in the legal literature per se, see: D. A. POSEY, "Commodification of the sacred through intellectual property rights," *Journal of Ethnopharmacology* 2001, p. 3-12; P. MÍGUEZ, "Intellectual property and the forced commodification of knowledge," *Universitas* 2018, p. 41-62. There is also some discussion of this in the literature on plant breeding which contains a discussion of this in places, including: T. WATTNEM, "Seed laws, certification and standardization: Outlawing informal seed systems in the Global South," *The Journal of Peasant Studies* 2016, p. 850-67; G. AISTARA "Seeds of kin, kin of seeds: The commodification of organic seeds and social relations in Costa Rica and Latvia," *Ethnography* 2011, p. 490-517; E. DEIBEL, "Open variety rights: Rethinking the commodification of plants," *Journal of Agrarian Change* 2013,

contractualisation, and the dejuridification that accompanies marketisation. The grant of a patent is, in form and substance, a direct instance of commodification because once granted the patented product and process comes under the control of the patent-holder who can determine use of that product/process through the grant or refusal of licenses. In short, licensing supports this system of commodification acting as a form of contract which the patent holder can enter into with the licensee for use of the invention following a negotiation of terms which are agreeable to the patent holder, whereby the "use" of the product/process is granted to the licensee in exchange for money or other value, and often the "use" will be granted subject to conditions on use that the patent holder may apply. Patent law contains precisely defined routes to enforce and challenge patents focusing on the technical application of patent criteria (namely whether the patented product/process meets tests of novelty, inventive step, and industrial application).[20] If it meets such criteria, considerations such as the impact of particular patents on health or human lives are rarely taken into consideration within patent law at grant or opposition stage, and even when they are, they tend to be treated as outside the purview of patent law, as one of us has argued elsewhere. This reflects the institutional preference in favour of patent grant at the EPO, and the marginalisation of ethical issues by the EPO lest these engender uncertainty in patent law and reduce the incentives patents create.[21] Hence, the broader ethical issues posed by patents are often readily dismissed within patent systems. The main public policy limitations on patents – the provisions on morality and *ordre public* – exclude patents when the commercial exploitation of the invention is against *ordre public* or morality in Europe.[22] However, these provisions have been interpreted highly restrictively in practice,[23] and have never to date been used to deny patents on the basis of the health-related implications arising due to the use or subject-matter of the patent.[24]

Furthermore, patents exhibit the other characteristics set out in Table 1. *Derelationalisation* and *dejuridification* occur because the commodification of the invention (the patented product or process) as an object under license (contract) means that the personal links or relationships that might otherwise generate duties or obligations between the licensee or patent holder and third parties are broken. Instead, the focus shifts to one where party A has a patent and therefore can control use, with the question being whether those using the invention obtained the correct licence (a form of contract) from the patent holder to use the invention. The effects on other parties, or duties a patent holder or licensee may have to other parties, become subsumed within the market-based nature of the transaction, through

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p. 282-309 ; J. K. KLOPPENBURG, *First the Seed*, 2nd ed., Cambridge University Press, [1988] 2004; D. RANGNEKAR, "Commodification of seeds," *Science as Culture* 1996, p. 301-312. This is also alluded to in: S STERCKX & J COCKBAIN, *Exclusions from Patentability: How Far Has the European Patent Office Eroded Boundaries?*, Cambridge University Press, 2012.

[20] This is the terminology for patent criteria in Europe, as set out in the European Patent Convention 1973, Art. 52. Similar criteria apply in other patent jurisdictions, as all WTO States are party to the TRIPS Agreement which states at Art. 27(1) that: "Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."

[21] A. MCMAHON, "Gene patenting and the marginalisation of ethical issues," *European Intellectual Property Review* 2019, p. 608-620; A. MCMAHON, "An institutional examination of the implications of the unitary patent package for the morality provisions: A fragmented future too far?" *IIC International Review of Intellectual Property and Competition Law* 2017, p. 42-70; See also S. STERCKX & J. COCKBAIN, *op. cit.*; M. A. BAGLEY, "Patent first, ask questions later: Morality and biotechnology in patent law," *William Mary Law Rev.* 2003.

[22] Art 53(a) EPC, and Art 6 Biotechnology Directive 98/44EC.

[23] A. MCMAHON, *The morality provisions in the European patent system: An institutional examination*, PhD Thesis, University of Edinburgh 2016. See also S. STERCKX & J. COCKBAIN, *op. cit.*; O. MILLS, *Biotechnological Inventions: Moral Restraints and Patent Law*, Ashgate Publishing 2005.

[24] Examples of health-related implication of patents include potential issues of access, high costs of patented product/process, or impediments the patented invention may cause for research and development in a health-related area. See A. MCMAHON, "Gene patenting and the marginalisation of ethical issues," *loc. cit.*

presenting the contract as a neutral exchange. The patent licence, in consequence, becomes the sole focus: other rights are neutralised or stripped away and the issues become conceived of around the licence, to the exclusion of potential broader rights or interests of individuals seeking to access patented medicines or diagnostic tests involving patented genes, where applicable. Similarly, *exchangeability* and *fungibility* apply in such contexts because the quality or nature of a particular invention is irrelevant – the neutrality of patents, markets, and licences mean that it is of little relevance whether the patented invention is a component of a computer device or a life-saving medicine under patent. Instead, the way in which the system operates means that the core concern is the fact that legally it is an invention under patent, to which the same rules apply regardless of what the invention is. Taking these characteristics together, we argue that the commodification process has the effect of changing the ordinary perception of the underlying invention in ways which actively prioritise market-based values and erase the human-value-laden characteristics or impacts which such patented inventions (medicines, isolated genes, genetic tests, etc.) would otherwise be viewed within. In effect, by conceiving of, or labelling these aspects of the body or medicines etc. as inventions subject to patents, they are displaced out of standard social contexts and viewed within a market-based framework which has important effects. The commodification for which patent is an instrument, and the private governance for which contract is an instrument, acting together thus subsist in a self-reinforcing cycle.

