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‘COMMENSURATION AND PROLIFERATION: SIMILARITY AND DIVERGENCE IN LAW’S SHAPING OF MEDICAL TECHNOLOGY ‘

In press as at October 2012 for Special Issue of ***‘Law, Innovation & Technology’*** (Hart Journals)**COMMENSURATION AND PROLIFERATION: SIMILARITY AND DIVERGENCE IN LAW’S SHAPING OF MEDICAL TECHNOLOGY**

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**Abstract**

The concept of commensuration – ‘making things the same’ - is receiving increased attention in studies of fields of social practice such as climate regimes, accounting and medical error reporting. The part played by analogy in common law is well known, but the way cognate processes work through regulatory institutions and regimes (i.e commensuration) is less recognized. Connected to commensuration and arising from it, one can propose a concept of ‘proliferation’ to capture instances of enactment of law (institutional design, development and practices) where commensuration is not possible or attempted, or where it is challenged in some way. This paper will explore and review recent more or less explicit developments of the concept of commensuration, propose the related concept of institutional proliferation, and explore the application of these to recent developments in the European Medicines Agency (EMA). The focus will be on EMA’s implementation of the EU’s Advanced Therapy Medicinal Products Regulation, how ‘combination products’ (medicine/device combinations) are being managed in that evolving regime, on EMA’s design of a number of innovative institutional forums for stakeholder inclusion and linkages to scientific societies (proliferation), and its recent involvement in proposals for a ‘recast’ of medical device regulation.

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**COMMENSURATION AND PROLIFERATION: SIMILARITY AND DIVERGENCE IN LAW’S SHAPING OF MEDICAL TECHNOLOGY**

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1. **INTRODUCTION**

Taxonomy in the Western tradition can be traced to Aristotle’s *History of Animals*, which distinguished for example between land-dwelling and water-dwelling classes of animals, and between animals with blood and those without. The Linnaean system of botanical classification remains the basis of plant classification today. Thus there are many ancient and honourable precedents for the systematic classification of the natural world. Social scientists, especially social anthropologists (for example, Mary Douglas and Claude Levi-Strauss) and scholars of the evolution of science and technology, have more recently shown how classification is a fundamental meaning-making and deep-structuring activity in the social ordering of society and its various domains of activity.[[1]](#footnote-1) It also is key to the design and workings of law. Classification of different domains of science, materials and products has become a key part of the regulation of science and technology in contemporary societies.

This paper begins with a brief conceptual assessment of the role of classification in society. This leads to a closer focus upon ‘commensuration’ as a particular type of societal classification process, drawing on a case study of recent developments in biomedical regulation in the European Union (EU), focusing upon a single Regulation.[[2]](#footnote-2) Following this, I present some observations and documentary evidence of how commensurating strategies have been followed in the design and subsequent enactment of this piece of EU legislation. This has resulted in a particular configuration of the Regulation, which favours some producers of regenerative medicine products more than others. Drawing on this approach, I argue that the particularity of the design of the novel part of the regulatory framework has in turn provoked a proliferation of non-legislative *institutional* innovations in the regulatory regime, which are partly continuous with existing institutional forms but partly novel, and which are properly interpreted as attempts to cope with legal and interest-based political conflict caused by the particular shape of the new regulatory regime. These institutional innovations are part of the work of the European Medicines Agency (EMA), and take the form of various working groups, novel fora unique to the ATMP regime, and linkages formed between the EMA and external bodies.

The new ATMP Regulation that I discuss here applies in the field of ‘regenerative medicine’. It is widely envisaged as being a revolutionary development, and the term ‘Regenerative medicine’ has become a key slogan among promoters of new healthcare products and practitioners of biomedical science. Applications are envisaged for treatment of major medical conditions such as heart disease, cancer, diabetes and arthritis. The over-riding principle is to regenerate and repair normal functioning either by introducing new material or by helping the body to repair itself. Therapies to repair heart muscles with live cells are also the subject of research. Some therapies are already available which use cells to regenerate cartilage and to treat chronic wounds by using ‘living skin’. Some products produced by ‘tissue engineering’ combine live human cells with manufactured materials such as polymers. Because some of these emerging technologies involve manipulation of viable human and animal materials at the cellular level, they have become controversial, with human embryonic stem cells and human-animal hybrids having provoked political controversy and conflict over social, ethical and religious values. ‘Combination products’ are equally controversial because they bring different biomedical sectors and their corresponding regulatory traditions into close contact. Regenerative medicine is at once a scientific, technological, symbolic and institutional phenomenon involving actors such as hospitals, biomedical charities, commercial researchers and producers. National and regional economies promote the field and compete in an internationally variegated regulatory environment. Hundreds of ‘regenerative medicine’ research centres have emerged in the space of a decade or so, and some of the world’s largest pharmaceutical companies have introduced regenerative medicine divisions. The developments challenge existing classificatory sectoral boundaries such as those between biotechnology, pharmaceuticals and medical devices.

