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*The Self and the Commodified Self: Biotechnologies before the Bare Life**

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I. THE HUMAN BODY AND THE BUILDING OF THE IMPERSONAL

Every law student knows that persons and things are mutually exclusive categories. Persons are subjects of rights, whereas things are objects that can be bought, sold or freely given, used, modified, and even destroyed by the persons who own them. Yet through history these seemingly inflexible and irreconcilable categories have been proved so malleable and amenable to hybridisations and trade-offs that their purpose, one may assume, is not so much that of drawing an impassable line as to control the processes through which 'things' are treated as persons and 'persons' as things.[1]

That Roman law did not consider human beings *as such* as persons, following this insight, is less contingent on the institution of slavery than on the irrelevance of ontological distinctions to a concept set up for the expediency of circulation of wealth.[2] By contrast, the injunction *de homine libero exhibendo* that marked the nullity of stipulations through which a citizen was sold or agreed to be sold as a slave – *quia nec dari oportere intendi, nec aestimatio eius praestari potest*[3] – suggests that 'citizenship' in that culture transferred at least some of the ideas that in our culture are transferred by 'personhood', first and foremost its subtraction to relationships based on exchange value.

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[1] See R Esposito, *Third Person: Politics of Life and Philosophy of the Impersonal* (Oxford, Polity Press, 2018).

[2] Y Thomas, 'Le sujet de droit, la personne et la nature. Sur la critique contemporaine du sujet de droit' (1998) *Le Débat*, 85ff; Y Thomas, 'La valeur des choses. Le droit romain hors de la religion' (2002) 57 *Annales. Histoire, Sciences sociales*, 1431; Y Thomas, 'Fictio legis. L'empire de la fiction romaine et ses limites médiévales' (1995) *Droits* 17.

[3] D 45.1.103 (Modestinus). Adde: Pomp. 9 ad Sab. D. 18, 1, 6 pr.: 'Sed Celsus filius ait hominem liberum scientem te emere non posse nec cuiuscumque rei si scias <prohibitam> alienationem esse: ut sacra et religiosa loca aut quorum commercium non sit, ut publica, quae non in pecunia populi, sed in publico usu habeantur'.

Unlike modern law, Roman law carefully distinguished freedom according to the *ius civile* from freedom according to the *ius naturale*.[4] This abstraction from (the idea of) nature allowed Roman jurists to liken the status of free men to that of the *res nullius in bonis*, unseizable by reason of their religious or civic destination, thereby unifying the concepts of *res* and *persona* from a purely functional and remedial perspective.[5]

Medieval jurists, imbued with scholastic theology, first proposed that every man is a *persona*, laying the ground for the 'imperious' antithesis[6] of persons and things known by modern legal systems. The meaning of *res* shifted accordingly through the winding and perilous tracks connecting law, theology and politics in the early modern age.[7] A reverse function can be detected: as the concept of 'thing' becomes ever more abstract, that of 'person' seems to lean towards human nature. To the commentators, the notions of *res corporalis* still provided the foundations on which all owners' *dominia*, *directa* or *utilia*, must rest; to the humanist lawyers, it stretched beyond property rights to encompass the indirect object of claim rights on other people; to Jean Domat, well acquainted with Port-Royal Logic, the name '*chose*' is the correlative of '*droit*', understood as a general predicate about the subject of a legal clause, or 'personne', seen in the capacity of rightsholder: 'de sorte qu'on peut dire que l'état des personnes consiste dans cette capacité ou cette incapacité'.[8]

By the end of the eighteenth century, the idea of personhood as an abstract capacity, acknowledged in principle with respect to every human being as such, had crystallised in solemn declarations, beautifully exemplified by the first sentence of §16 ABGB: 'Jeder Mensch hat angeborne, schon durch die Vernunft einleuchtende Rechte, und ist daher als eine Person zu betrachten'. Here, the human body comes to the fore as the embodied person, *la personne en son corps*:[9] 'Sclaverey oder Leibeigenschaft, und die Ausübung einer darauf sich beziehenden Macht, wird in diesen Ländern nicht gestattet', §16 goes on, in perhaps the earliest apprehension of 'bare life' into a Civil Code.[10]