This is problematic, because it ignores the features and characteristics of the specific object under patent. For instance, patents over elements related to the human body, pharmaceuticals, or traditional medicines can have an impact on individuals' access to, and experience of, medicines or genetic tests. Whilst public systems of regulation decry commodification of the body in all forms, and indeed direct commodification of the body *per se* is expressly excluded from patentability within the Biotechnology Directive,[25] the indirect commodification achieved by patents has potentially devastating effects. Despite this, the role of patent and licensing structures is to move such issues outside the purview of traditional public governance frameworks to within the private regulatory system created by contracts (via licensing) thereby masking these effects. The combination of commodification and contractualisation thus curtails access indirectly, typically for an individual not directly involved in the primary "transaction," i.e., the licensing parties (patent holder and licensee). As we show, this can lead to potential limitations on access to medicines or genetic testing, and also on how such medicines/tests are provided, if at all, for individuals, often affecting in particular those most in need.

The remainder of this section employs examples from patents related to the human body as case studies to demonstrate how patents and licensing regimes around patenting shift perceptions of the underlying "invention." This leads to problematic outcomes which often entirely fail to account for impacts upon third parties and the public interest. In doing so, the section takes up two key examples, namely, a) patents directly related to elements of the body, specifically patents on isolated genes, and the impacts of such patents on the human body; b) patents on medicines, which influence human health and thus indirectly, albeit often significantly, impact upon the human body.

A. – *Patents on elements of the body – isolated genes*

[25] Art. 5(1) states that the human body in all its stages is not patentable. However, 5(2) reduces the effect of this by stating that elements isolated from the body are patentable.

Although patents are not available on the human body as such,[26] elements isolated from the human body or produced by a technical means, such as human genes, are in the European context still patentable.[27] In contrast, following several recent high-profile challenges in the United States and Australia, in 2013 and 2015 respectively, isolated genes are no longer patentable in these jurisdictions.[28] Looking at these recent challenges to gene patents and earlier challenges in the European context provides an ideal case study to demonstrate the effect of commodification through patents and licensing on human health and on control over the human body. Furthermore, it illustrates the displacing effect which commodification and contractualisation, through patents and licensing, have on broader public interests at stake. As will be shown, and as one of us has argued elsewhere,[29] there is a sharp disconnect between the concerns around gene patenting from a public interest context, and the concerns raised within the patent law context. Moreover, legal objections to gene patentability in Europe, Australia, and the United States, even where successful, tend to focus on technical patentability criteria with minimal engagement in all jurisdictions within patent law with the key public interest issues, including healthcare implications.[30] Despite different jurisdictional approaches on gene patents, a discernible common thread is the way in which commodification and contractualisation mask such underlying public health values and interests.

In analysing such issues, we are not arguing that removing medicines or isolated genes from a commodification framework would automatically address such issues: this would likely be pragmatically impossible and could lead to a host of unintended consequences. Instead, our point is that there must be a deeper engagement with the way in which commodification and contractualisation mask broader rights and interests at stake, and that active attempts must be undertaken to minimise such displacing effects by expanding such frameworks beyond a purely exchanged-based rationale.

(i) Early European challenges: Considering first the patentability of genes within Europe, of key relevance is the Biotechnology Directive 98/44/EC which clarified what types of biotechnological inventions were patentable in Europe. However, both before the adoption of the Directive and after its coming into force, questions were raised around the appropriateness of granting patents to isolated genes and were challenged before the European Patent Office (EPO).[31] The *Relaxin*[32] case, which concerned the patentability of H2-preprorelaxin – developed by using a sample of the hormone (which is produced by the body naturally during childbirth) donated by a pregnant woman and useful for pain relief – spans both sides of the Directive's adoption and highlights the minimal engagement with broader human interests at stake before and after the Directive's adoption. The challenge to

[26] Art. 5 of the European Biotechnology Directive states that: "1. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions."

[27] Art. 5(2) of the European Biotechnology Directive 98/44EC states that: "An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element."

[28] In the US see: *Association for Molecular Pathology, et al. v. Myriad Genetics, Inc., et al*. (2013) 569 US 576; and in Australia see *D'Arcy v Myriad Genetics Inc* [2015] HCA 35.

[29] A. MCMAHON, "Gene patents and access to health: Speaking at but not to each other," *Ethox Blog* 2017, https://ethoxblog.wordpress.com/2017/04/19/gene-patents-access-to-health-speaking-at-but-not-to-each-other/.

[30] For broader discussion of this, see A. MCMAHON, "Gene patenting and the marginalisation of ethical issues", *loc. cit*.