1. **SOCIAL CLASSIFICATION AND SCIENCE & TECHNOLOGY LAW**

In an article analysing the differences between the American and French wine industries, Zhao has pointed out key features of society’s classification activity: ‘(First,) classifications *confer identities* on social actors (or objects), and inherently imply social control. (Second,) classifications *create social boundaries* and signify social standing of actors (or objects). (Third,) classification-making often involves *political struggles* between different interest groups, and classification systems embody the political power’ (author’s emphases). The article further presents a sociological framework to understand classifications, stressing the multi-dimensionality and complexity of classifications.[[3]](#footnote-3)

This formulation of key functions and consequences of classification activity is useful in pointing to some aspects of its social significance. It raises key points that I will discuss in this paper concerning: identity (of regulators, regulated material objects and participants in a regulated field); boundaries (between regulated fields, industry sectors, types of biomedical technology); and the ‘politics’ of contestation of classificatory boundaries between interest groups. However, what Zhao’s useful conceptualization does not quite formulate sufficiently is a focus on the *institutional* dimension of classificatory work. In other words, in what ways are conceptual classifications expressed in ‘institutions’, such as organized interest groups, research institutions, technology manufacturers, professional associations, and the various groupings that comprise regulatory agencies themselves? This paper will illustrate in some detail aspects of regulatory bodies, regulated techno-economic fields and regulated industry actors as socioeconomic institutions having attributes such as social structure, norms of behaviour, enacted roles, and so on, which social institutions typically display. Given that the paper concerns an unfolding pathway of regulatory design and social enactment, the dynamically evolving aspect of this institutional process is a key focus.

Classification is a core activity of law-making. It is a constructive process, shaping societies’ sectoral domains and establishing boundaries that have economic and social policy effects, as well as enacting the normative and morality-defining dimension of law. A social theory perspective supports the insight that regulatory policy-making contributes to the defining of the boundaries of scientific and technological jurisdictions which can be supported, funded, structured, organized, standardized, contested, legitimated and governed. Equally, classification processes can define the boundaries between socially acceptable behaviours and unlawful activities in given domains and societal identities associated with them, thus defining specific ‘rules of engagement’ for a sphere of society’s activity.[[4]](#footnote-4) In this paper, I will analyse particular classification processes, both ideational and institutional, evident in the regulatory space of regenerative medicine in the European Union (EU). The political and economic phenomenon of ‘Europe’ can be regarded as in part constituted by regulatory policymaking work, requiring political and economic agreement between national states and their regulators about emerging sectors, typically covering scientific, product, commodity, risk, consumer information, ethical and market aspects. Constructivist social theory points to the importance of classification processes to regions of politic-economic jurisdiction: the ‘EU’s governance blend… requires European domains to be constituted in order that they may be governed.’[[5]](#footnote-5)

The constitution of regulatable domains through strategic innovation in linguistic terminology is a key part of the socio-legal process in science and technology. Linguistic innovation is key to the shaping of fields of innovation in science and medicine, as shown for example in the naming of new fields such as proteomics, and in the dissemination of the prefix *bio* (biomedicine, biocitizenship, bioprospecting and so on). The contemporary biosciences and biotechnologies are extremely complex, challenging moral principles and legal framings. From the perspective of legal theory, ‘formal legal categorizations are themselves unstable symptoms of complexity’.[[6]](#footnote-6) Socio-legal studies of biotechnology have pointed to the co-construction of textual legal definitions and social activities and institutions: ‘… although there have been various legal or administrative definitions of biotechnology … these definitions are themselves immersed in the economic, scientific, or political strategies that constitute biotechnologies.’[[7]](#footnote-7) The emerging legislative lexicon of scientific and economic fields such as regenerative medicine including terms such as ‘advanced therapies’, ‘biotechnology sector’, ‘tissue-engineered’ and so on are thus properly read as powerful indicators of the defining characteristics and parameters of the emergence into society of a new scientific or biomedical field, as I examine in this paper. Such examination shows how the arrangement of such terms into a coherent framework in which relationships of equivalence and hierarchy are laid out, is key to the process of commensuration.

The innovative nature of regenerative medicine, like other innovative sciences and technologies whose level of technical unpredictability is high, raises the legislative – and social – issue of the ‘matching’ of regulatory design to the regulated zone or field. Recent scholarship has formulated this issue from a variety of perspectives, ranging from a normative concern about ‘regulatory lag’,[[8]](#footnote-8) through to the analysis of the complexities of matching of hybrid and fluid fields of techno-science to equally malleable regulatory jurisdictions.[[9]](#footnote-9) This is in addition to what Roger Brownsword has called ‘regulatory connection’, which is seen as the overriding generic problem of contemporary innovative sciences and technologies.[[10]](#footnote-10) The central thesis of my argument is that institutions are the means by which contestation of the forces of commensuration is conducted. I now turn to consider ‘commensuration’ as one of the strategies used by regulatory policy-makers to establish and maintain regulatory connection.

1. **THE CONCEPT OF COMMENSURATION**

Commensuration is a form of classificatory work that draws attention to the aligning of otherwise distinct cognitive or practical domains. It draws attention especially to the relative elasticity and resilience of cognitive and institutional boundaries. Applied to law, it draws our attention to the potential adaptablilty or ‘stretchability’ of what have been called ‘inherited regulatory environments’,[[11]](#footnote-11) and concomitantly, the limits of that adaptability.