[4] D 50. 17. 32: 'Quod attinet ad ius civile, servi pro nullis habentur. Non tamen et iure naturali, quia quod ad ius naturale attinet, omnes homines aequales sunt'. See Y Thomas, 'Imago naturae. Note sur l'institutionnalité de la nature à Rome', in 'Théologie et droit dans la science politique de l'État moderne. Actes de la table ronde de Rome (12–14 novembre 1987)' (Rome, Publications de l'École française de Rome, 1991) 201, 202: 'Les juristes pensent nettement ces deux droits comme deux genres successifs et contradictoires: entre esclavage et liberté, statuts et égalité, propriété et jouissance commune, il y a toute la distance qui sépare l'histoire de ce qui n'est pas encore elle'.

[5] Y Thomas, 'Res, chose et patrimoine. Note sur le rapport sujet-objet en droit romain' (1980) 25 *Archives de philosophie du Droit* 413.

[6] S Pugliatti, 'Cosa in senso giuridico (Teoria generale)' in *Enciclopedia del diritto* XI (1962) 28.

[7] See R Tuck, *Natural Rights Theories. Their Origin and Development* (Cambridge, Cambridge University Press 1987); Y Thomas, 'Le sujet concret et sa personne. Essai d'histoire juridique rétrospective' in O Cayla and Y Thomas, *Du droit de ne pas naître. À propos de l'affaire Perruche* (Paris, Gallimard 2002) 89.

[8] J Domat, *Les loix civiles dans leur ordre naturel, Livre Préliminaire, Titre II* (Paris, Coignard, 1689–1694) 4, gallica.bnf.fr/ark:/12148/bpt6k3103451?rk=42918.

[9] X Dijon, *Le sujet de droit en son corps, une mise à l'épreuve du droit subjectif* (Bruxelles, Larcier, 1982).

[10] On 'bare life' as life exposed to (legal) violence, see G Agamben, *Homo sacer. Il potere sovrano e la nuda vita* (Torino, Einaudi, 1995) 74ff, developing a theme from W Benjamin, 'Zur Kritik der Gewalt' in R Tiedemann and H Schweppenhäuser (eds), *Gesammelte Schriften*, Band II-1 (Frankfurt aM, Suhrkamp, 1999) 179.

Through several shifts and turns, this representation endures. Personhood in our legal cultures applies to all living humans, considered as individuals and members of humankind: *Gattungswesen*.[11] This duplicity mirrors the legal regimes attached to physical persons – personality rights and fundamental rights – and the ambivalent status of the human body, at once an object to the exercise of individual choices and a barrier against seizure by public and private powers.

But the ancient notion of personhood as a pure enabling fiction[12] did not disappear. Besides juridical persons and a few remnants in inheritance law,[13] the notion can be seen at work whenever social and technological innovation 'nibbles away' at the special consideration given to the human body vis-à-vis the world of 'things'.[14] Through the Industrial Revolution, the fiction of an abstract subject mastering their body stood behind the separation of labour-power from personhood and ascription of an exchange value to the former in the early contractual infrastructures of mass production.[15] Today, the same fiction enables the race to recognise property interests in the human body, prompted by sweeping advances in the sciences and technologies of life.[16]

Long prepared by the steady enmeshing of bare life into creation of capital value,[17] the theological-political metaphor of body duplication is making a strange comeback

[11] J Habermas, *Die Zukunft der menschlichen Natur. Auf dem Weg einer liberalen Eugenik?* (Frankfurt aM, Suhrkamp, 2001) 76.

[12] P Vinogradoff, 'Juridical Persons' (1924) 24 *Columbia Law Review* 594, 602.

[13] See, eg, Art 119 Fr cc and Arts 462.3 and 784 It cc, concerning the capacity of conceptures – the child who has not yet been conceived – to succeed and receive as donee.

[14] BM Knoppers and HT Greely, 'Biotechnologies nibbling at the legal human' (2019) 366 *Science* 1455.