[31] For a discussion of these challenges, see: N. HAWKINS, "Human gene patents and genetic testing in Europe: A reappraisal," *SCRIPTed* 2010, p. 453; N. HAWKINS, "A red herring: Invalidity of human gene sequence patents," *European Intellectual Property Law Review* 2016, p. 83-91; J. LAI, "Myriad genetics and the BRCA patents in Europe: The implications of the U.S. Supreme Court decision," *UC Irvine Law Review* 2013, p. 1041.

[32] Case T 0272/95 (Relaxin/HOWARD FLOREY INSTITUTE) of 23.10.2002.

patentability was brought in 1995 prior to the adoption of the Directive, but the appeal case was heard in 2002 after the Directive had come into force. At all stages the EPO upheld the patentability of isolated human genes

In the EPO's initial Opposition Division (OD) decision on the patentability of the isolated gene, a key question was whether granting the patent would be against Art 53(a) of the European Patent Convention (EPC), which states that inventions whose commercial exploitation are against *ordre public* or morality shall be unpatentable. The OD dismissed this challenge, finding that only inventions which would be "universally regarded as outrageous" should be denied patentability. The OD also dismissed the claim that patenting of a human gene was akin to patenting a living substance and hence immoral, stating that "DNA as such was not life but one of the chemical entities participating in biological processes."[33] By dismissing this argument with such short shrift, the EPO failed to engage with the implications of having a right of control (that is implied within the patent right) over isolated DNA. Such patents over isolated genes can potentially be interpreted or enforced in a way which allows the patent holder the sole right to isolate the DNA and conduct testing on the patented gene for mutations indicating higher risks of certain conditions. This in turn can give the patent holder significant control over diagnostic testing, and has been used by some patent holders (including Myriad, examined below) to prohibit other genetic testing providers operating. This thereby creates a monopoly over genetic testing for the patent holder and can drive up the prices for genetic testing. It can also mean that there is no way to obtain a second medical opinion – as only one genetic test provider would exist.[34] Such consequences of gene patents from a public health perspective however were not explored in the EPO decision of *Relaxin*.[35]

The reasoning highlights a derelationalised understanding of the issues. It frames the question of whether isolated genes should be patented in respect of the direct participants in the patenting process only, namely the patent holder and the individual who donated the biological sample used to isolate the DNA. However, this reasoning does not consider the implications of the patent for third parties, including how such patents might curtail the isolation of DNA of third parties. Indeed, in considering whether granting such a patent infringes "human dignity" the EPO stated that "no offence to human dignity had occurred as the woman who donated tissue was asked for her consent and her self-determination was not affected by the exploitation of the claimed molecules."[36] However, this reasoning focused exclusively on the donor of the hormone, and did not consider the implications for other human bodies, including that granting such a patent had the potential to limit what others could do with their biological materials.[37] This illustrates a blinkered view of the effect of patents, ignoring the broader consequences, and is fundamentally indicative of a de-relationalised effect. Moreover, the underlying object of the patent, the invention (here the isolated gene), is not treated any differently to any other type of invention, despite its connection to the human

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[33] OJ EPO, 1995, 388 as cited in para IV of Case T 0272/95 (Relaxin/HOWARD FLOREY INSTITUTE) of 23.10.2002.

[34] See discussion *in* N. HAWKINS, "Human gene patents and genetic testing in Europe: A reappraisal," *loc. cit.*; NUFFIELD COUNCIL, *The Ethics of Patenting DNA: A Discussion Paper* (2002) available at http://nuffieldbioethics.org/project/patenting-dna; R. C. DEEGAN and A. NIEHAUS, "After Myriad: Genetic testing in the wake of recent Supreme Court decisions about gene patents," *Current Genetic Medicine Reports*, 2014, p. 223-241.

[35] For a broader discussion, see A. MCMAHON, "Gene patenting and the marginalisation of ethical issues," *loc. cit.*, and A. MCMAHON, "Biotechnology and patents as private governance: The good, the bad and the potential for ugly," paper presented at the UCD School of Law Research Seminar Series, September 19, 2018.

[36] OJ EPO, 1995, 388 as cited in para IV of Case T 0272/95 (*Relaxin/HOWARD FLOREY INSTITUTE*) of 23.10.2002.

[37] This can occur if patents on genes should be interpreted or enforced by the patent holder in a way that stopped other companies providing genetic testing for that particular gene.

body: it is treated as *fungible* – and the main question for the EPO is whether the patent application met the standard patentability criteria. Similarly, the exclusions to patentability on the basis of morality are applied in a light-touch manner as they are applied for other inventions,[38] without consideration of the potential distinguishing characteristics of patents on human genes as they are related to the human body. On appeal, the arguments based on morality were again dismissed, and the EPO referred to the new Rule 23(e) of the European Patent Convention (EPC) Implementing Regulations which directly replicated Art 5(2) of the EU Biotech Directive, which states that

> An element isolated from the human body or otherwise produced by means of a technical process including the sequence or partial sequence of a gene may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

The EPO stated that it followed from this text that isolated genes were not to be excluded from patentability.[39] No further examination of the morality exclusion as it applied to gene patenting is evident in the EPO's decision. Rule 23(e) was adopted to align the EPC text with the EU Biotech Directive, but the Directive was only ever intended to be a supplementary interpretation for the EPO of the EPC, and is not binding *per se* on the EPO. Thus, there could have been some questioning of the patentability of isolated genes or exploration of the effect of adopting this rule in the EPO's decision; but none is evident. Similarly, on appeal, questions of patentability of isolated genes in terms of whether they meet patent criteria were examined with no reference to the peculiar nature of genes.[40]

The sparse engagement with the issue illustrates an EPO framing of such questions based on a purely exchange interaction, which assumes that once inventions meet set out technical patent criteria they should be patentable. However, this fails to acknowledge the effects such patentability has on third parties not involved in patenting. In particular, it fails to appreciate that patentability indirectly impacts human dignity, by potentially limiting what third parties can do with their bodies, namely whether they can isolate their genes and who can provide testing of their biological samples.