The concept of commensuration has been surprisingly little used in socio-legal or sociological scholarship. However, this is beginning to change which is perhaps due to the increasing cross-disciplinary attention to a loosely linked set of societal issues including regulation, standard-setting, science and technology innovation, risk and safety, and globalization. The primary reference point of sociological studies using the concept of commensuration was published in the late 1990s, making a case for the wide applicability of the concept.[[12]](#footnote-12) These authors have subsequently applied the concept in the field of climate change and the environment.[[13]](#footnote-13) The concept is especially suitable for understanding the development of classes of products in economic and commodity markets, where it has been defined as ‘…process of making goods measurable and comparable…standardization of product categories …is a socially embedded driver of market evolution’.[[14]](#footnote-14) It has also been applied, by a leading scholar of the sociology of science, technology and economic markets, to the carbon trading marketplace as shaped by the Kyoto Protocol.[[15]](#footnote-15) Drawing attention to the interest representation in commensurating projects, MacKenzie has analysed ‘the politics of market design’ of the carbon economy as attempting to create standard metrics that would show ‘how the destruction of one gas in one place is made commensurate with emissions of a different gas in a different place…’ [[16]](#footnote-16)

Equally, a recent collection of papers examining the intersections of law, science and technology shows more and less achieved commensuration processes at work in the development of, or resistance to, new regulatory measures alongside emerging technologies including (again) carbon trading,[[17]](#footnote-17) anonymity of reproductive material donors in assisted reproductive technologies (ART), [[18]](#footnote-18) trans-national biobanking in Europe,[[19]](#footnote-19) the contested regulatory classification of nicotine gum,[[20]](#footnote-20) and an attempt to contain nanotechnology within existing bulk chemicals consumer regulation in the EU.[[21]](#footnote-21) The extension of the material world, for example through biomedical innovation or carbon emission testing, tests the limits of law and broader regulatory processes. Thus a common theme in these analyses is the key dynamic of regulatory actors and regulatees wrestling with the path-dependence of existing regulatory regimes, or to use Stokes’ term, ‘inherited regulatory environments’.[[22]](#footnote-22) Although such wrestling, which is often conducted in terms of the persuasiveness of claims to commensurability may sometimes result in new or extended regimes (or proposals for such), at other times it does not. The analysis of pharmaceutical regime-building in this paper provides an example of successful *legislative* commensuration, followed by some measures of innovative design of a regulatory institution in response to pressures arising from the particular scope of that legislation. However, this institutional regulatory commensuration is demonstrably less successful, as shown.

Commensuration may be achieved or attempted through processes of analogical reasoning. Analogy is a well-known tactic in both law-making and adjudication in common law contexts, though it is much more widely recognized in the latter, where the deployment of precedent and analogy in legal reasoning is endemic to Western democratic legal processes. Thus commensuration, as described above, owes much to the tradition of analogical reasoning. Analogy can be seen to have a broadly structuring, consensus-building, and standardizing function in the face of pluralist moralities and social organization. This is particularly apt where, as in the case of innovative science and technologies, both uncertainty and plurality are conspicuous. In the circumstances, analogy ‘serves to compensate for some of the indeterminacy which flows from fragmented materials and the pluralism of decision-makers.’ [[23]](#footnote-23)

In considering ‘rules and analogies’, it has been argued that these devices promote one of the major goals of ‘heterogeneous societies’, namely ‘to make it possible to obtain agreement when agreement is necessary.’[[24]](#footnote-24) Sunstein has argued that analogical thinking can operate at what might be termed a ‘meta’ level (author’s term) that allows for divergence of positions at lower levels of reasoning: ‘People can often agree on what rules mean even when they can agree on little else’.[[25]](#footnote-25) The negotiation of legislative rules through debate about commensurability of classifications shows that that analogical thinking is of great importance in law-making, as well as jurisprudence: ‘in civil law analogical reasoning constitutes a tool to fill a gap in a code’. [[26]](#footnote-26)

In this paper, I focus on processes of commensuration pursued through tactics of analogy and classification in order to understand the development of recent EU legislation relating to regenerative medicine. The following section outlines the trajectory that the development of this legislation has taken, noting (following Zhao, above) how attempts were made to define *boundaries* within which products would be legally equivalent (commensuration), the implications this has for actors in the regulated field (*identity*) and drawing attention to the contested nature of this process (*political conflict*). Following this brief outline, I report on the recent institutional developments in the regulatory arena that I argue are part of the continuing process of regulatory design of this techno-scientific field and show resistance to, and extenuation of, the impetus for commensuration.