[15] See L Mengoni, 'La tutela giuridica della vita materiale nelle varie età dell'uomo' (1982) *Rivista trimestrale di diritto e procedura civile* 1117.

[16] MA Hermitte, 'Le corps humain hors du commerce, hors du marché' (1988) 33 *Archives de Philosophie du Droit* 323; JP Baude, *L'affaire de la main volée. Une histoire juridique du corps* (Paris, Éditions du Seuil, 1993); MJ Radin, *Contested Commodities: The Trouble with Trade in Sex, Children, Body Parts and Other Things* (Cambridge Mass, Harvard University Press, 1996); R Rao 'Property Privacy and the Human Body' (2000) 80 *Boston University Law Review* 359; FS Kieff (ed), *Perspectives on Properties of the Human Genome Project* (Amsterdam, Elsevier, 2003); D Dickenson, *Body Shopping: Converting Body Parts to Profit* (Oxford, Oneworld, 2009); N Hoppe, *Bioequity. Property and the Human Body* (Ashgate, Farnham, 2009); C Roth, *Eigentum an Körperteilen: Rechtsfragen der Kommerzialisierung des menschlichen Körpers* (Berlin, Springer, 2009); H Widdows and C Mullen, *The Governance of Genetic Information. Who Decides?* (Cambridge, Cambridge University Press, 2009); C Lenk, N Hoppe, K Beier and C Wiesemann (eds), *Human Tissue Research: A European perspective on the ethical and legal challenges* (Oxford, Oxford University Press, 2011); I Goold, K Greasley, J Herring et al (eds), *Persons, Parts and Property: How Should We Regulate Human Tissue in the 21st Century?* (Oxford, Hart, 2014); C Lafontaine, *Le corps-marché: La marchandisation de la vie humaine a l'ère de la bioéconomie* (Paris, Editions du Seuil, 2014; J Wall, *Being and Owning: The Body, Bodily Material, and the Law* (Oxford, Oxford University Press, 2015); JD Rainhorn and S El Boudamoussi (eds), *New Cannibal Markets. Globalization and Commodification of the Human Body* (Paris, Éditions de la Maison des sciences de l'homme 2015); M Cooper and C Waldby, *Clinical Labor: Tissue Donors and Research Subjects in the Global Bioeconomy* (Durham, Duke University Press, 2014); D Dickenson, *Property in the Body: Feminist Perspectives* (Cambridge, Cambridge University Press, 2017); KJ Strandburg, BM Frischmann, MJ Madison and (eds), *Governing Medical Knowledge Commons* (Cambridge, Cambridge University Press, 2017); M Quigley, *Self-Ownership, Property Rights, and the Human Body. A Legal and Philosophical Analysis* (Cambridge, Cambridge University Press, 2018); J Pila, 'Property in Human Body Parts: An Old Legal Question for a New Technological Age' in D Orentlicher and TK Hervey (eds), *Oxford Handbook of Comparative Health Law* (New York, Oxford University Press, 2020) 808.

[17] KS Rajan, *Biocapital. The Constitution of Post-genomic Life* (Durham, Duke University Press, 2006); Cooper and Waldby (n 16) 18ff.; A Fumagalli 'Twenty Theses on Contemporary Capitalism

amidst the secularised ideological fabric of the contemporary knowledge economy.[18] Whereas the 'mystic fiction' of the king's two bodies symbolised the permanence of sovereign power, the distinction between the body as a 'raw material or means of production'[19] and the body as an attribute of personhood testifies to the ongoing struggle to keep rights-bearing persons out of the market at the moment in which their bodies are traded.[20] Interestingly, both metaphors reference 'dignity' as representation.[21] As the king's body 'became the *instrumentum dignitatis* and the incarnation of his immortal office',[22] by the operation of human dignity the body of every single human stands as the body of humanity itself: *homo instrumentum humanitatis*. Finally, both concepts exhibit a characteristic vagueness. Just as the idea of sovereign dignity has historically worked both to strengthen and undermine the charismatic power of kings, the 'elusive' concept of dignity as representation can work either to 'constrain' or to 'empower' individual agency.[23]