Such considerations take us outside the standard patent/licensing exchange-based interaction to reflect on wider implications of the granting of a patent based on what the nature of the underlying invention is – and hence breaks away from treating inventions as fungible. However, patent systems are reluctant to engage in such exercises,[41] and generally dismiss

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[38] The morality provisions in the European Patent Convention 1973 pre-date the development of biotechnology or gene patenting. These provisions were applied in a light-touch manner in the mechanical/industrial invention context since the EPC adoption in 1973, but also continued to be applied in a light-touch manner in the context of biotechnological inventions. See O. MILLS, *Biotechnological Inventions: Moral Restraints and Patent law,* Rev. Edn., Ashgate Publishing, 2010; A. W. JONES, "Vital parameters for patent morality – a question of form," *Journal of Intellectual Property Law and Practice* 2007, p. 832. For an earlier discussion of the drafting of the EPC and role of morality provisions in that context, see E. ARMITAGE and I. DAVIES, *Patents and Morality in Perspective*, Common Law Institute of Intellectual Property, 1994.

[39] Case T 0272/95 (Relaxin/HOWARD FLOREY INSTITUTE) of 23.10.2002, para. 8, p. 11.

[40] *Ibid*., para. 10, p. 15. The failure to consider the distinctiveness of the issues raised by isolated genes similarly characterises the case law of the ECJ, which has linked patentability under Article 5(2) to the requirement of industrial application under Article 5(3). The effect is that although a DNA sequence is not in itself patentable, the fact that the work is expected to lead to industrial application makes it patentable. See CJEU, 9 Oct 2001, Netherlands v. European Parliament and Council (Case C-377/98), para. 74. In this, the ECJ's approach closely parallels that taken by the EPO, by treating genetic material as not raising any distinct issues from material inventions, and basing outcomes wholly on technical criteria.

[41] For a discussion of the institutional issues within patent law and an argument of there being a core institutional predilection towards marginalisation of broader ethical issues in patent law, see: A. MCMAHON, *The Morality*

them as outside the scope of patent law, as damaging to the market-based focus of patent law which is dependent upon certainty, and as generally problematic for encouraging innovation.[42] Our argument is that such responses must be questioned. Instead of focusing on the exchange-based context for patent licensing that contractualisation treats as the default, a framework based on ideas of reciprocity could incorporate broader values. Alternately, this institutional weakness of the exchange-based context could be acknowledged and active steps taken to provide third-party rights by taking the matter outside the contractualised framework. These issues are more starkly demonstrated by considering Myriad's practices in the United States.

(ii) Myriad litigation in the United States and Australia: The Myriad litigation in the United States related to patents granted on BRCA1 and BRCA2 isolated genes, and methods for isolation. Individuals who have particular mutations on the BRCA1 and BRCA2 genes are known to have an increased risk of developing breast and ovarian cancers.[43] Thus, individuals carrying such mutations may wish to undergo preventive surgeries to minimise the risk or halt the development of such cancers. In the United States, Myriad obtained patents over the BRCA1 and BRCA2 genes and subsequently established itself as the main provider of genetic testing for mutations on these genes. Myriad issued cease and desist letters against the other laboratories who were testing for these mutations, threatening to sue if they did not stop testing.[44] Accordingly, other labs halted the provision of testing and Myriad became a monopoly provider.[45] In addition to its relatively high costs , some doctors questioned the reliability of Myriad's testing, and whether better genetic testing could be provided by other laboratories. Furthermore, there was no other company to send the DNA sample to if a patient was unsatisfied with the Myriad testing, which meant patients had no opportunity to get a second medical opinion. Given these concerns around the testing, the American Civil Liberties Union (ACLU) commenced a patent challenge assembling over twenty plaintiffs composed of scientists, genetic counsellors, doctors, patients – the main impetus for the patent challenge being the health and research implications of the patent.[46]

Accordingly, in June 2013, the US Supreme Court found that isolated genes are not patentable subject matter under US law. Thus, Myriad's patents over isolated BRCA1 and BRCA2 were no longer valid in the United States. However, the health care implications of such patents were not the focus of the litigation or judgment. Instead, the focus was on the technical patentability criteria and whether isolated genes met these. The broader rights and interests affected by the nature of the object under patent were displaced within the legal challenge to patentability. Isolated genes were again seen as a fungible invention. The Supreme Court focused on the requirements of patentability under s. 101 of the US Patents Act and held that: "Myriad found the location of the BRCA1 and BRCA2 genes, but that discovery, by itself, does not render the BRCA genes 'new … composition[s] of matter,' §101, that are patent

