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## **Body Extension and the Law: Medical Devices, Intellectual Property, Prosthetics and Marginalisation (Again)**

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# **Body Extension and the Law: Medical Devices, Intellectual Property, Prosthetics and Marginalisation (Again)**

This interdisciplinary paper, drawing on empirical and doctrinal research regarding artificial limbs and digital avatars, analyses two concepts which are argued to be core to the person – integrity and identity. From the perspective of a person who is a prosthetic user, the paper then evaluates the extent to which two legal regimes which are highly relevant to prosthetics, medical devices regulation (and its delivery) and intellectual property (and its power), engage with the person, integrity and identity with a focus on approaches taken to authority and control. The paper criticises the meaning which law generates regarding the person. It calls for new approaches to be taken by the legal regimes explored to the person, identity and integrity; and for a new multifaceted interdisciplinary driven approach to the person.

Keywords: Person; integrity; identity; intellectual property; medical devices.

## **1. Introduction**

Human beings – persons bounded in a physiological form – sit at the heart of many of our governance frameworks, moral and legal. The law often focuses, however, on particular outcomes rather than the person; law leaves mostly unaddressed much that might be important to the identity, boundaries and expression of the person. Yet in turn, the ability of the law to effectively govern the person is increasingly challenged, by the growing complexity and fragmentation of the person in a postmodern and technology-entangled society. Whereas the person has traditionally been positioned as a binary (human v. nature, human v. machine, individual v. group, man v. woman, non-disabled v. disabled),<sup>1</sup> there is increasing argument that the person is an ‘assemblage’<sup>2</sup> – a

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<sup>1</sup> This is an approach much criticised by followers of the affirmative model of disability,

variably integrated collection of physical/physiological, material/mechanical, and virtual/digital elements in fluid relation to one another.

In this context, here we (an interdisciplinary group, from law, performance and medicine) explore law as it relates to the person, as extended through physical prosthetics. Our focus is on artificial limbs applied due to an absence caused by congenital condition, physical illness or injury, or personal choice.<sup>3</sup> Our analysis draws heavily on doctrinal legal research, practical medical clinical experiences of one of the authors, and from a small but highly relevant set of interviews and Focus Groups. The work is grounded in ‘Identity and Governance of Bodily Extensions: The Case of Prosthetics and Avatars’, an interdisciplinary project funded by the Wellcome Trust,<sup>4</sup>

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which broadly focuses on what people can do; and indeed by supporters of the social model which sees disability as the restrictions imposed on individuals by society through the social and physical barriers that characterise common interactions and built environments, rather than on how individuals may be ‘impaired’ John Swain and Sally French “Conclusions: Some Reflections on Key Questions” in John Swain and French, S. (eds.) *Disability on Equal Terms* (London: Sage, 2008) in contrast to the more traditional medical model of disability, which sees disability (which would include the absence of a limb) as a physiological and functional problem to be remedied or otherwise managed so that the individual can better operate and be accepted in a society not designed for them – see Union of the Physically Impaired Against Segregation, *Fundamental Principles of Disability* (London: London UPIAS, 1976). For a critique on how medical law and bioethics has engaged with disability, see Alicia Ouellette *Bioethics and Disability: Toward a Disability-Conscious Bioethics* (Cambridge: CUP, 2011), and Shawn Harmon “The Invisibility of Disability: Using Dance to Shake from Bioethics the Idea of ‘Broken Bodies’” (2015) 29 *Bioethics* 488-498; the social model has achieved significant recognition in policy and law-making, notably the Convention on the Rights of Persons with Disabilities (2006).

<sup>2</sup> Guattari Deleuze and Felix Guattari (transl. Bruab Massumi) *A Thousand Plateaus* (London: Continuum, 1987).

<sup>3</sup> Elizabeth Wicks *The State and the Body: Legal Regulation of Bodily Autonomy* (Oxford: Hart, 2016), which, at 107, discusses bodily modification. Also note the sociological work of the late Debra Gimlin:

[https://www.researchgate.net/profile/Debra\\_Gimlin/publications?pubType=article](https://www.researchgate.net/profile/Debra_Gimlin/publications?pubType=article). It is with affection and respect that Brown expresses deep sadness that she will be unable to continue their conversations on this issue.

<sup>4</sup> See <http://www.pci.leeds.ac.uk/research/featured-research-projects/identity-and-governance-of-bodily-extensions-the-case-of-prosthetics-and-avatars/>. In the context of this project, we have undertaken discursive meetings and user focus groups. Interviewees were selected to provide a range of perspectives on limb and avatar usage and design. Interviews were semi structured, lasted approximately one hour, were recorded and transcribed with verbal

and also, as will be noted, on previous empirical research in the disability and digital settings.

Our intent is to uncover the extent to which laws in general, and two specific legal regimes in particular – medical devices and intellectual property (“IP”) - are sensitive to, or appropriately reflect, the reality of persons who use these particular extensions. The first regime is chosen as prosthetics are medical devices, the marketing and deployment of which typically require regulatory approval and meeting quality and safety standards. The second regime is explored, with a UK focus, as prosthetics or their components can be the results of innovation and creativity; as such intellectual property (“IP”) rights (particularly patent, design and copyright) can be obtained claimed and exercised. This is also against the backdrop of technology making it increasingly easy to reproduce the work of others – thus potentially infringing IP rights while enhancing personal experiences.<sup>5</sup> We argue that these regimes have the potential to impact directly on prosthetic development, allocation, and use; empower or marginalise prosthetic users, a group already long and widely discriminated against;<sup>6</sup> and contribute to how

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recorded consent to quotation in inter alia publications. 3 interviews were carried out with amputees (one an artist, runner, advocate and lower limb above knee amputee, one a dancer and lower limb above knee amputee and one a computer gamer and cybernet athlete paralysed from shoulder downwards. Another interview was held with the director of a prosthetic limb manufacturer. The interviewees were all already known to the members of the project team and in some cases are involved in the project. An avatar focus group was attended by 8 people, all players with massively multiplayer online games, recruited via postings on massively multiplayer online game Facebook groups. The prosthetic user group was attended by 3 people, 2 limb users and one carer, recruited via the Seacroft Hospital Prosthetics User. Focus groups were semi-structured, lasted 2 hours, were audio recorded and transcribed and consent forms were signed at the events.

<sup>5</sup> For example, 3D printing allows individuals to build/print devices in their home with very little oversight, and in the process to copy IP-enclosed products: with a focus on technology, see Adam Thierer and Adam Marcus “Guns, Limbs, and Toys: What Future for 3D Printing” (2016) 17 Minnesota Journal of Law, Science & Technology 805-854; with a focus on legal pathways, see

<sup>6</sup> Paul Abberley “The Concept of Oppression and the Development of a Social Theory of Disability” (1987) 2 Disability, Handicap & Society 5-19; Fiona Campbell “Inciting Legal

prosthetic users are constructed and treated more broadly in society.

First, in the section 2, we identify and explore two concepts that, however vague and contested they may be, are central to ‘meaning-making’ in the disability and prosthetics context, namely ‘identity’ and ‘integrity’.<sup>7</sup> These provide a lens through which we can examine the law and its adequacy.<sup>8</sup> Next, in section 3 we examine in more depth the extent to which the medical devices and IP frameworks engaged with prosthetic limbs. In Section 4, we discuss the level of engagement between each of the two legal frameworks and identity and integrity. Section 4.1.1 explores a medical device regulatory focus on safety and on patients; section 4.1.2 analyses the practical delivery of prosthetic limbs, regarding relevant factors, budget and the opportunity for court action; and section 4.2 critiques the impact of IP rights in terms of their existence and power. Building on this, section 4.3 argues that there the control and authority which results from these legal regimes has inadequate regard to identity and integrity, particularly in the light of some empirical conclusions; and proposals for change are made. Section 5, the conclusion, builds on this, calling for a new, multifaceted approach to the person. Some initial and innovative contributions are made regarding the extent to which the law, through these two regimes specifically, could change to empower prosthetic users, facilitate their capacity to act and engage with society, and engage with

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Fictions: Disability’s Date with Ontology and the Ableist Body of the Law” (2001) 10 Griffith Law Review 42-62; Susan Schweik, *The Ugly Laws: Disability in Public* (NY: NYU Press, 2009).

<sup>7</sup> We acknowledge that there may well be other concepts of significance to prosthetic-users, but our research highlights these as particularly important, and they potentially have some resonance with the frameworks we are exploring.

<sup>8</sup> Note separation discussion in an analysis piece Shawn H. E. Harmon, Abbe Brown, Sita Popat, Sarah Whatley, and Rory O’Connor, "Struggling to be Fit: Identity, Integrity, and the Law", (2017) 14:2 SCRIPTed 326 <https://script-ed.org/?p=3411>  
DOI: 10.2966/scrip.140217.326 regarding the location of these concepts in the broader legal landscape offering an overview of the extent to which they are noticed and how they are understood.

the concepts of integrity and identity in ways that are positive and enabling.