Nowhere is the tension between the sacralisation of the embodied person and the remorseless commodification of 'bare life' more apparent than in medical research. In private law scholarship, hostility to the commodification of human body parts is sometimes grounded on personal identity.[24] Instead, a cross-referenced reading of the scattered regulations relevant to the supply chain of innovative medical therapies suggests that limits on property rights are less a tribute to personal identity and sovereign power of human beings over 'their' bodies than a reflex of the impersonal – as such, open to sharing – character of scientific enterprise as 'knowledge without a knower, … knowledge without a knowing subject'.[25] The epistemology of a great liberal thinker unmasks the anti-scientific strain in the neoliberal agenda of fully fledged processing of human bodies into ultimate 'fictitious commodities'.[26] Yet there is more to the debate on commodification than a cautionary tale on the tragedies of anti-commons[27] as the knowledge of life itself ultimately rests on the ambivalent

(Cognitive Biocapitalism)' (2011) 16 *Angelaki. Journal of the Theoretical Humanities* 7; N Rose, *The Politics of Life Itself: Biomedicine, Power and Subjectivity in the Twenty-First Century* (Princeton, Princeton University Press, 2007) 11ff.

[18] See EH Kantorowicz, *The King's Two Bodies. A Study in Medieval Political Theology* (Princeton, Princeton University Press 2016).

[19] Hermitte (n 16) 323.

[20] Pila (n 16) 823ff.

[21] See J Waldron, 'Dignity and Rank: In memory of Gregory Vlastos (1907–1991)' (2007) *European Journal of Sociology/Archives Européennes de Sociologie* 201, 235.

[22] Kantorowicz (n 18) 502.

[23] R Brownsword, 'Bioethics Today, Bioethics Tomorrow: Stem Cell Research and the Dignitarian Alliance' (2003) *Notre Dame Journal of Law, Ethics and Public Policy* 15, 20ff.

[24] H Schünemann, *Die Rechte am menschlichen Körper* (Frankfurt aM, Lang 1985) 58; C Halàsz, *Das Recht auf bio-materielle Selbstbestimmung. Grenzen und Möglichkeiten der Weiterverwendung von Körpersubstanzen* (Berlin, Springer, 2004) 20ff, 69ff; P Zatti, 'Il corpo e la nebulosa dell'appartenenza' (2007) *Nuova giurisprudenza civile commentata* 1.

[25] KR Popper, *Objective Knowledge: An Evolutionary Approach* (Oxford, Oxford University Press, 1979) 109.

[26] K Polanyi, *The Great Transformation. The Political and Economic Origins of Our Time*, 2nd edn (Boston, Beacon, 2001) 71ff; K Polanyi, 'Our Obsolete Market Mentality. Civilization Must Find a New Pattern' (1947) 3 *Commentary* 109.

[27] See MA Heller, 'The Tragedy of the Anticommons: Property in the Transition from Marx to Markets' (1998) 111 *Harvard Law Review* 621; MA Heller, *The Gridlock Economy: How Too Much Ownership Wrecks Markets, Stops Innovation and Costs Lives* (New York, Basic Books, 2008); MA Heller and

ontology of the human body, at once what makes each of us oneself and what we share with all human beings. Inextricably personal and impersonal, the body stands at the intersection between self-recognition and mutual recognition, individual and collective identities.[28]

II. THE OWNERSHIP DILEMMA

Because of its unique relation to donors, research on human tissues has the potential to trigger a paradigm shift in developmental biology and personalised healthcare.[29] However, along with expectations it also stirs concerns for the broad or open consent procedures required by research institutions to meet the interests of tissue donors and comply with the European framework on data protection.[30] Proposals have been advanced towards a change of paradigm based on dynamic consent and self-ownership.[31]

The standard approach to liabilities and rights over human tissues leads from the primacy of individual autonomy to the freedom to dispose of one's body within limits set by public policy. These limits can be sorted out into: (i) inalienability rules addressed to the rightholder, a somewhat unsettled category that nonetheless includes, for our purposes, commercialisation of the human body and its parts 'as such';[32] and (ii) prohibitions on unauthorised appropriation of the human body,