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Provisions in the European Patent System: An Institutional Examination, *op. cit.*; and A. MCMAHON, "Gene patenting and the marginalisation of ethical issues," *loc. cit.*

[42] See also: P. DRAHOS, "Biotechnology patents, markets and morality," *European Intellectual Property Review* 1999, p. 441-49; I. SCHNEIDER, "Governing the patent system in Europe: The EPO's supranational autonomy and its need for a regulatory perspective," *Science and Public Policy* 2009, p. 619-29; I. SCHNEIDER, "Exclusions and exceptions to patent eligibility revisited: Examining the political functions of the 'discovery' and 'ordre public' clauses in the European Patent Convention and the arenas of negotiation," *in* I. DE MIGUEL. and C. M. ROMEO CASABONA, *Synbio and Human Health: A Challenge to the Current IP Framework?*, Springer, 2014, p. 145-173.

[43] See discussion *in* R.C. DEEGAN, "Impact of gene patents and licensing practices on access to genetic testing for inherited susceptibility to cancer: Comparing breast and ovarian cancers to colon cancers," *Genetic Medicine* 2014, p. 15-38.

[44] *Association for Molecular Pathology v. Myriad Genetics*, Inc., 569 U.S., 133 S. Ct. 2107 (2013), 7.

[45] *Id.*

[46] *Id.*

eligible." Thus in the Court's view, Myriad had failed to comply with the technical patentability criteria for eligible subject matter.

However, there was no consideration of gene patents' effects on health care or research, or the implications this may have had on third-party rights to health/life etc. As in the European context, such interests are displaced as a result of the commodified and contractualised framework which shifts the focus to whether the object under patent was appropriately granted via patent law, regardless of its effect on others. As one of us has argued elsewhere,[47] this is highly problematic for future cases because it perpetuates presumptions of patentability: although patents are ostensibly now not available in the United States on isolated genes such as BRCA1 and BRCA2, as science develops the subject matter that might be claimed to count as inventions will also develop, and in the future such subject matters might have similar implications for control of the human body or for genetic testing, which will have to be litigated upon again.

The case aptly illustrates the difficulties posed by the commodification and contractualisation to which patents on inventions related to the human body give rise. It illustrates the derelationalisation within patent law, where the implications of such patents on individuals and broader public health contexts downstream are overlooked. Instead, patents and the licensing regimes within which they operate are employed as inert devices, and patents once granted are deemed legitimate unless they can be challenged based on patentability criteria wherein exclusions/exceptions are generally difficult to claim. No consideration is made of the effects of such patents and the associated licences consequent upon the nature of the "invention" in question, as inventions are deemed to be fungible. More problematically, it often takes years for such litigation to come before courts, and patents are deemed valid until legally revoked by the court – which, as in the Myriad case, can happen at the end of the 20-year patent term.[48]

This is not confined to the US context. In Australia, Yvonne D'Arcy initiated a similar legal challenge to Myriad's patents on BRCA1 and BRCA2, which were held by the Australian High Court to be unpatentable on almost identical reasoning focusing on technical patent criteria.[49] Similarly, the impact on healthcare was not considered in detail by the court, instantiating again the displacement of the broader effects of patents through a contractualised lens.

B. – *Patents on medicines*

Aside from the implications patents have for isolated elements derived from the body, patents also have impacts upon medicines necessary for the continued functioning and survival of the human body. The effect of patents and licensing structures in obscuring the underlying public interest issues arising from the commodification of medicines through patenting is also starkly evident.

Historically, patent laws were dictated by the national State, which had freedom to decide which types of technologies would be patentable based on that State's economic and social needs. Accordingly, some States including India and Brazil did not allow patents for medicines,[50] and this allowed them to develop generic medicines at lower prices. However, all

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[47] A. MCMAHON, "Gene patenting and the marginalisation of ethical issues," *loc. cit.*

[48] M. A. BAGLEY, *loc. cit.*, p. 469-547.

[49] *D'Arcy v. Myriad Genetics Inc* [2015] HCA 35.

[50] C. CORREA and D. MATHEWS, *The Doha Declaration Ten Years on and its Impact on Access to Medicine and the Right to Health*, WHO Discussion Paper, 2011, p. 5, available at https://qmro.qmul.ac.uk/xmlui/bitstream/handle/123456789/3109/MATTHEWSTheDohaDeclaration2011FINAL.pdf?sequence=2.

States wishing to participate in World Trade Organisation (WTO) frameworks had to sign up to the TRIPS Agreement (which came into force in 1995) which expressly provided that patents would be available on all technologies including medicines.[51] In other words, States that wanted to participate in the WTO for trade purposes had to adopt the TRIPS agreement and therefore had no choice but to allow for patents on medicines, regardless of any attendant consequences for health.[52] Moreover, some States signed further bilateral agreements with additional requirements going beyond what was required in TRIPS (so-called TRIPS-plus agreements),[53] which in some cases limited States' abilities to invoke exceptions under TRIPS on, e.g., a public health basis, which can be particularly problematic in the context of developing countries agreeing to such TRIPS-plus provisions with developed countries.[54]

Patents on medicines have significant public health implications, as they create a right to control uses of patented medicines for the patent holder, giving them a right to decide who they will give a licence to, on what basis, and for what cost. Accordingly, patent holders can create a monopoly over medicines, and can drive up costs of the patented medicines. This can cause issues of affordability of medicines, with knock-on effects on individuals' access to patented medicines. This was starkly demonstrated by the AIDS crisis in the 1990s and early 2000s, where patented anti-retroviral drugs (ARVs) were sold for prices far more than what many individuals (and particularly individuals in developing countries) could afford.[55] Individuals most in need of ARVs were unable to access them, and by the end of 2003 less than 7% of those in need of ARVs in developing countries had access to them.[56] Generic versions of drugs could be made more cheaply, but would have been contrary to patent laws. Widespread protest and criticism of the patent system resulted, as millions of people were dying from AIDS for the lack of practical access to medicines despite the theoretical availability of drugs to treat the disease, attributed at least in part to patents.