## **2. Concepts Important to Meaning-Making in the Prosthetics Context**

Meanings are the cognitive categories that make up our view of reality.<sup>9</sup> The making or taking of meaning is critical to human life, because humans have a natural tendency to make meaning out of their experiences and out of, and for, their lives.<sup>10</sup> Indeed it has been argued that:

The most fundamental aspect of a human social setting is that of meanings. These are the linguistic categories that make up a participant's view of reality and with which actions are defined. Meanings are also referred to by social analysts as culture, norms, understandings, social reality, and definitions of the situation, typifications, ideology, beliefs, worldview, perspective or stereotypes. Terms such as these share a common focus with humanly constructed ideas that are consciously singled out as important aspects of reality. Meanings are transbehavioral in the sense that they do more than describe behavior – they define, justify, and otherwise interpret it as well.<sup>11</sup>

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<sup>9</sup> Charles Chen "On exploring meanings: Combining humanistic and career psychology theories in counselling" (2001) 14 *Counselling Psychology Quarterly* 317-331.

<sup>10</sup> Viktor Frankl et al *Man's Search For Meaning* (Boston: Beacon Press, 1963).

<sup>11</sup> Steven Krauss "Research Paradigms and Meaning Making: A Primer" (2005) 10 (4) *The Qualitative Report* 758-770.

While meanings can be broad (e.g., ideologies or philosophies) or narrow (e.g., attached to defined aspects of the human existence or a person's life and experience), they all shape narrative identity, or that sense of personal unity and purpose and place which is derived from diverse experiences and interactions.<sup>12</sup> In short, however broad or narrow, or whether derived from human relations or contact with social systems, meanings have impacts on the individual. Moreover, these impacts are often psycho-socially significant (i.e., they are important both to disposition and psychological wellbeing, on the one hand, and to social reality and standing, on the other).

Previous interdisciplinary research undertaken by the authors in the context of elite/professional dance made and performed by disabled dancers suggests that the concepts of 'identity' (including the potential for a person to have and to choose multiple identities) and 'integrity' are particularly important for meaning-making in the prosthetics setting.<sup>13</sup> These concepts are properly, indeed unavoidably, viewed as holding psycho-social significance for prosthetic users; through their conduct, relationships, experiences, and points of contact with the built and social worlds, prosthetic users (indeed all of us) give meaning to these concepts. In turn, these concepts influence, for better or for worse, our understanding(s) of ourselves and each other, the world, and our place in that world. As such, we consider each briefly below.

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<sup>12</sup> Jefferson Singer "Narrative Identity and Meaning Making Across the Adult Lifespan: An Introduction" (2004) 72 *Journal of Personality* 437-460.

<sup>13</sup> See the InVisible Difference Project (<http://www.invisibledifference.org.uk/>), an AHRC-funded project that sought to extend thinking around the making, status, ownership and value of work by contemporary dance choreographers, focusing specifically on that made and performed by disabled dance artists; and the Projecting Performance Project, an AHRC-funded project that examined methods of digital extension to the technical operator's body in theatrical performance contexts: Sita Popat & Scott Palmer, "Embodied Interfaces: Dancing with Digital Sprites" (2008) *Digital Creativity* 19:2, 125-137.



As should be apparent from any interaction with the world, ‘identity’ (and ‘identities’ although for present purpose it will mainly be discussed in the singular) is critical to the person. Identity is, however, a contested and multifaceted concept, bearing both subjective and objective elements.<sup>14</sup> With respect to the former, it is used to describe a variety of phenomena, including core personal values and interests, and self-perceptions. With respect to the latter, it encompasses public statuses that might be assigned at birth or later and third-party descriptions. Thus, identities can be constructed through individual and fluid narrative practices, or imposed externally and set more permanently through formal institutions.<sup>15</sup> As such, it has been argued that individuation is a process in which individuals express an identity to the extent permitted by those with whom they are in communication and partnership; and that we construct our identity in large part by learning from, and drawing on, the perspectives of others toward our qualities and abilities.<sup>16</sup> However, the social entanglement that characterises identity renders us vulnerable to ‘disrespect’, which can not only upset our personal narrative, but also expose us to physical risk, and so to a loss of our second concept - integrity.

The concept of ‘integrity’ has a strong moral character, and is closely linked to dignity, which refers to the unity and wellbeing of the person.<sup>17</sup> It can be both

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<sup>14</sup> Augusto Blasi and Kimberly Glodis “The Development of Identity: A Critical Analysis from the Perspective of the Self as Subject” (1995) 15 *Developmental Review* 404-433.

<sup>15</sup> Donald Polkinghorne “Explorations of Narrative Identity” (1996) 7 *Psychological Inquiry* 363-367; Leonie Huddy “From Social to Political Identity: A Critical Examination of Social Identity Theory” (2001) 22 *Political Psychology* 127-156. Regarding specific settings, see Ingegard Fagerberg and Mona Kihlgren “Experiencing a Nurse Identity: The Meaning of Identity to Swedish Registered Nurses 2 Years After Graduation” (2001) 34 *Journal of Advanced Nursing* 137-145; and more.

<sup>16</sup> Georg Hegel (transl. Michael Petry) *Hegel’s Philosophy of Subjective Spirit* (Dordrecht: Reidel, 1978).

<sup>17</sup> For more on dignity, see Charles Foster *Human Dignity in Bioethics and Law* (Oxford: Hart,

measured against and infringed by various forms of personal insult. As such, the constitution of human integrity (including physical integrity), which is particularly relevant to the prosthetics setting because of its links with questions of perceived wholeness, is dependent on the experience of ‘intersubjective recognition’ (i.e., it depends on receiving approval and respect from others).<sup>18</sup> This again links back to identity. What is not often appreciated, is that (physical) integrity can be achieved in the absence of conformity to the social norm (i.e., to the normatively constructed whole or healthy or idealised body). Indeed, physical perfection is often cited as a damaging myth,<sup>19</sup> and physical normality as a socio-political tool that too often distracts us from the variety and malleability of the human form; and from the fact that different forms of embodiment or ways of being can be just as exemplary of integrity as others despite their traditional association with non-wholeness or disability.<sup>20</sup> In other words, one can achieve a sense of (physical) integrity within a wide array of embodiments that do not comply with the metrics of the normative body,<sup>21</sup> and so the notion of integrity is a potentially empowering concept. Integrity is also critical to the above-mentioned notion of body as assemblage. It is the integrity or unity that defines the assemblage, and sets it apart from just a collection of parts.<sup>22</sup>

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2011).

<sup>18</sup> Axel Honneth “Integrity and Disrespect: Principles of a Conception of Morality on the Theory of Recognition” (1992) 20 *Political Theory* 187-201.

<sup>19</sup> Roberta Galler “The Myth of the Perfect Body” in Carole Vance (ed.) *Pleasure and Danger: Exploring Female Sexuality* (London: Routledge & Kegan Paul, 1984) 165-172.

<sup>20</sup> Nikki Sullivan “Integrity, Mayhem, and the Question of Self-Demand Amputation” (2005) 19 *Continuum: Journal of Media & Culture Studies* 325-333.

<sup>21</sup> See Charlotte Waelde, Mathilde Pavis, Karen Wood, Sarah Whatley, Shawn Harmon, Kate Marsh, Abbe Brown “A new foundation: physical Integrity, disabled dance and cultural heritage” in Sarah Whatley, Charlotte Waelde, Abbe Brown, Shawn Harmon, Karen Wood (eds) *InVisible Difference: Dance, Disability and Law* (Bristol: Intellect, 2018 forthcoming).

<sup>22</sup> Manuel DeLanda *A New Philosophy of Society: Assemblage Theory and Social Complexity* (London: Continuum, 2006). DeLanda argues that the whole and the parts exist simultaneously on the ontological plane; the properties of the whole are contingent upon the relationship of the parts with each other, and to some extent vice-versa, which means that the 4-limbed, upright, bipedal human norm still strongly shapes the relationship between the

Further, the concepts of identity and integrity are linked in both subtle and complex, and even inconsistent, ways to the individual's prosthesis and lived experience. This is not only borne out by our own research introduced above, where dancers held multiple and situationally-driven feelings toward, and relationships with, their prosthesis;<sup>23</sup> but also by research involving amputees, which has shown that the use of a prosthesis can be associated with the perception of an effective extension of the arm,<sup>24</sup> and by brain-imaging research, which has shown cortical reorganisation on the part of amputees after use of assistive tools.<sup>25</sup> Neuroscientific studies have also demonstrated that, under certain conditions, the brain is able to treat a tool as part of the body.<sup>26</sup> Similarly, research into digital gaming and performance has shown that people readily extend their presence and identity into virtual worlds via embodiment of their avatars; and that they were enabled and restricted by the technology made available to them, in some cases creating new identities<sup>27</sup> - which may or may not be bipedal or humanoid (for example, the human player might choose a different gender, to become an animal not found in real world nature and/or to have new traits, such as the ability to

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parts in the assemblage.

<sup>23</sup> For example, some of our participants slipped quite readily back and forth between talking about their prosthetic legs as inanimate objects, and as parts of their own bodies.

<sup>24</sup> Paul McDonnell, Robert Scott, et al. "Do artificial limbs become part of the user? New evidence" (1989) 26 *Journal of Rehabilitation Research and Development* 17-24.