1. **THE CONTENT AND IMPLMENTATION OF THE EU REGULATION FOR ADVANCED THERAPY MEDICINAL PRODUCTS**

The legislation that I now examine is the Regulation for Advanced Therapy Medicinal Products’ (ATMPs) which was adopted at EU level in 2007and was required to be implemented by Member States by 2008.[[27]](#footnote-27) It has undoubted major significance for the regenerative medicine field globally. Needless to say, the European Commission’s (Commission) initial draft legislative proposal proceeded through countless drafts, amendments, counter-amendments, debates, committee and working group deliberations, as well as regulator-stakeholder-public conferences, written consultations and so on, which do not need detailing here. The key points in the story are sketched below.[[28]](#footnote-28)

In order to track the trajectory of the development of this legislation, it is important to know that the Commission included three organizational sections relevant for the medical sector, one for medical devices, one for pharmaceuticals and one for biotechnology. The initial responsibility for developing regulation lay with the medical devices section. One of the purposes of the ATMP regulation was to make legal provision for tissue-engineered (TE) technologies. Although not always, TE technologies typically combine manufactured biomaterials with living, viable human tissues or cells. The manufactured part would be classified as a medical device for regulatory purposes. The TE technology was believed to fall into a ‘regulatory gap’, in other words, a gap or omission in the existing classificatory framework. During the late 1990s and early 2000s, multiple definitions of TE technology were circulated and this was crucial to the development of regulatory activity that has attempted to map a clear regulatable domain for it. In this context, it was widely believed amongst the relevant policy actors that a specific, *stand alone* regulatory regime for this class of products was appropriate and would be put in place.

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| --- | --- | --- | --- | --- |
| **TISSUES/TISSUE BANKS****Tissues & Cells Directive[[29]](#footnote-29)** non-manipulated cells: e.g. cornea, thighbone, blood vessels, skin | *Demarcation based on* *degree of manipulation* | **TISSUE ENGINEERED PRODUCTS**EnvisagedNew Regulatione.g. cultured chondrocytes, engineered skin, cultured myoblasts, Primary physical or mechanical mode of action | *Demarcation based on primary mode of action* | **MEDICINAL PRODUCTS****Medicinal Product Regulation[[30]](#footnote-30)**e.g. fused cells for cancer vaccines,genetically modified cellsPharmacologic, immunologic or metabolic mode of action |

**Figure 1. Is TE special? The original model of a standalone, specific ‘third
pillar’ regulation for tissue-engineered technologies.[[31]](#footnote-31)**

As Figure 1 shows, the proposed TE product regulation was seen as fitting between and separate from the existing Tissues and Cells Directive,[[32]](#footnote-32) and pre-existing EU medicinal products legislation.[[33]](#footnote-33) In this scenario, tissue engineering was seen as a distinctive technology not catered for by the ‘inherited regulatory environment’. For reasons and through processes discussed in detail elsewhere,[[34]](#footnote-34) however, this scenario of specific legislation was superseded by a second approach. This involved a shift in responsibility for developing the regulation from the medical devices section of the Commission, via the biotechnology section, to the pharmaceutical section. At the same time, debate and argument amongst stakeholders resulted in a shift in the perceived fundamental organizing principle of the technology from one based on the riskiness of the risk-related *provenance* of the biomaterials used to one based on the *mode of action* of the products in question.[[35]](#footnote-35) The new model is illustrated in Figure 2.

Before considering the significance of this shift it is necessary to emphasize the way in which the primary EU medical devices regulatory regime has been designed, not least because it is very different from that which now applies to pharmaceuticals. This difference is important to understanding the contested features of the ATMP Regulation and recent proposals that would make the medical devices regime similar to, or even in some cases part of, the pharmaceutical regime. It is also important to understanding the issue of ‘combination products’ which is dealt with in the next section of the paper. Since 1993, medical devices have been regulated through a system combining self-certification for low-risk, and assessment by external scientific bodies known as ‘Notified Bodies’ for higher-risk devices. The British Standards Institute, for example, is a notified body. Manufacturers must apply the well-known Conformité Européenne (CE) mark before placing a product on the market. Notified bodies are designated under guidance at EU level and national competent authorities are responsible for ensuring compliance. Manufacturers can approach one in any Member State provided they have suitable expertise, and receive the CE mark from them. The legal authority for such self-certification is to be found in what is known as the ‘New Approach’ form of Directive, which is designed to encourage technical standards and safety harmonization in the context of the internal market.[[36]](#footnote-36) The definition of a medical device under the Medical Device Directive focuses on the extent and method of interaction with, or in, the human body, which is typically physical or mechanical (leaving aside ‘active implantable’ and in vitro diagnostic devices for which there are separate though related Directives). There are tens of thousands of medical devices circulating in the EU marketplace and it is typical for the ‘same’ device to evolve through multiple new versions, for example, through progressive miniaturization.

**Medical Devices**

**Chemicals**

**Biotech**

**Gene Therapy**

**Cell** **Therapy**

**Tissue Engineering**

***Advanced Therapies***

Medicinal

Products

Directive 2001/83/EC

Medical

Devices Directive 93/42/EEC

**?**

**Figure 2. European Commission’s commensurative proposal for TE products as one of a ‘coherent ensemble’ of ‘advanced therapies’.**

The new model encapsulates commensuration at work, showing that the more recent formulation of ‘Advanced Therapies’ has been applied. This was proposed by the Commission as providing for a ‘coherent ensemble’ comprising tissue engineering, cell therapy and gene therapy. However, cell therapy and gene therapy were already regulated under the medicinal products regime.[[37]](#footnote-37) Indeed, they had been designated as advanced therapies in the first deployment of this concept, in Annex 1 of Directive 2001/83/EC defining somatic cell therapy medicinal products and gene therapy medicinal products.[[38]](#footnote-38) Thus, the eventual ATMP Regulation provides a new legal definition of TE products within the EU of an expanding class of ‘advanced therapies’ within the architecture of the pharmaceutical regulatory framework. The legal definition of TE products established by the ATMP Regulation itself assembles a range of different types of distinctive materials of potential products into a single overarching frame of reference:

A tissue engineered product may contain cells or tissues of human or animal origin, or both. The cells or tissues may be viable or non-viable. It may also contain additional substances, such as cellular products, bio-molecules, biomaterials, chemical substances, scaffolds or matrices.[[39]](#footnote-39)

As an amendment to Directive 2001/83/EC , the ATMP Regulation appears to be deliberately imprecise about who the producers of advanced therapy products might be,[[40]](#footnote-40) conferring on them the vague identity of ‘marketing authorization applicants’ and not identifying a regenerative medicine sector as such but referring more broadly to the biotechnology sector and ‘the industry’. In this regard it is important to note some of the particular measures established by the Regulation, designed in principle to provide incentives to small and medium-sized enterprises (SMEs). Two relevant measures were introduced, namely a reduction in application fees for the assessment and approval process and a unique, new option for ‘pre-certification’ of product applications. This was designed in particular to take account of the high degree of scientific uncertainty associated with the research and development (R & D) and product commercialization processes. Special provision was also made, after a great deal of opposition from industry stakeholders, for a ‘hospital exemption’ for one-off hospital-based products (or ‘preparations’ in some jurisdictions)[[41]](#footnote-41) designed to free from the necessity of central EU authorization in order to fulfil individual medical prescriptions. This had been opposed on the grounds that it would create a non-level playing field for different types of therapy producer. It is important to note here is that the lead Directorate-General (DG) of the European Commission was DG Enterprise (now Enterprise & Industry), rather than DG Sanco which deals with public health and consumer protection. It was believed within DG Enterprise, partly on the basis of market intelligence and projections commissioned from an independent research centre,[[42]](#footnote-42) that SMEs would be the predominant type of producer. Together with these provisions, the ATMP Regulation established a new Committee for Advanced Therapies (CAT) within the jurisdiction of the European Medicines Agency (EMA), which would advise on market authorization decisions on products presented to the regulator. Thus, the trajectory of the ATMP Regulation moved from a medical device focus to one where commensuration with the existing pharmaceutical regime dominated. In order to illustrate how commensuration highlighted conflict over sectoral boundaries, it is useful to examine the way in which so-called ‘combination products’ were dealt with in the negotiations over the final text of the ATMP Regulation.

1. **Combination products**

Combination products present a special, technical challenge to the commensurating impetus at the heart of the ATMP Regulation because they explicitly combine ‘pharmaceutical’ elements with ‘medical device’ elements in regulatory terms. This was a contentious issue during the negotiation of the Regulation and was fiercely debated:

… say a heart valve covered by cells. .. the main mode of action is…not the cells, it’s the valve itself. However the cells are there for a certain function but it might be secondary to the physical mode of action by the valve or by the artificial hip…[[43]](#footnote-43)

The alignment of the product with the iconic artificial hip device emphasizes the threat perceived by medical device interests to a pharmaceutical framing of such products. Further commentaries confirmed the difficulty of the combination products issue.[[44]](#footnote-44) The Council of Ministers’ Working Group representing all Member States, not unusually, held multiple meetings to discuss the ATMP Regulation, but this issue was especially controversial in their debates:

The Presidency has also suggested…all combined products containing viable cells or tissues should be considered ATMPs (the document then notes Members States’ positions on this point): Support: Belgian, Estonian, Lithuanian, Hungarian, Portuguese and Slovenian delegations; Against: Danish, Spanish, French, Netherlands, Swedish and United Kingdom delegations hold that the principal mode of action should be
decisive.[[45]](#footnote-45)

In other words, a range of the north-western EU governments/regulatory agencies wanted to preserve the medical device route to authorization – a heart valve covered by viable cells would be regarded from a regulatory point of view as a medical device because the principal mode of action is biomechanical rather than pharmaceutical or metabolic. The final text of the ATMP Regulation dealt with this sub-class of product in its non legally-binding Recital:

…the complexity of combined advanced therapy medicinal products containing viable cells or tissues requires a specific approach. For these products, whatever the role of the medical device, the pharmacological, immunological or metabolic action of these cells or tissues should be considered to be the principal mode of action of the combination product. Such combination products should always be regulated under this Regulation.[[46]](#footnote-46)

The ATMP Regulation thus appears to be equivocal (‘whatever the role’) about this class of product while embracing them into the regulatory frame of advanced therapies. The substantive part of the Regulation contains a number of references to the Medical Device Directive[[47]](#footnote-47) which covers the ‘device’ part of such products, indicating that their principles should be followed where applicable, emphasizing that:

Where a combined advanced therapy medicinal product is concerned, the whole product shall be subject to final evaluation by the Agency (i.e. EMA).[[48]](#footnote-48)

However, the text of the ATMP Regulation itself makes it clear that regulators foresaw potential conflicts arising especially from this extended aspect of the legislative framework:

In this report, the Commission shall assess the impact of technical progress on the application of this Regulation. It shall also review the scope of this Regulation, including in particular the regulatory framework for combined advanced therapy medicinal products.[[49]](#footnote-49)

In this section, therefore, I have shown how the medical devices regulatory regime and the pharmaceutical regime sought different definitions of the technology in question, as the basis for formulating a new regulatory regime or the extension of an existing, inherited one. We can note that the medical devices industry’s attempts to resist commensuration with the pharmaceutical regime were less than successful. In the following section, I will examine how these tensions have led to continued resistance to the commensurating project of the Commission and subsequently the EMA, as well as how institutional innovations have developed in response.