The displacement of the rights and interests of third parties arising from the enforcement of patents is brought to sharp focus by this crisis. Moreover, whilst initiatives were undertaken to ameliorate tensions between patent rights and the right to health, these were met with resistance which focused on the potential harms to the market, and the likely impacts to medicines innovation if such patents were not upheld. For example, South Africa introduced the Medicines and Related Substances Control Act (1997) which sought to amend the patent system to allow easier access to essential medicines, including by allowing parallel importation of drugs under patent. However, the South African Pharmaceutical Manufacturers Association and 40 multinational pharmaceutical companies instigated litigation arguing that this

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[51] Article 27(1) TRIPS Agreement.

[52] For example, India allowed for patents on medicines by 2005 (which marked the end of the transitional period for the TRIPS Agreement).

[53] E. T'HOEN *et al*., "Medicine procurement and the use of flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights, 2001–2016," *Bulletin of World Health Organ* 2018, p. 189, available at http://www.who.int/bulletin/volumes/96/3/17-199364.pdf. In TRIPS-plus standards, States agree to higher standards than set out in TRIPS when conducting trade agreements with other countries – effectively, countries can contract out of some of the flexibilities set out in TRIPS or undertake to only use flexibilities such as compulsory licensing where, for example, there is a public health emergency.

[54] See discussion *in* M. EL SAID, *Public Health Related TRIPS-plus Provisions in Bilateral Trade Agreements*, World Health Organisation 2010.

[55] Reports suggest that companies were charging US$ 10,000-15,000 per year's supply of ARV in early 2000s – see C. PEREZ-CASAS *et al*., *Accessing ARVs: Untangling the Web of Antiretroviral Price Reductions*, Medecins Sans Frontieres/Campaign for Access to Essential Medicines, 2001, available at http://www.msfaccess.org/fileadmin/user_upload/diseases/hiv-aids/Untangling_the_Web/UTW%201%20Sep%202001.pdf.

[56] See *World Health Report 21*, World Health Organisation, 2004; *2004 Report on the Global AIDS Epidemic*, UNAIDS, 2004, p. 101-102 as cited in W. W. FISHER and C. P. RIGAMONTI, *The South Africa AIDS Controversy: A Case Study in Patent Law and Policy*, Harvard Law School, 2005, p. 2.

legislation was contrary to the TRIPS agreement.[57] Alongside this, South Africa was threatened with economic sanctions for failing to comply with TRIPS by the United States and the EC (as it was then).[58] These opposition attempts using patent law under the TRIPS Agreement to stop national States amending laws to address the public health crisis posed by AIDS were taken in spite of the millions dying from the disease, demonstrating the obscuring of broader human rights at stake. It attracted global media attention and opposition from NGOs, and eventually this opposition to the pharmaceutical companies' challenge led to them withdrawing the case in April 2001. Nonetheless, the case lasted for three years, and was only withdrawn due to strong international opposition and arguably the likely threat of consequent reputational damage to pharmaceutical companies. Before it was withdrawn South Africa assured the industry it would only use parallel imports to obtain brand-name drugs from other countries where they were sold cheaply (but not generics).[59] This demonstrates the marginalisation of the broader public interest issues at stake.

It also continues to be a contemporary issue, demonstrated by current debates around access to Cystic Fibrosis drugs in the United Kingdom,[60] and illustrating that the effect of patents on access to medicines is not an issue confined to developing countries. This would be difficult to explain, were patents actually based on a wider theoretical basis of interaction other than the current exchange-based framework.

In effect, solutions within a commodification/contractualisation-based framework are simply not likely to be capable of incorporating the rights/interests of third parties if they continue to be based solely on an exchange-based framework which is blinkered to the effects of activities on parties not directly linked to the core transaction at stake. Instead, institutional change is needed to ground patent law on a broader basis or to ensure safeguards for third party rights/interests. For example, the response of the TRIPS framework to the AIDS crisis was too little too late, focusing on clarifying existing provisions but not involving any meaningful institutional changes to TRIPS or the WTO framework. In this vein, flexibilities had indeed existed within the TRIPS framework since its adoption to provide leeway to States where there was a need for essential medicines on a public health basis. The WTO's response to the AIDS crises was to reaffirm and expand on these flexibilities by the adoption of the Doha Declaration in 2001, which states at para 4 that:

> The TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

The Doha Declaration flexibilities also included circumstances in which compulsory licences could be introduced to facilitate access to cheaper versions of essential medicines in the event of a public health crisis. They were supplemented by the introduction of a waiver to TRIPS (Art 31 bis) which allowed States facing a public health crisis who did not have manufacturing capacity to produce generic versions of a drug, to import generic versions of a

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[57] See P. BOND, "Globalization, pharmaceutical pricing, and South African health policy: Managing confrontation with US firms and politicians," *International Journal of Heath Services* 1999, p. 765-792.