<sup>25</sup> Martin Lotze, Wolfgang Grodd, et al. "Does use of a myoelectric prosthesis prevent cortical reorganization and phantom limb pain?" (1999) 2 *Nature Neuroscience* 501-502; Pascal Giroux, Angela Sirigu, et al. "Cortical Reorganization in Motor Cortex after Graft of Both Hands" (2001) 4 *Nature Neuroscience* 691-692; Masaharu Maruishi, Yoshiyuki Tanaka, et al. "Brain activation during manipulation of the myoelectric prosthetic hand: A functional magnetic resonance imaging study" (2004) 21 *NeuroImage* 1604-1611.

<sup>26</sup> See Atsushi Iriki, Michio Tanaka, et al. "Coding of Modified Body Schema During Tool Use by Macaque Postcentral Neurons" (1996) 7 *NeuroReport* 2325-2330, and Angelo Maravita and Atsushi Iriki "Tools for the Body (Schema)" (2004) 8 *Trends Cognitive Science* 79-86.

<sup>27</sup> Angela Adrian Law and Order in Virtual Worlds: Exploring Avatars, their ownership and rights (Hershey: Information Science Reference, 2010) 33-88; and Tracy Spaight "Who Killed Miss Norway" and Susan Crawford "Who's in Charge of Who I Am? Identity and Law Online" both in Jack Balkin (ed) *The State of Play: Law and Virtual Worlds* (New York: New York University Press, 2006) 189-216.

fly).<sup>28</sup>

All told, it would seem that body representation, which is critical to identity formation, is plastic, capable of incorporating salient external objects, tools and assistive devices.<sup>29</sup> The reason or objective for the prosthesis (as rehabilitative or functional replacement, as tool, as aesthetic addition through choice, or as something else), together with other external factors (like its appearance, capabilities or who controls it and how) may also influence how the prosthesis is perceived within the bodily assemblage. These can give rise to a greater sense of embeddedness and ownership, thereby undermining characterisations of ‘artificiality’.<sup>30</sup> Parenthetically, the objectives associated with it (as tool, replacement, or other) may also (or ought to) have

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<sup>28</sup> Jaime Banks “Object, Me, Symbiote, Other: A Social Typology of Player-Avatar Relationships” (2015) 20 *First Monday* <http://firstmonday.org/ojs/index.php/fm/article/view/5433/4208> (last accessed 13 September 2017), and Sita Popat “Missing in Action: Embodied Experience and Virtual Reality” (2016) 68 *Theatre Journal* 357-378; Julia Shaw “From homo economicus to homo roboticus: an exploration of the transformative impact of the technological imagery” (2015) *International Journal of Law in Context* 245-263; Jack Balkin “Virtual Liberty: Freedom to Design and Freedom to Play in Virtual Worlds” 2004 90 (8) *Virginia Law Review* 2043-2098; Greg Lastowka “Virtual Justice: the New Laws of Online Worlds” (New Haven: Yale University Press, 2012 (Paperback)) 35 et seq, discussing development of avatars and gaming, 45 et seq; Woodrow Barfield “Intellectual Property Rights in Virtual Environments: Considering the Rights of Owners, Programmers and Virtual Avatars” 2006 39 *Akron Law Review* 649-700; Woodrow Barfield “The Law of Looks and Artificial Bodies” in Woodrow Barfield *Cyber-Humans: Our Future with Machines* (Gottingen: Copernicus, 2015) 215-266; Edward Castronova “Theory of the Avatar” (2003) CESifo Working Paper 863 [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=385103](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=385103) (last accessed 13 September 2017).

<sup>29</sup> Angelo Maravita, Charles Spence et al. “Driver Tool-Use Changes Multimodal Spatial Interactions between Vision and Touch in Normal Humans” (2002) 83 *Cognition* B25-B34; James Lewis “Cortical Networks Related to Human Use of Tools” (2006) 12 *Neuroscientist* 211-231; Alessandro Farne, Andrea Serino et al. “Dynamic size-change of peri-hand space following tool-use: Determinants and spatial characteristics revealed through cross-modal extinction” (2007) 43 *Cortex* 436-443; and Oyvind Standal “Re-embodiment: Incorporation through Embodied Learning of Wheelchair Skills” (2011) 14 *Medical, Health Care and Philosophy* 177-184.

<sup>30</sup> Keisuke Suzuki, Sarah Garfinkel, et al “Multisensory integration across exteroceptive and interoceptive domains modulates self-experience in the rubber-hand illusion” (2013) 1 *Neuropsychologia* 2909-2917; Jane Aspell, Lukas Heydrich, et al. “Turning body and self inside out: Visualized heartbeats alter bodily self-consciousness and tactile perception” (2013) 24 *Psychological Science* 2445-2453.

different implications for the design and functional parameters of the prosthesis.<sup>31</sup>

In summary, identity is shaped in part by physiology. And while society imposes bipedal uprightness as the physical norm and creates social and environmental pressures to conform,<sup>32</sup> prosthetic users can nonetheless achieve a sense of physical integrity regardless of the particulars of their embodiment. They may feel whole and internally harmonious despite their divergence from the ‘normal’ parameters of wholeness and idealised embodiment which may be imposed by society. Further, the users’ identity and sense of integrity will almost certainly be influenced by the prosthesis; and so, even if a prosthesis is developed in and designed for the rehabilitative setting, their characterisation as a rehabilitative tool or mere functional replacement may not be appropriate.<sup>33</sup> The prosthesis may be additionally desired for its constitutive function and its influence on individuation. Indeed, the prosthesis might be inculcated into the individual’s personal narrative such that one’s sense of ‘ownership’ over it (not necessarily in a legal sense) might be comparable to that of the usual physiological body part it is meant to replace. Given the above, it seems clear that how key specific legal frameworks approach both these core meaning-making concepts, and prosthetics more specifically, is important.

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<sup>31</sup> Luke Miller, Matthew Longo, et al. “Tool Morphology Constrains the Effects of Tool Use on Body Representations” (2014) 40 *Journal of Experimental Psychology: Human Perception and Perform* 2143-2153.

<sup>32</sup> Sharon Betcher “Putting my Foot (Prosthesis, Crutches, Phantom) Down: Considering Technology as Transcendence in the Writings of Donna Haraway” (2001) *Women’s Studies Quarterly* 29(3/4) 35-53.

<sup>33</sup> Donna Reeve “Cyborgs, Cripples and iCrip: Reflections on the Contribution of Haraway to Disability Studies” in Dan Goodley et al (eds.) *Disability and Social Theory: New Developments and Directions* (London: Palgrave Macmillan, 2012) 91-111, which notes that technology is frequently overly associated with normalisation, rehabilitation, and cure; see also Dan Goodley *Disability Studies: An Interdisciplinary Approach* (London: Sage, 2011); and Margaret Quinlan and Benjamin Bates “Bionic Woman (2007): Gender, Disability and Cyborgs” (2009) (1) *Journal of Research in Special Educational Needs* 48-58, 51

### 3 Legal Frameworks and their approaches to prosthetics

So informed, we are now equipped to explore in greater depth the principles and the rules of the two legal frameworks (medical devices and IP) in an effort to evaluate their worldview. This discussion could sit alongside a broader system of laws and norms such as property<sup>34</sup> and contract<sup>35</sup> law regarding the ownership of the physical prosthesis, information control law regarding the structure and use of the prosthesis,<sup>36</sup> tax status<sup>37</sup> and how well the law respects and facilitates our diversity.<sup>38</sup> However, these issues must lie outside the scope of this paper. As a preliminary point, we will explore the extent to

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<sup>34</sup> See eg European Convention on Human Rights and Fundamental Freedoms (1951) Protocol 1 art 1 ECHR; Caterina Sganga “Cracking the citadel walls: a functional approach to cosmopolitan models within and beyond national property regimes” (2014) *Cambridge Journal of International and Comparative Law* 770-794, from 776; Neil A Silberman “From Cultural Property to Cultural Data: The Multiple Dimensions of “Ownerships” in a Global Digital Age” (2014) 21(3) *International Journal of Cultural Property* 365-374; Andrew Murray *Information Technology Law: The Law and Society* (Oxford: OUP, 3<sup>rd</sup> ed 2016) 91-109; Joshua Fairfield “Virtual Property” 2005 85 (4) *Boston University Law Review* 1047-1102.

<sup>35</sup> Lee Bygrave “Contract vs statute in internet governance” in Ian Brown (ed) *Research Handbook on Governance of the Internet* (Cheltenham: Edward Elgar, 2013) 168-197 raises interesting questions on forms of regulation, flexibility and power imbalances.

<sup>36</sup> UK Data Protection Act 1998, Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data OJ L 119 4 May 2016 1-88 (General Data Protection Regulation).

<sup>37</sup> *Amoena (UK) Ltd v The Commissioners for HM Revenue and Customs* [2011] UKFTT 675 (TC) regarding a mastectomy bra; this discusses mass production, individual need, substitutability for the body - rather than disability.