1. **Strategies of commensuration: implementation and institutional proliferation**

The ATMP Regulation has brought a degree of ordering to what was a confused internationally variegated marketplace with widely differing regulatory regimes, or indeed in some cases, no clear national regulatory regime at all. To this point, the paper has shown firstly how the development of the ATMP Regulation highlighted boundary contests about the types of product and their modes of production, contests in which a project of pharmaceutical commensuration became dominant. The account so far shows clearly, however, that conflicts and tensions remain. While some of these are due to the open-ended, unpredictable nature of regenerative science and technology, others have emerged in response to the pharmaceutical framing of the ATMP regulatory regime.

In this section, therefore, I will examine how a number of developments subsequent to the introduction of the ATMP Regulation have contributed to continuing tensions between commensurative pharmaceuticalization embodied in the EMA and the ATMP Regulation’s constitution of a new Committee for Advanced Therapies (CAT). These developments highlight the identity and boundary-work[[50]](#footnote-50) of the medical device sector and its stance on the material nature of its products and the appropriate modes of assessment of their risk and safety. These developments are most clearly seen in resistance to a proposal to transfer responsibility for some classes of medical devices within the existing regulatory regime to the EMA, and in the development of institutional responses to the pharmaceutical configuration of the ATMP Regulation. I characterize these developments as an *institutional* *proliferation* in the regulatory space of the ATMP regulatory regime. In this discussion, it will be clear that Zhao’s three key aspects of classification – conferring identity, drawing boundaries, and political conflict – are strongly in evidence.

During the final stages of debate of the ATMP Regulation, there had been in parallel a growing move within the Commission to improve the medical devices regulatory regime. The regime was seen as weak in a number of respects, and was thus subject to proposals and consultation for a ‘recast’ of the Directives.[[51]](#footnote-51) The proposals for this ‘recast’ made explicit reference to the ATMP Regulation – a strong commensurative strategy. Crucial to the ‘essential principles’ of the medical devices regime is the principle of regulation proportionate to risk, and the Directives utilize a classification scheme for different levels of imputed risk. Thus the recast identified ‘high-risk’ devices as candidates for moving from the medical devices regime into the pharmaceutical regime[[52]](#footnote-52) - an extremely radical proposal in terms of the sectoral identity of the industries involved. The text of this Commission proposal is worth quoting at length, in order to illustrate the commensurative arguments that were put forward (author’s highlighting):

**ii. Highest risk category medical devices**

Currently there is no systematic public authority input or say in the approval of the

highest risk category medical devices, such as coronary stents, pacemakers, HIV test

kits or diagnostics **to accompanying advanced therapy medicinal products**, before

they are placed on the market. However, the European Medicines Agency (EMEA)[[53]](#footnote-53)

or a national medicines authority are involved in the evaluation of some devices -

**those that are combined with an ancillary medicinal product** - and EMEA is always involved in the assessment of medical devices combined with ancillary human blood derivatives. The question arises as to whether there should be either a de jure or a de facto premarket authorization of these highest risk category medical devices. **The competence of EMEA could be extended**, in particular to the involvement in the evaluation of the **highest risk category devices**, thus introducing a ‘public health’ component into the evaluation process, with the question being still open as to the involvement of Notified Bodies in the process. EMEA has over 10 years of experience in the protection and promotion of public health, through the evaluation and supervision of medicines for human and veterinary use in Europe. EMEA already works with Member States’ national authorities, many of whom have dual responsibility for both medicinal products and medical devices. **EMEA therefore** **already has the structures and networks in place** to pool scientific and technical expertise to guarantee a harmonized high level of evaluation. **It could therefore be appropriate to adapt** the existing structure of EMEA. Specific, multidisciplinary expertise would need to be brought on board to **create a specific Medical Device component of EMEA**, on an **equal footing** with medicinal products. Coupled with this, and, in a similar way to medicinal product, it could also be appropriate to **create a specific Committee in EMEA on Medical Devices** (COMD). [[54]](#footnote-54)

Further, the Recast consultation document proposed and asked:

As the EMEA expertise and approval process is already foreseen for 'viable' human

tissues (under Regulation (EC) No 1394/2007 of the European Parliament and of the

Council of 13 November 2007 on advanced therapy medicinal products and amending

Directive 2001/83/EC and Regulation (EC) No 726/2004), **it would seem logical to also submit 'nonviable' tissues to approval via the same expertise and process**. What in your opinion would be the social and economic impacts if this was the case?[[55]](#footnote-55)

A number of discursive attempts at commensuration can be seen in these controversial texts. Especially note the attempt to argue that the existing (i.e. including the ATMP Regulation) legal provision for assessing device components in the EMA, in cases where ‘combination products’ are at issue, should be taken as a precedent for taking the further step of establishing a specific institutional set-up within the EMA for assessing medical devices classified as high-risk. Unsurprisingly, this evoked a multitude of counter-arguments from the medical devices industry. To give just one typical example, the formal consultation response from the European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR), stated that:

It would be completely wrong to shift the responsibility from NBs[[56]](#footnote-56) to EMEA based on the risk class. If a safety concern is confirmed concerning high class devices, it

would be more efficient to allow only a limited number of NBs, specialized in high

risk class product to assess the conformity assessment, so that, in term of process

we would keep the same process independent of classification. There is simply no

reason to assume EMEA would be more competent to evaluate high risk class

devices than a NB with proven competence.[[57]](#footnote-57)

Thus, it is clear that the commensurative moves of the Commission and the EMA were strongly (and in fact in this case, successfully) resisted by the medical devices sectoral interests. In Zhao’s terms the identity of the medical device industry was defended against a re-classificatory threat to the boundaries of its normal territory. As we saw in the previous section, the uncertainties about the mode of operation of regenerative products was at the centre of debates between the device and pharmaceutical sectors, and combination products in particular gave rise to conflict.

The CAT established by the ATMP Regulation has the task of deciding on the classification of advanced therapy products and advising the EMA on marketing authorization decisions. It is clear that one of the CAT’s *main* tasks has become that of making judgments about the classification of products presented to them by producers, nearly 50 classification opinions having been given between 2009 and 2011.[[58]](#footnote-58) Since its inception, the Committee has advised formally on five products, only one of which, a cell therapy product for articular cartilage repair, has been authorized. Apart from the approved product, two negative opinions were given and two products were withdrawn by the producer. Exemplifying the complexity of classification issues, for example, the July 2011 meeting arrived at the following ‘scientific recommendation’:

the following product was classified as a Tissue Engineered Product, non-combined:

*Suspension of allogeneic bone-marrow derived osteoblastic cells, intended for the treatment of non-union, delayed union or other fractures* [[59]](#footnote-59)

This means that because the product is deemed a ‘non-combined’ ATMP (i.e. there is no ‘device’ part and viable cells are integral to the primary mode of action of the product) the product falls into a particular class within the remit of the ATMP Regulation, separate, notably, from cell therapy. The fact that such products are presented to the CAT initially for a classification decision illustrates the high degree of uncertainty that continues to exist around the workability of the definitional boundaries between tissue engineered and cell therapy products in the context of the definition provided for ‘advanced therapy’ in the ATMP Regulation.

The continued negotiation of the boundaries with the medical device industry is signalled in a number of other ways, including the development of novel organization structures that provide forums for discussion of contentious issues. Thus, for example, an ‘EMA/CAT-Notified Body Collaboration Group’ has been established. The primary remit of this group is to provide: ‘The overview, coordination and the need for any update of any process and guidance for consultation of a notified body for medical devices during an assessment undertaken by the CAT of a combined ATMP/MD’ (i.e. a product that combines an advanced therapy product with a medical device component, for example a cell-based wound therapy on a fabricated polymer ‘scaffold’).[[60]](#footnote-60)

A second example of the proliferation of institutional responses to inform the ‘collaboration’ between medical device (and other) interests and the ATMP regulatory regime is the creation of a ‘CAT-Interested Parties’ forum, and associated ‘Focus Groups’. The first meeting of this group, on ‘non-clinical (i.e. *in vitro* and animal studies) development of ATMPs, again shows the continuing resistance of medical device interests to the pharmaceuticalization agenda. The summary report from the first meeting of this forum notes:

Combined ATMPs: - It would be worthwhile exploring emerging specific animal models such as those presented by EUCOMED (i.e. the EU level trade association of the medical devices industry). - When considering the non-clinical requirement for combined ATMPs, CAT was invited to review the non-clinical testing performed on the device part as part of the medical device essential requirements (i.e. relevant ISO standards) and any other pertinent standards that deal with risk management. The comparison of criteria used to evaluate the medical device part of combined ATMP would avoid repetitions of studies already performed.[[61]](#footnote-61)

The medical device industry interests are clear here. Interestingly, the EMA’s justification for introducing the novel ‘focus group’ approach to dealing with contentious issues makes explicit reference to sociological ‘small group theory’, ‘from the United States’, and the Focus Group has been portrayed as ‘a model for a fruitful interaction between CAT and its stakeholders.’[[62]](#footnote-62) Such a Group usually comprises 6-10 members of the CAT and EMA secretariat and around six stakeholder representatives, typically from the commercial sector. At the time of writing, the other topics identified for the Focus Group approach were a ‘system to navigate guidelines for ATMPs’, and ‘incentives for academia, hospitals and charities’. As previously mentioned, a proposal from a prominent industry representative was for a further Focus Group to examine the controversial ‘hospital exemption.’[[63]](#footnote-63)

A further example of the institutional proliferation process is a novel linking that has been initiated by the EMA between the CAT and scientific learned societies. Stated to be just one of the strategies of the CAT in its progressive implementation of the ATMP regime, the first such meeting, which was given the institutional designation of a ‘workshop’, was between the CAT and the European Society for Gene and Cell Therapy (ESGCT).[[64]](#footnote-64)

Summarizing the current strategies for dealing with the conflicts and uncertainties surround the ATMP commensuration project, the CAT/EMA listed the following: 1. CAT-IP Focus Group on Incentives for academia, hospitals, charities; 2. closer interaction between academic producers and EMA; 3. meeting between CAT and national clinical trial authorities; 4. EMA linking to funding bodies; scientific societies strongly encouraged to contact CAT about issues; and 5. urging of the European Commission to allow re-certification for non-SMEs (the latter would require revision of the ATMP Regulation).[[65]](#footnote-65) We see here not only further instances of institutional proliferation in the form of the establishment of networks between the EMA/CAT and various stakeholders, but also a strong identification of the problems associated with the hospital exemption and the introduction of incentives for SMEs, but not the academic/hospital sector.