[58] For a discussion, see E. T'HOEN, "TRIPS, pharmaceutical patents, and access to essential medicines: A long way from Seattle to Doha," *Chicago Journal of International Law* 2002, p. 27-46.

[59] P. SIDLEY, "Drug companies withdraw lawsuit against South Africa" *British Medical Journal* 2001, 7293.

[60] See discussion of current proposal by Labour in the UK to introduce a compulsory license for access to Orkambi in England *in* E. T'HOEN, "Corbyn's compulsory licenses. Will they work?," *Medicines, Law and Policy*, September 26, 2019, available at https://medicineslawandpolicy.org/2019/09/corbyns-compulsory-licenses-will-they-work/.

drug made in a third country. This waiver was incorporated in 2005 but not fully ratified until 2017.[61] However, the use of these flexibilities as a solution to the issue had a number of shortcomings, and there is much debate over how often such flexibilities are used in practice, alongside calls for better reporting of this.[62] A recent study suggests that countries are using flexibilities more than previously thought; nonetheless, it also acknowledges that difficulties remain, particularly due to TRIPS-plus standards in trade agreements, including in bilateral treaties whose 'highest international standard' can have the effect of generalising TRIPS-plus provisions to states which have not specifically ratified them.[63]

Moreover, States may be reluctant to use TRIPS flexibilities due to a fear of retaliatory trade sanctions from other states. This fear is not without cause: for example, India was placed on the US Special 301 watchlist following US concerns over its IP regime, including India's granting of compulsory licences to produce generic versions of patented drugs such as Nexaver, a locally produced generic version of Bayer's medicine used to treat cancer, which is produced and sold by Natco Ltd in India for one tenth of the price of the branded drug.[64] Thus, contracts are being used to water down flexibilities in TRIPS. The fact that patent protection is directly linked to trade is a powerful lever against developing countries – arguably the most vulnerable to economic and trade sanctions – from using flexibilities.

In short, patents and licensing structures neutralise the underlying issues giving patent holders legitimate legal claims to assert their rights – but within a contractualised structure which limits third parties' claims to access such medicines. Moreover, even within the Doha context the main flexibility, compulsory licensing, is a solution situated within the licensing context. However, purporting to offer a solution to a problem by using the very same framework, with no institutional changes to the system of commodification and contractualisation applicable through patenting and licensing of medicines, is likely to have limited effect. Difficulties are exacerbated by the power imbalances between developing countries – where the issue of access to medicines is often most stark – and the pharmaceutical companies. Unless such imbalances are addressed, or, at the very least, mediatory bodies are actively used to advocate for developing countries' interests, TRIPS flexibilities are likely to be under-utilised. Arguably, one of the reasons why the Doha reforms have been repeatedly criticised as not as effective as they could be, is the fact that they are framed within a patent/contractualised context, without addressing the power imbalance faced by developing countries, the limitations of contractual frameworks for readjusting socio-economic imbalances without the active and sustained intervention on behalf of parties with weaker bargaining powers, and the institutional limitations of exchange-based frameworks for incorporating considerations of non-commercial interests.

PART III: CONCLUSION: COMMODIFICATION AND CONTRACTUALISATION – A TIME FOR PAUSE?

[61] "WTO IP rules amended to ease poor countries' access to affordable medicines," WTO, January 23, 2017, available at https://www.wto.org/english/news_e/news17_e/trip_23jan17_e.htm.

[62] E. T'HOEN *et al*., "Medicine procurement and the use of flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights, 2001–2016," *loc. cit.*, p. 185.

[63] *Ibid.*, p. 189. For a review of EU practice, see M. M. ALEMAN, "Impact of TRIPS-Plus Obligations in Economic Partnership- and Free Trade Agreements on International IP Law," *in* J. DREXL *et al*, *EU Bilateral Trade Agreements and Intellectual Property: For Better or Worse?*, Springer, 2014, p. 61-86.

[64] Z. SIDDIQUI, "India defends right to issue drug 'compulsory licenses'," Reuters, 23 March 2016, available at https://www.reuters.com/article/us-india-patents-usa-idUSKCN0WP0T4.

The critique of commodification we have advanced in this chapter differs in fundamental ways from the critique that is usually advanced in the English-language literature. In the literature, the limits of the market are conceptualised with reference to the moral quality of the things that are sought to be traded on the market. Yet, as with many moral matters, the moral quality of any given thing, and the normative significance of that moral quality, are open to contestation[65]. Our critique, in contrast, is grounded not in the moral quality of the commodified thing, but in its distance from natural commodities, and the social consequence of the dejuridification that is a necessary consequence of the reliance of commodification and marketisation on contract. In levelling a critique from a different angle, we do not seek in any way to argue that the moral quality of the commodified thing is irrelevant. We seek, rather, to point out that markets also suffer from a deeper weakness, which is also more fundamental, springing from the institutional limits of contracts and markets, particularly when such frameworks are modelled solely on an exchange-based rationale.