<sup>38</sup> For more on the role of law in recognising and normalising diversity, see Sarah Whatley, Charlotte Waelde et al. “Validation and Virtuosity: Perspectives on Difference and Authorship/Control in Dance” (2015) 6 *Choreographic Practices* 59-83, and Shawn Harmon, Hannah Donaldson et al. “Disability and the Dancing Body: A Symposium on Ownership, Identity and Difference in Dance” (2015) 12 *SCRIPTed* 59-69 <https://script-ed.org/article/disability-and-the-dancing-body-a-symposium-on-ownership-identity-and-difference-in-dance/> (last accessed 13 September 2017).

which the frameworks explicitly recognise prosthetics as within their remit. This may impact on how cognisant they are of the particularities of the prosthetics environment.

The medical devices regime will be explored on the basis of an EU Regulation of 2017.<sup>39</sup> This will come into effect in 2020, preserves many of the key features of the existing regime, and once in force, must be applied in its entirety across the EU - as with so many issues, the approach to be taken in the UK after Brexit remains to be seen. The EU Regulation defines a ‘medical device’ as any instrument, apparatus, appliance, implant or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of a number of specific medical purposes - one of which is the ‘replacement or modification of the anatomy or of a physiological or pathological process or state’.<sup>40</sup> Such devices can only be ‘placed on the market or put into service’ if they comply with the EU Regulation, and are supplied and properly installed, maintained, and used in accordance with their intended purpose.<sup>41</sup> In short, a wide range of artefacts are captured, including prosthetics. Their availability is contingent on compliance with the regime established.

In contrast, IP laws focus on whether the requirements are met for a right to exist, rather on the uses of the underlying subject matter. IP law is found in national<sup>42</sup>

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<sup>39</sup> Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices OJ L 117 5 May 2017 1-175. This builds on Document 2012/0266 (COD), 22 February 2017, which represents the final text of the new Regulation of the European Parliament and of the Council on Medical Devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002, and Regulation (EC) No 1223/2009, and repealing Council Directives 90/385/ and 93/42/EEC. See [https://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework\\_en](https://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework_en) (last accessed 13 September 2017) (EU Regulation).

<sup>40</sup> EU Regulation (n5), art 2.1(1).

<sup>41</sup> EU Regulation (n5), art 5.1.

<sup>42</sup> Eg UK Patents Act 1977, UK Copyright Designs and Patents Act 1988, UK Registered

and EU<sup>43</sup> law (again for the UK there is the Brexit uncertainty), under the umbrella of international treaties like the TRIPS Agreement,<sup>44</sup> within the World Trade Organisation.<sup>45</sup> For an IP right to exist, there needs to be an invention, the non-functional appearance of a product or an original piece of work which meets the thresholds for (respectively), the patent, design, or copyright to exist. Key issues for patents are that the invention is new and inventive as compared to common knowledge or the general state of the art;<sup>46</sup> for registered design it needs to be new and of individual character with the overall impression on the informed user differing from the overall impression of others;<sup>47</sup> for a UK unregistered design the shape or configuration of whole or part article is not to be common place;<sup>48</sup> and for copyright (which is also an unregistered right) the works needs to be original in the sense of not copied from the work of another,<sup>49</sup> and to come within a relevant category – key examples relevant here are literary works for drawings,<sup>50</sup> sculptures and graphic work irrespective of artistic quality<sup>51</sup> and works of artistic craftsmanship.<sup>52</sup> There are differences in the forms of protection which are conferred by each right. Broadly, again, the patent<sup>53</sup> and registered

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Designs Act 1949.

<sup>43</sup> Council Regulation (EC) No. 2002/6 of 12 December 2001 on community designs OJ L 3 5 January 2002, 1-24 (Community Design Regulation); Directive 98/71 on the legal protection of designs OJ L 289 28 October 1998 28-35; Directive 98/44 of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions OJ L 213 30 July 1998.

<sup>44</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1 C to the WTO Agreement (TRIPS)

<sup>45</sup> See WTO website <https://www.wto.org> (last accessed 13 September 2017).

<sup>46</sup> Patents Act 1977, ss1-3.

<sup>47</sup> Registered Designs Act 1949, ss1(2), 1B(1) and (3), 1C and Community Design Regulation (n7), arts 4, 5, 6.

<sup>48</sup> Copyright Designs and Patents Act 1988, s213(4); but it not need to be novel, see *Amoena v Trulife* [1995] 12 D-346

<sup>49</sup> *University of London Press v University Tutorial Press* [1916] 2 Ch 601, note also *Infopaq International A/S v Danske Dagblades Forening* (C-5/08) [2009] ECDR 26

<sup>50</sup> Copyright Designs and Patents Act 1988, s1(1)(a).

<sup>51</sup> Copyright Designs and Patents Act 1988, s4(1)(a).

<sup>52</sup> Copyright Designs and Patents Act 1988, s4(1)(c).

<sup>53</sup> Patents Act 1977, s 125 (1) referring to European Patent Convention, art 69 and Protocol;



design<sup>54</sup> tests focus on the similarity between products and the scope of the IP right, even if they were independently created; whereas copyright requires, as the name suggests, copying in a 2D or 3D form, although this can be indirect<sup>55</sup> (e.g. the person may have forgotten that they saw an existing product which they then build – this raises obvious problems of evidence).

It should be stressed that in contrast with the position in respect of EU Regulation, it is possible for prosthetics to exist without IP. Further, IP rights regarding, say, control of the shape or function of a prosthetic leg, are quite distinct from the ownership of a particular physical prosthetic leg. Where there is a relevant IP right, however, the owner of the IP right will have the power to influence use of the prosthesis made, exactly or similarly, in 2 or 3 D form, to that particular shape or function.<sup>56</sup> Accordingly, and as is considered further below, the IP owner could forbid the use of a prosthesis without their permission even if the medical devices regime, the prosthetic user, and the clinical team would like this to be done. And as prosthetics are being further developed and directly sourced by suppliers complementing traditional medical public hospital based structures, for example by Touch Bionics<sup>57</sup> and the Alternative Limb Project,<sup>58</sup> there is the prospect of private control through the power of IP being more visible, rather than hidden behind medical walls.

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Kirin-Amgen v Hoechst Marion Roussel [2005] 1 All ER 667 and Actavis UK Ltd v Eli Lilly & Co [2017] UKSC 48.

<sup>54</sup> Registered Designs Act 1949, s 7(1), Magmatic Ltd v PMS International Group Plc [2016] UKSC 12.

<sup>55</sup> Copyright Designs and Patents Act 1988, s 16.

<sup>56</sup> Copyright Designs and Patents Act 1988, s 17(3).

<sup>57</sup> See Touch Bionics website <http://www.touchbionics.com/> (last accessed 13 September 2017).

<sup>58</sup> See website <http://www.thealternativelimbproject.com> (last accessed 13 September 2017).

IP can indeed be relevant to the outputs of all manufacturers and makers. In addition to the growth of private entities, there are community maker voluntary initiatives such as Knitted Knockers for homemade breast prosthesis.<sup>59</sup> It will be interested to monitor the impact of these activities and their attitudes to IP. Unregistered design and copyright will arise automatically if the thresholds are met, and it is quite possible that the other forms of IP protection will also be sought; whether or not all manufacturers and makers then choose to rely on IP rights to prevent activity by others is their choice. There are examples of this not being done, with patents not being sought and relevant information being made available, to enable the prostheses to be reproduced more readily - including through 3D printing<sup>60</sup> (which was introduced above from its opposite perspective, as providing a new opportunity for infringement).<sup>61</sup> Yet although makers may be open to their work being reproduced by some,<sup>62</sup> what about this being done by a large company who seeks to charge high (or any) fees?

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<sup>59</sup> See website <https://www.knittedknockers.org> (last accessed 13 September 2017); Donna Reeve and Richard Sewell “The rise of the Maker Movement and open source prosthetics: An example of Braidotti’s ‘critical posthuman subject’” paper presented at Theorizing Normalcy and the Mundane, 5th International Conference, Sheffield University, 7-8 July 2014 <http://donnareeve.co.uk/?tag=maker-movement> (last accessed 13 September 2017).

<sup>60</sup> For discussion of collaboration, and lessons which can be learnt from the software community in this respect, and drawing on empirical work, see Rosa Maria Ballardini, Juho Lindman and Flores Ituarte “Co-creation, commercialization and intellectual property – challenges with 3D printing” (2016) 7(3) *European Journal of Law and Technology* Internet; Dinusha Mendis “‘The clone wars’ – episode 1 – the rise of 3D printing and its implications for intellectual property law – learning lessons from the past?” 2013 35(3) *European Intellectual Property Review* 155-169 and Dinusha Mendis “Clone Wars Episode II – The Next Generation: The Copyright Implications Relating to 3D Printing and Computer-Aided Design (CAD) Files” 2014 6(2) *Law, Innovation and Technology* 265-281.

<sup>61</sup> See e-NABLE project which focuses on 3D printing prosthetic hands <http://enablingthefuture.org/about/> (last accessed 13 September 2017), and “Engineer creates a 3D exoskeleton ‘Spider hand’ for stroke victims” <http://www.3ders.org/articles/20150728-engineer-creates-a-3d-printed-exoskeleton-spiderhand-for-stroke-victims.html> (last accessed 13 September 2017).