RS Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 *Science* 698; J Buchanan and YJ Yoon, 'Symmetric Tragedies: Commons and Anticommons' (2000) 43 *Journal of Law and Economics* 1; S Levmore, 'Two Stories about the Evolution of Property Rights' (2003) 31 *Journal of Legal Studies* 421; MA Hall, 'Property, Privacy, and the Pursuit of Interconnected Electronic Medical Records' (2010) 95 *Iowa Law Review* 631; J Boyle, *The Public Domain. Enclosing the Commons of the Mind* (New Haven-London, Yale University Press, 2008) 160ff; G Resta, 'The Case against the Privatization of Knowledge: Some Thoughts on the Myriad Genetics Controversy' in R Bin, S Lorenzon and N Lucchi (eds), *Biotech Innovations and Fundamental Rights* (Milano, Springer, 2012) 11; JL Contreras, 'Genetic Property' (2016) 105 *Georgetown Law Journal* 1; JL Contreras, 'The False Promise of Health Data Ownership' (2019) 94 *NYU Law Review* 624; K Liddell et al, 'Patient data ownership: who owns your health?' (2021) 8 *Journal of Law and Biosciences* 1; L Determann, 'No One Owns Data' (2019) 70 *Hastings Law Journal* 1.

[28] P Ricoeur, *Soi-même comme un autre* (Paris, Éditions du Seuil, 1996) 369ff; P Ricoeur, *Le Juste* 1 (Paris, Esprit, 1995) 29ff.

[29] See the report of the Expert Group: European Commission, Directorate-General for Research and Innovation, 'Biobanks for Europe. A Challenge for Governance' (Brussels, Publication Office of the European Union, 2012); J Kinkorová, 'Biobanks in the era of personalised medicine: Objectives, challenges, and innovation' (2016) 7 *EPMA Journal* 2016; M Huch et al, 'The hope and the hype of organoid research' (2017) 144 *Development* 938; G Schneider, *Health Data Pools Under European Data Protection and Competition Law. Health as a Digital Business* (Cham, Springer, 2022).

[30] D Hallinan, 'Broad consent under the GDPR: an optimistic perspective on a bright future' (2020) 16 *Life Sciences, Society and Policy* 1.

[31] SN Boers, JJ Van Delden and AL Bredenoord, 'Broad consent is consent for governance' (2015) 15 *American Journal of Bioethics* 53; LM Beskow and KP Weinfurt, 'Exploring understanding of "understanding": The paradigm case of biobank consent comprehension' (2019) 19 *American Journal of Bioethics* 6; MA Lensink et al, 'Understanding (in) Consent for Governance' (2019) 19 *American Journal of Bioethics* 43.

[32] See Art 21 European Convention on Human Rights and Biomedicine (Oviedo, 1 December 1999) (ECHRB). This formula is almost literally repeated by Art 3.2 European Charter of Fundamental Rights (Nice, 18 December 2020, OJ 2000/C 326/391) and the European Directives on the Collection and Processing of Biological Materials and Experiments – respectively, Directive 2004/23/EC of the European

also in the form of intellectual property, protected by civil, administrative and criminal sanctions.[33]

Bolstered by a landmark decision of the California Supreme Court,[34] soon imitated by the European Convention on Human Rights in Biomedicine and the European Union,[35] the standard model entails two distinct allocation systems: raw materials circulate subject to market inalienability, whereas products obtained from the body are put on the market. In theory, each system can function independently from the other by combining specification and intellectual property: Taney gives her blood for free out of a commitment to human solidarity; Marshall, having discovered unique features in Taney's blood, develops a new product, for example a cell line, and obtains a patent, generating colossal profits. By contrast, in the standard model donor consent works as a switch point between market and non-market allocation: before consent is given, bodily materials are inalienable, and any act of disposal in return for payment would be null and void; after consent is legitimately obtained, they are a raw material like any other but unauthorised tampering is forbidden

Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells [2004] OJ L 102/48, Art 12; Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC [2003] OJ L 33/30; Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use [2001] OJ L121/34 Art 4.