Against this background, the example of patent rights in Part II was intended to demonstrate, firstly, the pervasiveness of commodification and its close links with contractualisation, and, secondly, the consequences of this link and the extent to which they are embedded in the systems of governance in the modern state. The Doha round also indicates the difficulty of finding solutions while remaining within the logic of markets, commodities, and contracts. So, too, in a different way, does the experience of traditional knowledge (a topic which, for reasons of space, we have not focused on in this chapter).[66] The history of attempts to protect traditional knowledge shows a similar trend to that discussed in the previous section, in which the subject of property rights (in this case, the human relationship with nature) only receives protection to the extent to which, and under the circumstances that, it can be made the subject of market transactions (in this case, through granting access to the knowledge to researchers). Equally, it has proven impossible to ameliorate the many issues that the adoption of a marketised frame have created in relation to traditional knowledge, save by doubling down on that very frame – as seen most clearly in the adoption of "informed consent" to deal with the problem of possible exploitation, despite the unsuitableness of informed consent as a tool for dealing with this problem.[67] To the extent that regulation, too, is grounded in a similar approach, which takes the contractualised frame as a given and simply seeks to make adjustments to it, it is likely to suffer from the same problem and, even in the best case, be able to do no more than address the underlying issues in at most a partial way. Nor is there any more promise in the concepts of *ordre public* and public policy, both of which are focused solely on the validity of contractual provisions, rather than the more pressing issue of infusing their content with a broader set of considerations from outside an exchange-based framework.

What, then, is the way forward? Any solution must begin by stepping out of the alluring conceptual framework of contract, commodities, and markets, to consider the issue from a different angle. An important insight of legal realism, particularly in the Scandinavian tradition, is the idea that legal concepts can be critically examined from the perspective of *samhällsnyttan* – the extent to which they embed evaluations that are of use to society. Different legal structures embed different types of evaluations into the legal framework. Human rights law, for example, brings one type of conceptual framework (or thought style) to bear in analysing social problems, assigning degrees of salience to individual dimensions of the problem, and prioritising interests when they are in conflict. Contract uses a very different framework, which,

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[65] E. Bertrand's and M. Jouan's chapters in this volume take up the criticism of "moralism" addressed at this literature.

[66] For a general overview, see WIPO, *Traditional Knowledge and Intellectual Property – Background Brief*, available at https://www.wipo.int/pressroom/en/briefs/tk_ip.html.

[67] See e.g. G. DUTFIELD, "Protecting the rights of indigenous peoples: Can prior informed consent help?" *in Indigenous Peoples, Consent and Benefit Sharing: Lessons from the San-Hoodia Case*, Springer, 2009, p. 53.

in most western legal systems, has a specific propensity to embed an alienated understanding of humans' relations with each other and their environment into the functioning of the legal system. In considering the limits of markets and alternatives to markets, the key issue is to consider alternative legal structures and frameworks that might be brought to bear, the evaluative approaches these frameworks and structures would embed into the legal system, and the type of interests each of these is (or is not) capable of weighing in consideration.

In an insightful contribution to the debate on commodification of nature, Marie-Angèle Hermitte explores the possible role of one such legal structure, namely, making nature a subject of law, and argues that such an approach has considerable symbolic and practical utility:

> Il s'agirait, sur le plan symbolique, de réaffirmer la spécificité du contenu des droits de la personne humaine, seule dans ces droits-là, tout en mettant en face d'elle des sujets non humains, ce qui viendrait marquer la réintégration de l'humanité dans le monde vivant. Nous ne sommes pas de purs esprits flottant dans un espace vide, mais des êtres de chair et de sang dépendant de l'air, de l'eau, de la terre, de l'énergie, et partageant le monde avec d'autres êtres. Il s'agirait d'utiliser les techniques du droit pour inscrire ce dualisme de l'isolement et de l'intégration dans le monde du droit.[68]

Such an approach has clear promise to counteract the commodification of nature, and steps in that direction have been taken in jurisdictions such as New Zealand.[69] Equitable structures originating in the jurisprudence of the Courts of Chancery, too, have long been used to mitigate the common law's contract-centricism, and could in theory play that role again in relation to novel markets in fictitious commodities. Could the law not, for example, draw on the legal tools created by the law of trusts in relation to the atmosphere, such that the commodification of pollution is also accompanied by the imposition of duties akin to that of a trustee in relation to the atmosphere?[70] Equally, could not the device of the fiduciary duty mitigate some of the harshness of the pure contractualised system of patents which we have discussed in Part II, and could not this basic approach be adopted in other areas where the institutional limits of contracts, as traditionally construed, make commodification and marketisation particularly problematic?

A full answer to these questions is beyond the scope of this chapter, but our purpose here has been to point out that it is in these terms that we must think about the issue. If we are to seriously engage with the limits of markets, then the limits of contracts as a legal device, and the relative strengths and weaknesses of other legal structures that could potentially be drawn upon, require considerably more attention than they have thus far received.

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[68] M-A. HERMITTE, "La Nature, sujet de droit ?" *Annales: Histoire, Sciences Sociales* 2011, p. 173, 211-2.

[69] *The Te Awa Tupua (Whanganui River Claims Settlement) Act* 2017.

[70] It is pertinent to note that the creation of trustees is an important element of New Zealand's approach to conferring legal personality on nature. See C. RODGERS, "A new approach to protecting ecosystems: The Te Awa Tupua (Whanganui River Claims Settlement) Act 2017", *Environmental Law Review* 2017, p. 266-279.