<sup>62</sup> See “Library Used its 3D Printer to Make Prosthetic Hand for Girl” [http://www.huffingtonpost.com/entry/texas-library-3d-printer-prosthetic-limb-girl-katelyn-vincik\\_us\\_57bdc30ae4b0287a6e7312c0](http://www.huffingtonpost.com/entry/texas-library-3d-printer-prosthetic-limb-girl-katelyn-vincik_us_57bdc30ae4b0287a6e7312c0) (last accessed 13 September 2017); Daniel McGlynn “Young makers build prosthetic hands for children in need” <http://engineering.berkeley.edu/2016/07/young-makers-build-prosthetic-hands-children-need>

Within these landscapes, the next section will explore the application of the two legal frameworks and their principles on and for prosthetic users and our two core concepts. Throughout, common threads and concerns will be the holding and exercise of power through development decisions regarding function and aesthetics; and control of allocation and limiting of opportunity and choice in different ways. It will be seen that these powers are held by various actors, invariably excluding the prosthesis user on the basis of their own perspectives and priorities.

## **4 Sensitivity and alignment of the legal frameworks regarding identity and integrity**

### 4.1 The Medical Devices Perspective

#### **4.1.1 Regulatory Content: safety and patients**

The medical devices framework addresses a dizzying array of artefacts, from tongue depressors, to scalpels, to arterial stents, to imaging machines and monitors, to implantable cardioverter-defibrillators, and more. Further, although the regulatory framework has direct application to prosthetics, it takes little specific notice of the nature of the prostheses and their impact. Despite the approach in the EU Regulation as including ‘modification’, which can be argued to cover ‘extensions of the body’, the framework as a whole appears to view prostheses entirely from a medical perspective,

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(last accessed 13 September 2017); Rachel Katz “High Schoolers make 9 year old a prosthetic hand for less than \$10” <http://abcnews.go.com/Health/high-schoolers-make-year-prosthetic-hand-10/story?id=23521043> (last accessed 13 September 2017).

and as having a purely curative or condition management character.<sup>63</sup> The regime fails to engage, therefore, with our notions of identity and integrity as multifaceted constitutive phenomena. There are separate regulations for medical and cosmetic devices<sup>64</sup> - although the EU Regulation notes that the distinction is unclear and calls for further action in this respect.<sup>65</sup> Further, the narrow approach to regulation and the prosthesis is taken notwithstanding the standard recital reference to EU Charter rights - and in this case, to dignity, freedom of art and integrity of the person.<sup>66</sup>

Rather, at the heart of the medical devices framework are the substantive principles of ‘safety’, ‘risk’, and ‘performance’, together with operational principles of ‘transparency’ and ‘proportionality’.<sup>67</sup> The ‘worldview’ of the EU Regulation is argued to be summed up in its instructions that devices must achieve the performance intended by the manufacturer; and that devices must be designed and manufactured in such a way that, during normal use, they are suitable for their intended purpose – meaning they must be safe and effective, and not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons.<sup>68</sup>

With respect to safety, devices are categorised by class, taking into account the purpose of the device as intended by the manufacturer, and the inherent risks of the

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<sup>63</sup> See again the definition: EU Regulation (n5), art 2.1(1).

<sup>64</sup> Regulation (EC) 1223/2009 of the European Parliament and the Council on Cosmetic Products OJ L 342 22 December 2009 59.

<sup>65</sup> EU Regulation (n5), recital 9 and art 1.6.

<sup>66</sup> EU Regulation (n5), recital 89.

<sup>67</sup> These principles must be read against the imperatives to get products to market quickly and efficiently, and to facilitate the single market: EU Regulation (n5), recitals 1,4,30,31,32,43,44,53,74,87,88,101 and arts 10, 22, 27, 30, 56, 83, 95, 97, 106, 113.

<sup>68</sup> EU Regulation (n5), art 95, 106 (regarding expertise), art I.1 of Annex I, Annex XIV.

device,<sup>69</sup> with criteria for each class set out in the EU Regulation.<sup>70</sup> The EU Regulation proceeds from an acceptance that absolute safety cannot be achieved, so every device and every act of classification is a matter of risk assessment and risk notification, with risk highlighted everywhere.<sup>71</sup> A central aim is to minimise the likelihood and consequences of an adverse or harm-causing event, which are approached in the context of medicine and functionality - quite distinct from the points discussed in respect of identity and integrity. Manufacturers must establish and maintain an iterative risk management system applicable to the lifecycle of a device, and must select solutions that result in only “acceptable risks”.<sup>72</sup> Further, devices must be designed and manufactured in such a way as to reduce as far as possible risks posed by the unintentional ingress of substances into the device, taking into account the device and the nature of the environment in which it is intended to be used;<sup>73</sup> their physical (i.e., ergonomic) features of the device or external or environmental conditions (i.e., pressure, humidity, temperature, acceleration);<sup>74</sup> and mechanical features such as movement, vibration, noise and heat.<sup>75</sup>

Within this, factors impacting on risk include degree of invasiveness, duration of

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<sup>69</sup> EU Regulation (n5), art 2.12, 32, 47, 52, 54, 55.

<sup>70</sup> See EU Regulation (n5), Annex VIII. For a discussion of some of the then proposed new rules in this respect, see Crom Source White Paper. Changes to EU Medical Device Legislation: What you Need to Know (June 2016) at <https://www.cromsource.com/wp-content/uploads/2012/12/Changes-to-EU-Medical-Device-legislation-What-you-need-to-know-White-paper-2016.pdf>. Note the prospect of these decisions being open to judicial challenge (also discussed more generally below) – for Scottish example under previous regime see Hyaltech Ltd (Petitioners) [2008] CSIH 64.

<sup>71</sup> Many of the specifications relating to labelling and instructions deal with safety and risk: EU Regulation (n5) Chapter 1 of Annex I.

<sup>72</sup> EU Regulation (n5), art 1.2, 1.3, 1.8, 1.9.

<sup>73</sup> EU Regulation (n5), art 10.5 of Annex I.

<sup>74</sup> EU Regulation (n5), article 4(a), 7, 14.2(b), Annex I.

<sup>75</sup> EU Regulation (n5), art 18.5, 19.1, 20.1, 20.2, Annex I.

contact, and body system affected.<sup>76</sup> One can see within this structure that, for the most part, it is manufacturers who set the parameters for performance, normal use, safety, and efficacy, and who undertake the primary risk assessments and design decisions.<sup>77</sup> The manufacturer will put together a comprehensive dossier with a range of technical evidence determined by the class that the manufacturer considers the device to be within, and this is then submitted to the relevant national Notified Body for assessment and authorisation.<sup>78</sup> Manufacturers are additionally responsible for ensuring traceability of the device, and follow-up of adverse events.<sup>79</sup>

The EU Regulation also provides that any risks which may be associated with use of a device must be evaluated against the benefits to the patient, and the need to achieve a high level of protection of health and safety, taking into account the state of

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<sup>76</sup> EU Regulation (n5), Annex VIII.

<sup>77</sup> Prior to the reforms of the 1990s, technical standards and specifications were written into regulatory directives. Post-1990s, and largely preserved in the EU Regulation (n5), a separation between law and technical standards was adopted (see e.g. arts 8, 9, 71). Generally, the law relies on essential requirements, as opposed to bespoke technical standards, and the CE mark that is awarded serves as a market entrance authorization, not a rigorous premarket approval of individual products relying on strict product-testing such as in the pharmaceutical sector: Christa Altenstetter “EU and Member State Medical Devices Regulation” (2003) 19 *International Journal of Technology Assessment in Health Care* 228-248.

<sup>78</sup> For a good articulation of the previous regulation and the manufacturer’s responsibilities and the approval process in the context of a product liability case based on failure of an implanted prosthetic, see *Wilkes v Depuy International Ltd.* [2016] EWHC 3096 (QB).

<sup>79</sup> In contrast, traceability and post-market surveillance of devices are addressed in Chapters III and VII respectively of the EU Regulation, and both areas have seen substantial changes. This is in keeping with the strengthening of surveillance in the USA, where the Safe Medical Devices Act 1990 and the Medical Device Amendments 1992 required healthcare facilities to track the use of certain high-risk devices, and to report to the US Food and Drug Administration (FDA) any device-related (serious) injuries or deaths. The FDA subsequently received numerous adverse event reports, including some 160,487 in 2004 alone, with most coming from manufacturers: William Maisel “Safety Issues Involving Medical Devices: Implications of Recent Implantable Cardioverter-Defibrillator Malfunctions” (2005) 294 *Journal of the American Medical Association* 955-958. See also Frederic Resnic and Sharonlise Normand “Postmarketing Surveillance of Medical Devices—Filling in the Gaps” (2012) 266 *New England Journal of Medicine* 875-877.

the art.<sup>80</sup> The word choice – “patient” - is revealing, although not unexpected given the medical and functional focus noted so far. Thus while this particular provision could provide scope for the opinions and assessment of the individual device user,<sup>81</sup> present indications are that this is not coming about. Indeed, whilst much current research on device development in the UK is funded through the National Institute for Health Research (NIHR),<sup>82</sup> and patient and public involvement is a prerequisite for NIHR funding,<sup>83</sup> much of the existing technology in the healthcare market has not had any prosthetic user engagement in its development other than some involvement of users as recipients of the ultimate product.