Thus, in spite of the harmonization introduced by adoption of the ATMP Regulation, negotiations and frictions continue through a proliferating variety of institutionalized, technical forums spawned by the EMA. On the one hand, the creation of these forums can be seen as stakeholder engagement strategies enacting transparency principles and responding to the political and industrial environment in which this EU regulator operates. On the other hand, they can be seen as direct attempts to cope with the conflictual consequences of the commensurative project of (attempting to) frame the ATMP Regulation as a pharmaceutical regime and to move some classes of medical device in the same direction.

1. **CONCLUDING COMMENTS: COMMENSURATION AND UNANTICIPATED PROLIFERATION**

Espeland and Stevens posed a key question about commensuration: ‘what determines the extent to which a commensurative act gets institutionalized?’[[66]](#footnote-66) In the context of the regulatory commensuration discussed in this paper, we can point to: the ‘force of law’; the extent of agreement or contestation; the mobilization of resources (such as lobbying); and the characteristics, themselves open to disputation, of the regulated techno-scientific object. In the analysis presented in this paper, we have seen that a particular, partial framing has been ‘institutionalized’ in the regulatory structures and legislative pronouncements of the ATMP regime, shown primarily in its foregrounding of pharmaceutical over ‘device’ modes of production. It has also been highlighted by the case of combination products and the Commission proposal to move some high risk medical devices under the institutional wing of the EMA. The tensions inscribed into law by the ATMP Regulation have given rise to a range of institutional innovations generated by the EMA itself. From a political science perspective, these innovations could doubtless be interpreted in part as a demonstration of how a ‘regulatory state’[[67]](#footnote-67) operates, as well as showing ‘network governance’[[68]](#footnote-68) at work, in which a range of interested actors are enrolled into the regulatory process. Further and more specifically, however, this analysis has shown the details of this regulatory institutional innovation in a competitive and scientifically complex industrial and regulatory space, some of which are unique to this area of regulation. In addition, it has traced how they grew from and relate to the trajectory of a commensurative regulatory project.

It is not surprising that the commensurating proposal to bring some medical device evaluation into the pharmaceutical fold was seen as opening the floodgates to an innovation-stifling pharmaceuticalization of the device sector. Equally, it is unsurprising that ‘combination products’ have emerged as a focus for inter-sectoral conflict, in which institutional actors contest sectoral boundaries and attempt to preserve collective identities that are deeply ingrained in long-established working practices and business models. Thus we have seen how the practice of commensuration, of ‘making things the same’,[[69]](#footnote-69) can be contested and constructed through discourses of the powerful or resourceful, and how some bioscientific and biotechnological artefacts by their character are open to malleable interpretations by actors in the regulatory space.

As noted early in this paper, Brownsword took regulatory connection to be the outstanding generic problem of the regulation of contemporary innovative science and technology, because of the speed of innovation.[[70]](#footnote-70) We have seen in this analysis that commensuration through analogy in regulatory design was a strategy for both maintaining and reconfiguring regulatory connection. In the case analysed here, this was sought by extending the parameters of an existing pharmaceutical regime and framing the ‘new’ regulation, especially to legislate for tissue engineered products, by extending recent, novel classificatory terms (advanced therapy medicinal products). We have seen that the drafting of the ATMP Regulation reflected the tension that Brownsword noted between the need for open-endedness (‘flexibility’) and the need to establish rules of engagement (‘consistency’) so that participants in the regenerative medicine field, regulatees, ‘know where they stand’[[71]](#footnote-71). This formulation aligns well with Zhao’s identification of identity (of participants) and boundaries (defining the field in a way acceptable to regulated participants) as key aspects of society’s socioeconomic classification activity, which is evident here in this regulatory domain.

By employing a sociological perspective, however, this analysis has further demonstrated how an unforeseen proliferative institutional innovation in the regulatory space contributes to attempts to maintain regulatory connection, apart from the substantive legislation or soft law guidance being developed in the field.[[72]](#footnote-72) While institutional innovation is in broad terms mandated by in this case the ATMP Regulation, this paper has pointed to the novel, unanticipated forms of institutional design that have emerged. Regulatory *dis*connection is not necessarily dysfunctional in terms of the legitimacy of social and economic behaviour. However, in the case study considered here, we see regulatory institutional proliferation as a strategic means of attempting to maintain in parts a tenuous regulatory connection. This has taken place in the context of an extension of an inherited regulatory regime seen as contentious by key actors in the field, in circumstances where commensurability has been stretched to the limit.

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30. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to Medicinal Products for Human Use. OJ L 311(Medicinal Products Directive). [↑](#footnote-ref-30)
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