Consistent with its worldview discussed above, the EU Regulation states that devices shall be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to laypersons, and the influence resulting from variation that can reasonably be anticipated in the layperson’s technique and environment. Rather like the reference to the “patient” above, this could provide a base for a deep interrogation of “environment” drawing on our two core concepts. The main requirements for action in this respect, however, in the EU Regulation involve information: instructions provided

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<sup>80</sup> EU Regulation (n5) art I.1 of Annex I; and proportionality is meant to inform this calculus: EU Regulation (n5) art 10.9. Related to safety and risk, manufacturers must establish and maintain a quality management system and an iterative risk management system applicable to the lifecycle of a device, and must select solutions that result in only acceptable risks: EU Regulation (n5), art 1.3, 5.5 and art 1 of Annex I.

<sup>81</sup> Indeed, references to ‘users’ usually means healthcare professionals: WHO, Medical Device Regulations: Global Overview and Guiding Principles (Geneva: WHO, 2003).

<sup>82</sup> See National Institute for Health Research website <https://www.nihr.ac.uk> (last accessed 13 September 2017), contributions made by eg Chief Scientist Office in Scotland <http://www.cso.scot.nhs.uk/funding-2/> (last accessed 13 September 2017).

<sup>83</sup> And see eg NIHR “Patients and the public” webpage <https://www.nihr.ac.uk/patients-and-public/> (last accessed 13 September 2017).

by the manufacturer shall be easy for the lay person to understand and apply,<sup>84</sup> and that labels are not to contain false or misleading information about the device's purpose, use, or performance.<sup>85</sup> So again, the user is viewed as a passive beneficiary and involvement of lay persons to any extent is not mandated. This is particularly interesting in the concept of "repairs". A prosthetic limb might need repair or replacement, including in the light of natural degradation and development of the rest of the body. Decisions in this respect, however, are much more (or wholly) under the control of the prescriber of the leg than of the user.<sup>86</sup>

This regulatory regime, at its extremes, can lead to the non-user having the power (and the responsibility) to make decisions about functionality without any regard to the aspirations of the user in this respect or indeed regarding more aesthetic matters. This will have an impact on identity - one which is so far unexplored in the existing discussion of bodily autonomy.<sup>87</sup> And it is perhaps as a result of this marginalisation (with respect to design, function, performance, and many other relevant details) that more informal maker movements have arisen such as those discussed above. The EU Regulation can apply to any prosthesis, howsoever developed. Devices which are manufactured and used within health institutions, however, are considered as being 'put into service',<sup>88</sup> and are therefore exempt from many requirements of the EU Regulation, although they must still comply with general safety and performance requirements.<sup>89</sup>

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<sup>84</sup> EU Regulation (n5), arts 18.1 and 22.1 of Annex I.

<sup>85</sup> EU Regulation (n5), art 7,

<sup>86</sup> Kate Sansam, Rory O'Connor et al "Clinician's perspectives on decision making in lower limb amputee rehabilitation" 2014 46(5) *Journal of Rehabilitation Medicine* 447-53.

<sup>87</sup> Note focus on abortion and euthanasia, eg Wicks (n3) 1 et seq.

<sup>88</sup> EU Regulation (n5), article 5.4; such devices cannot be transferred to another legal entity: Article 5.5a EU Regulation.

<sup>89</sup> EU Regulation (n5), article 5.



It is also valuable to explore how, within this regulatory framework medical devices are actually provided to people.

#### **4.1.2 Delivery of prosthetics: practical, financial and judicial**

There are 44 centres in the UK as a whole which provide prosthetic services.<sup>90</sup> Each centre provides a service for the surrounding population, defined by the commissioning arrangements that operate in each of the countries in the UK.<sup>91</sup> These centres run very similar programmes and offer a range of prostheses based on nationally agreed guidelines, although some services, such as children's prosthetics, are only available from the larger, more specialised centres.<sup>92</sup> Most centres provide a multidisciplinary team approach to the prosthetic user, with a rehabilitation physician, physiotherapist, occupational therapist, psychologist and prosthetist available, depending on the user's needs.

Taking the National Health Service setting in England and Wales as an example, patients are referred to a prosthetic limb fitting centre by another clinician, generally a physiotherapist or the surgeon who performed the amputation.<sup>93</sup> At the prosthetics centre, the first assessment is whether the patient is suitable for a prosthesis – many

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<sup>90</sup> National Amputee Statistical Database for the UK (2005) see <http://limbless-statistics.org/----NASDAB----.php> (last accessed 13 September 2017).

<sup>91</sup> See e.g. for English and Wales "NHS Commissioning" <https://www.england.nhs.uk/commissioning/> and for Scotland "Procurement, Commissioning and Facilities" <https://nhs.uk/our-structure/procurement-commissioning-and-facilities/> (both last accessed 13 September 2017).

<sup>92</sup> British Society of Rehabilitation Medicine "Amputee and Prosthetic Rehabilitation – Standards and Guidelines (2ed) 2003" <http://www.bsrm.org.uk/downloads/ars-gfinaltext.pdf> (last accessed 13 September 2017).

<sup>93</sup> Account provided by O'Connor, expert in this field and Charterhouse Professor of Rehabilitation Medicine, University of Leeds and Honorary Consultant Physician in Rehabilitation Medicines at Leeds Teaching Hospitals NHS Trusts

patients are frail or may not have walked for a considerable period of time due to another medical condition, such as heart disease. After an initial trial in the centre with a highly adjustable generic prosthesis, the decision to proceed to manufacturing a prosthesis is made. This matches the shape of the residual limb (the “stump”), accommodating any wounds or scars on the skin and is designed to take the forces through it commensurate to the use of the limb – in this case walking or activities involving the arm. The limb will comprise the socket (the interface between the user’s skin and the prosthesis – generally a rigid polypropylene shell), limb components (flexible joints, shock absorbers) that provide the function of the limb and a cover (foam, nylon, silicone) that provides the cosmesis.

The decision on the exact composition of the limb is reached by the team in the centre in consultation with the prosthetic user. Whilst a person with a newly acquired amputation would only rarely be familiar with prosthetic technology, their opinions on the appearance of the prosthesis and the required functions would be taken into account when formulating the prescription. These would, of course, be tempered by the knowledge and experience of the clinical team.<sup>94</sup> The elements comprising this “prescription” will be altered over time depending on the changing needs of the user. More minor repairs or modifications can be done in a day in the centre, but more extensive changes will require a new prescription and the manufacture of a new limb.

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<sup>94</sup> See also discussion of the process and the different roles played in a tax case *General Healthcare Group Ltd v The Commissioners for Her Majesty's Revenue & Customs* [2014] UKFTT 1087 (TC) and on appeal [2016] UKUT 315 (TCC).

The National Health Service and the private sector can also come together. Each centre will be associated with one of the major manufacturers and their products will be the preferred component starting points for the service. Prosthetic users should, however, be offered the most appropriate components for their needs, irrespective of whether the manufacturer tied to the centre supplies that component or not. This discussion, of course, raises the circular question of the meaning of need, and how it is able to be applied within the present framework and resource. At the time of writing in 2017-8, a user's desire to have a limb to pursue a specific need (e.g. swimming) will be problematic as this is not deemed a health need. In contrast, it is interesting to note that interviews and Focus Group meetings with prosthetic users carried out in our Wellcome Trust funded project<sup>95</sup> indicate that some users (likely those with more education, language skills and expert users such as dancers and athletes), are likely to have more regard paid to them, and be more proactive than others; and also that some teams are more open to users than others. Yet a strong theme from all users is that they would like greater regard to be had to their interests.

This discussion also raises the question of funding. As with other NHS services, provision of prosthetics is free at the point of use. Nevertheless, as with other healthcare services in the UK, a small number of individuals choose to purchase a prosthesis and the associated service from a private provider (such as those discussed above). In some cases this may be funded by an insurance company if the amputation was related to, say, a motor vehicle collision. Within the NHS, difficult funding decisions frequently have to be made and guidelines are issued from time to time in this respect. As an example in

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<sup>95</sup> See note 4 regarding method.

England, the NHS 2016 funding guidelines provide that prosthetics for lower limb loss are likely to be routinely funded.<sup>96</sup> There is scope for legal challenge to funding decisions by public bodies in this respect through the process of judicial review<sup>97</sup> (provided the applicant has sufficient interest in the matter).<sup>98</sup> The challenge will need to be on the basis, broadly, that the decision is irrational and follows unfair or unlawful policies or that proper process has not been followed - rather than raising any questions of substance. Decision in cases involving the funding of cancer treatments<sup>99</sup> and of breast augmentation for transsexuals<sup>100</sup> demonstrate how difficult it can be to advance judicial review arguments with success; and in any event success will lead to a reconsideration of the decision on the different bases, not necessarily a different substantive result.

This discussion of judicial review raises two further points. Firstly, the primary care trust policy in the cancer treatment case provided that there could be exceptional circumstances, with funding able to go beyond what is in the policies. This was to be assessed, however, on the basis of legitimate clinical needs; and continuing the themes identified in medical devices regulation, the court was clearly of the view that this would not cover personal characteristics not based on healthcare. This is consistent with the established practice set above and another worrying confirmation that law and

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<sup>96</sup> See NHS England “NHS England announces provisional investment decisions for specialised services (11 July 2016) <https://www.england.nhs.uk/2016/07/spec-services-investment/> (last accessed 13 September 2017). This is subject, in a reminder of the limited resource, to decisions regarding HIV funding.

<sup>97</sup> See eg *Association Provincial Picture Houses Ltd v Wednesbury Corp* [1948] 1 KB 223.

<sup>98</sup> English approach – see section 31(3) Senior Courts Act 1981 – includes a requirement of obtaining the consent of the court.

<sup>99</sup> *R (on app Rogers) v Swindon NHS PCT* 2006 EWHC Civ 392, [2006] 1 WLR 2649.

<sup>100</sup> *R (app C) v Berkshire West PCT* [2010] A.C.D. 75, 2020 EWHC 1162 (Admin).

regulation applying to prosthetics do not engage with the user or with the core concepts of integrity and identity. Secondly, judicial review not only has its limits but applies in the public sector; the fact that, say, a prosthetic user is unable, through whatever means, to afford a creative and frankly fabulous graphite and jewelled leg supplied directly by the Alternative Limb Project could not lead to a challenge on this basis. From the perspective of public law and limited budgets this might seem appropriate; when viewed through the lens of perceptions of self and opportunities of expression, a different position is argued to emerge.

In summary, it is the manufacturer, the clinician and other health professionals who are expected to act in advancement of the medical principles and who must comply with the EU Regulation and other guidelines and restrictions. There is no sense of acknowledgement from the legal, regulatory and funding perspective that a device (here the prosthesis) may be important to the individual's identity. Indeed, this concept is hardly implicated formally other than through the framework's attention to performance and risk - although this does speak indirectly to integrity. All matters and parameters are the manufacturer and medical perspectives; and all risk assessments and measures are tailored to that ideal. There is no direction that these standards must have any relevance to the lived experience of the user. A rather different silence and disengagement can be found when one explores the impact of IP law on identity and integrity for prosthetics users.

#### 4.2 The IP perspective

In addition to the basic thresholds to be met for IP rights to exist, there are some more specific provisions which may be relevant to prosthetics. Firstly, there is controversy as to when a software-related innovation can be the subject of a patent<sup>101</sup> (bearing in mind that it can always be the subject of copyright although this has the more limited form of protection, as discussed above). This restriction could be relevant to software innovation relating to the preparation of prosthetics and gathering data sets which enable prostheses to be prepared for individual users based on accumulated data from other users. It is also interesting to note, given discussion regarding the extent to which prostheses may be viewed by users as part of the body, that EU and the resulting UK legislation limits the patenting of biotechnological innovation, notably those which involve the use of human embryos for industrial or commercial purposes.<sup>102</sup> This area of law has seen controversies regarding the extent to which courts have been willing to engage with morality and ethics<sup>103</sup> - again raising a marked difference between “artificial” and “real” parts of the body.

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<sup>101</sup> European Patent Convention, art 52(2) and (3); and Patents Act 1977, s 1(2); Programs for Computers Case G03/08 (Enlarged Board of Appeal) [2010] EPOR 36; Symbian Ltd v Comptroller General of Patents, Designs and Trademarks [2008] EWCA Civ 1066.

<sup>102</sup> European Patent Convention, art 53(a), (b), (c); Patents Act 1977, s 1(3), 3(4A and Schedule A2; and Patents Act 1977, art 3(f) from Directive 98/44 of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions OJ L 213 30 July 1998, art 4; for examples of the complexities in its application, see Wisconsin Alumni Research Foundation/Stem Cells (G2/06) [2009] EPOR 15 (“WARF”), *Brustle v Greenpeace* [2011] ECR I-9821 (“Greenpeace”), *TECHNION/Culturing Stem Cells (T2221/10)* [2014] EPOR 12, *International Stem Cell Corp v Comptroller General of Patents, Designs and Trade Marks (C-364/13)*, [2015] 2 CMLR 26; see UKIPO Practice Note 25 March 2015 “Inventions involving human embryonic stem cells: 15 March 2015” <https://www.gov.uk/government/publications/inventions-involving-human-embryonic-stem-cells-25-march-2015> (last accessed 13 September 2017).

<sup>103</sup> WARF (n102) para 41.31; *Greenpeace* (n102) para AG 45-49, 75-97, 100; Howard Florey/Relaxin [1995] EPOR 541 (opposition board) section 6; T 0272/95 2002 Technical Board of Appeal para IV regarding proteins and childbirth; Sigrid Sterck and Julian Cockbain “Assessing the Morality of the Commercial Exploitation of Inventions Concerning Uses of Human Embryos and the Relevance of Moral Complicity: Comments on the EPO’s WARF Decision”, (2010) 7(1) SCRIPTed 83-103 <https://script-ed.org/wp-content/uploads/2016/07/7-1-Sterckx.pdf> (last accessed 13 September 2017; Shawn Harmon et al “Dignity, plurality and patentability: the unfinished story of *Brustle v Greenpeace*”

Within this framework, if IP rights exist in respect of a prosthesis, they will as indicated above confer power on the IP owner regarding use of the underlying subject matter (the shape of the prosthetic leg, say). This is confined, however, to carrying out specific acts particularly making and selling (but importantly for patents, not repairing which is quite distinct)<sup>104</sup> during the currency of term of the right. IP rights will expire across a varying landscape of dates, from 3 years for a Community unregistered design right to the life of the author plus 70 years in the case of the copyright in the drawings for a prosthetic limb).<sup>105</sup> There must also be infringing activity in a country where there is an IP right. This may become relevant if, say, a user moves from the UK to France.

A key point here is that if there is a relevant right and activity, then IP owners have no legal responsibility to have regard to the impact of their decisions on prosthetic users. There are some exceptions to IP infringement, however, and a key opportunity in respect of patents involves private and non-commercial use.<sup>106</sup> This may become highly relevant as 3D printing technologies become more widespread and cost effective, and there may be an increase in users making their own limbs by reproducing prostheses which are the subject of another's patent.<sup>107</sup>

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(2013) 38(1) *European Law Review* 92-106; Agnieszka Kupzok "Human rights in the case law of the EPO Boards of Appeal" in Christophe Geiger (ed) *Research Handbook on Human Rights and Intellectual Property* (Cheltenham: Edward Elgar, 2015); Nicola Lucchi *The Impact of Science and Technology on the Rights of the Individual* (Switzerland: Springer, 2016) 114-5, 141-175.

<sup>104</sup> *United Wire v Screen Repair Services (Scotland) Ltd* [2000] 4 All E.R. 35

<sup>105</sup> UK - copyright life plus 70 Copyright Designs and Patents Act 1988, s 12; UK unregistered design right 15 years with licence of right for last 5 Copyright Designs and Patents Act 1988, s216; 20 years patent Patents Act 1977, section 25; registered community design term sets of 5 years up to 25 years and unregistered community design rights 3 years Community Design Regulation (n7), arts 11, 12.

<sup>106</sup> *Smith Kline & French v Evans Medical* [1989] FSR 153, Patents Act 1977, section 60(5)(a).

<sup>107</sup> See discussion and comparison between jurisdictions in Stefan Bechtold "3D printing,

There is a possibility, therefore, of IP law having a restrictive impact on choices made by and (largely) for prosthesis users. This increases when it is considered that developers of prosthetic limbs are indeed engaging with IP rights. There are patents, for example US3908201A from 1972 for a prosthetic device made of a particular plastic material and cases involving patents for silicon foam for covering prostheses for implanting in the body;<sup>108</sup> and there are registered designs, for example UK D462767 from 2001 for a slideable and rotatable coupler for a prosthetic leg. Copyright and unregistered designs cannot be evidenced in the same way (given their more informal nature of creation), however there are examples of infringement actions being raised. Notably, a court rejected an argument<sup>109</sup> that because of the so-called “must fit” provision in UK unregistered design law,<sup>110</sup> there was no protection for the shape of a breast prosthesis. The court found that although the shape of the bra might influence the shape of the breast prosthesis, a bra shape did not determine the detail or circumstances of it – indeed, the prosthesis would fit several bras.

At present, there are no accounts of IP rights being an obstacle to prosthetic provision in the NHS. If there is greater use of 3D technology, and more privately funded prosthetic provision outside the NHS, then IP may become more of an immediate issue. This would then provide yet another area of challenge to the short term private power conferred by IP;<sup>111</sup> and also to the conventional position that this

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intellectual property and innovation policy” 2016 47(5) *International Review of Intellectual Property and Competition Law* 517-536.

<sup>108</sup> *McGhan Medical UK Ltd v Nagor Ltd* (2001) 24(7) *IPD* 240043

<sup>109</sup> *Amoena v Trulife* [1995] 12 D-346

<sup>110</sup> Copyright, Designs and Patents Act 1988, s213(3)(b)(i).

<sup>111</sup> Susan Sell *Private Power, Public Goods: The Globalization of Intellectual Property Rights*



should be accepted given the argument that IP encourages innovation and creativity, dissemination of the results and investment in the process, to the longer term benefit to all.<sup>112</sup>

In summary, IP is an opportunity to be pursued by those who innovate and create in prostheses, looking across both the functional and the aesthetic. When assessed in the present context, the development of new prostheses which may be encouraged by and lead to IP rights, can indeed have positive outcomes for society and for individual users as they pursue ways of displaying and developing their varied interests and choices. This can assist in engaging with identity/identities and integrity. However, the discussion so far has shown that this is a hope and a consequential outcome, rather than the goal of IP. Further, those owning IP rights have, through national legislation under the umbrella of international treaty, an entitlement to object to use and to raise a court action, such as those discussed above.<sup>113</sup> Exercising this power can be costly and time-consuming,<sup>114</sup> and as has been discussed, the IP owner may be vulnerable on various points regarding infringing activity, term or a relevant exception. Yet the other party is still faced with the problem of facing the action – and looking forward, this could influence decision-making in allocation of prosthetic limbs.

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(Cambridge: CUP, 2003); Keith Maskus and Jerome Reichman “The globalization of private knowledge goods and the privatization of global public goods” 2004 7(2) *Journal of International Economic Law* 279-320.

<sup>112</sup> Frederic Scherer “The Innovation Lottery” in Rochelle Cooper Dreyfuss et al (eds) *Expanding the Boundaries of Intellectual Property: Innovation Policy for the Knowledge Society* (Oxford: OUP, 2001); Robin Jacob “Is intellectual property the grit in the wheels of industry?” 2012 1(1) *University College London Journal of Law and Jurisprudence* 1(2) 1-14.

<sup>113</sup> See also TRIPS (n8), Part III and Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights OJ L 195 2 June 2004 16-25.

<sup>114</sup> See eg WIPO Magazine “IP Litigation Costs. Special Edition” (2010) [http://www.wipo.int/export/sites/www/wipo\\_magazine/en/pdf/2010/wipo\\_pub\\_121\\_2010\\_01.pdf](http://www.wipo.int/export/sites/www/wipo_magazine/en/pdf/2010/wipo_pub_121_2010_01.pdf) (last accessed 13 September 2017).

What do these discussions on the legal frameworks of medical devices and IP indicate for the core concepts revealed for key themes which run throughout this paper: control and authority?

### **4.3 Control and Authority for Prosthetics – Reflections**

The analysis of the legal and regulatory framework, and the results of the research interviews and Focus Groups, reveal that the power in determining which prosthetic limb can be issued and of what kind (e.g. a leg for rockclimbing), does not always involve the user; and that even if the desire is identified and supported, frequently insufficient budget has been allocated to fulfil it. A research interview also indicated that private fundraising (one way of addressing this outside the NHS) can be perceived by prosthetic users as leading to a prosthesis which belongs more to the donors – and is less aligned with the user's identity and integrity. Further, if notwithstanding this, a particular prosthesis is able to be allocated which supports identity and integrity (e.g. running, climbing, decoration) in some circumstances an IP owner can restrict or prevent this. And the identity/identities and integrity of the prosthetic user are not required to be relevant for those with authority and control in respect of these prosthetic related decisions; rather, there are obligations and restrictions under NHS funding rules and the EU Regulation, and rights held by others under IP legislation.

Steps could be taken to change these regimes. In IP, a special exception could

be created relating to prosthetic users and 3D printing for copyright, designs, and patents. This would have echoes with debates elsewhere in IP in respect of users' rights, which have their own intersections with human rights discussed above, such as parody.<sup>115</sup> Analogies could also be drawn from changes to IP law to enable greater and more accessible use of works by people with disabilities – e.g. conversion into Braille or audio versions - as can be seen from national and international developments.<sup>116</sup> Another opportunity might be to create a prosthetic specific licensing regime<sup>117</sup> which could avoid prosthetic users being denied particular opportunities on the basis of disputes over cost – whether funding is being provided personally, privately or through the NHS. Another pathway is to argue for change within the medical devices regulatory framework to have greater regard for the lives, aspirations and indeed views of users when assessing questions of need and health. This could build on the identification in the EU Regulation for exploration of the link between medicinal and cosmetic, as discussed above. Aligned with this, a third pathway would be to argue for a wider approach to need within the NHS policy and budgetary frameworks. These three approaches, taken together, would address specific issues and go some way to addressing the disregard of the person, as prosthetic user, in two key legal and regulatory regimes. They could also be a movement to delivering new approaches to authority and control, to identity and integrity, and to the person.

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<sup>115</sup> See EU consideration of parody in *Deckmyn v Vandersteen* (C-201/13) [2014] Bus. L.R. 1368.

<sup>116</sup> Marrakesh Treaty to Facilitate Access to Published Works for Persons Who are Blind, Visually Impaired or Otherwise Print Disabled (2013) and the UK Copyright and Rights in Performances (Disability) Regulations 2014 No. 1384 reg 2 creating sections 31A, 31B, 31BA, 31BB, 31F, Schedule 2 of the UK Copyright Designs and Patents Act 1988.

<sup>117</sup> See Copyright Designs and Patents Act 1988, chapter VII.

## 5. Conclusions

Like the physical states to which they are applied, prosthetic limbs can challenge our perception of what it means to be human, to be a person. They can challenge our symbolic order, or the binary categories and differentiations that we use to structure society (such as nature/construct, human/non-human, self/other, friend/stranger).<sup>118</sup> Indeed, they may offer new categories and measures, and new possibilities and capabilities. Yet their allocation and usage are characterised by social, legal and ethical debates around risk, boundaries, and power. The result is often a collage, or indeed a cacophony, rather than a consensus of values, visions, and decision-making models associated with specific interventions or technologies.<sup>119</sup> And all of this is positioned against a legal landscape which fails to engage (at least sufficiently) with the person, and the concepts of identity and integrity.

More specifically, our preliminary findings from doctrinal research are that the current medical devices and IP frameworks, both of which are relevant to prosthetic limbs, adopt a decidedly internally focused perspective. Accordingly, the principles of each field are more important as shaping concepts than those deemed important (for meaning-making) by the prosthetics community, insofar at least as we have engaged with them. The regimes have their own drivers and are not focussed on the person. Generally, inadequate direct or effective regard is had to the impact of legal approaches

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<sup>118</sup> Mary Douglas *Purity and Danger: An Analysis of the Concepts of Pollution and Taboo* (London: Routledge & Kegan Paul, 1966).

<sup>119</sup> Tsjalling Swiersta and Arie Rip “NEST-Ethics: Patterns of Moral Argumentation about New and Emerging Science and Technology” in David Kaplan (ed) *Readings in the Philosophy of Technology* (London, Rowman & Littlefield, 2009 2edn) 208-227.

and decisions on the user from both an existential and a practical perspective.

Additionally, the regimes discussed are insufficiently joined up, though they share an over-reliance on largely unexamined understandings of the 'normal' and lack of engagement with others.

Medical devices and IP focus on shaping particular activities aimed at solving particular problems. Key drivers are safety and functionality on the one hand, and money/commerce and reward (with some unfocussed regard to public benefit) on the other. Each of these has their own control and authority structures as discussed. Across these, there is limited space for user views or participation in the prosthetic user context, and no focus on the core of the person and what the person could aspire to become. Regarding medical devices, it is tempting to argue that when seeking to deliver patient safety and to manage risk, there is no place for a focus on, or indeed engagement with, the core concepts and their legal reflections. But this ignores the arguments put forward here; it accords greater weight to the values of one legal and value system than to another, and stresses economics rather than enabling the pursuit of the identity and choices of the user. Further, this approach accords power to those who have traditionally held it – doctors, the NHS, managers, IP owners and corporate manufacturers - rather than to users. An approach which is more open to users may not of course appeal to all users; not all may wish to exercise their choice. Yet this does not mean that the opportunity, together with structures which could embed, for example, wider regard for user groups (both locally, in each centre for the benefit of users of that centre, and nationally, such as the All-Party Parliamentary Limb Loss Group - who advocate for amputees throughout the UK), should not be pursued.

We conclude that there is a need for a new fair and holistic landscape for multi-faceted decision-making regarding extensions to the person. In addition to delivering a new approach to decision-making by clinicians, budget setters and IP owners, this should enable more attention to be paid by lawyers, policymakers and other actors to issues, values, and ambitions shared by users, and also to the essential relevance of the person. In turn, this would support identity and integrity. At the moment, law has been shown to fail to support effective practical delivery of prostheses or theoretical approaches to the person. This inadequacy cannot continue. The suggestions made above regarding more exceptions to IP and a wider looking approach to medical device regulation can, as indicated, assist. But the issue is wider. One of the aims of this Wellcome Trust funded research is to encourage scholars, policymakers, industry, and others to think about body extensions not as functional tools or attachments, but as profound elements of identity in a way similar to race and gender. To inform and justify this, and to further identify areas for new issue specific regulation, much would be gained from greater recognition of empirical evidence from the field/users and the undertaking of more such research. This should be supported by engaging with attitudes which render this more relevant, for example the maker movement and those supporting and creating the pursuit of excellence and of flourishing lives by those with prosthetic limbs. This would be a decisive change in perspective – the creation of a new normality and approaches to control and authority, discarding the restrictions and tyranny of the narrow older one, and one which will ultimately combines law, practice, business and users of prosthetics in a fairer way. Pursuing this research, and how best to deliver this goal, is the objective of the authors.