[33] See Art 22 ECHRB (making the right of medical personnel to store and use biological material taken during an operation for purposes unrelated to the operation subject to the patient's informed consent) and Arts 21–22 of the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin (Strasbourg, 24 January 2002) (2002 ECHRB Protocol), Art 13, vii of the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research (Strasbourg, 25 January 2005) (2005 ECHRB Protocol), imposing an obligation on researchers to obtain consent in relation to any 'foreseen potential further uses, including commercial uses, of the research results, data, or biological materials'). Following Art 5 of Directive 44/98/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions [1998] OJ L213/13: 'The human body, at the various stages of its formation and development, and at the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions'.

[34] *Moore v Regents of the University of California*, 51 Cal 3d 120 (1990). John Moore, *aka* 'l'homme aux cellules d'or' – B Edelman, *La personne en danger* (Paris, Presses Universitaires de France, 1999) 289ff – on the pretext of therapy a leukaemia patient, unwitting holder of a treasure *sub specie* of a rare blood protein, had endured overlong clinical trials, after which the researchers of the world-class university clinic that had treated him obtained a cell line (Mo Cell-Line), patented it and sold it to a pharmaceutical company, which in turn obtained nine patents, for a total value estimated at several billion dollars. Moore's action was based on the tort of conversion. This remedy grants the dispossessed owner of movable property damages, in this case, quantified based on the profits extracted from the commercial exploitation of the patent. The claim was dismissed by the district court (no property in the human body), affirmed by the Court of Appeal (recognition of a property right on one's own body), and finally rejected by the California Supreme Court, which nevertheless found the researchers liable for breaching the fiduciary patient–doctor relationship. See J Boyle, 'A Theory of Law and Information: Copyright, Spleens, Blackmail, and Insider Trading' (1992) 80 *California Law Review* 1416, 1516: 'As far as the majority is concerned, Mr. Moore is the author of his own destiny, but not of his spleen'. R Epstein, 'Steady the Course: Property Rights in Genetic Materials' in Kieff (n 16) 153, 158: 'The better view is conversion because it creates cleaner property rights in those cases in which individuals do enter into various kinds of business transactions'.

[35] See nn 32 and 33.

('car il n'est pas forcément satisfaisant pour l'individu de s'achever en cosmétiques'[36]). The dissociation of the power of disposal in return for payment from the right to consent to treatments testifies to the decoupling, in the representation of the human *soma*, between person (inestimable and unexploitable 'as such') and artefact (technically reproducible, indefinitely malleable, and subject to economic exploitation).

The question who can claim rights of access and control over human tissues and the products obtained from them is deemed pivotal within the scientific community.[37] Indeed, several important issues ultimately depend on whether we accept or deny the assumption that human tissues and cells extracted from the body are subjected to standards identical or akin to ownership. In the first case, donor consent transferred property rights over 'their' tissues, and research participants could freely choose whether to maintain or relinquish at least some rights over them, including a right over secondary uses, and eventually share in the proceeds of patents obtained by researchers.[38] By the same token, consent addressees – biobanks, researchers and research funders – would be the owners of tissues legitimately obtained.[39] In the second case,[40] donor consent would seem more like an act of authorisation and destination to research, while consent addressees would be regarded as custodians (biobanks) and users (researchers) of research infrastructures.[41] Likewise, different conclusions would follow regarding the rights and liabilities of researchers and research funders, the processing and sharing of samples and data, intellectual property rights over intermediate products instrumental to further research, and openness to commercialisation of final products.

III. WHAT PRICE CONSENT?

The tension between the no-property rule on the human body 'as such' and allocation to researchers and funding organisations of exclusionary rights over human

[36] Hermitte (n 16) 339.

[37] H Langhof et al, 'Access policies in biobank research: what criteria do they include and how publicly available are they? A cross-sectional study' (2017) 25 *European Journal of Human Genetics* 293; H Langhof et al 'Current practices for access, compensation, and prioritization in biobanks. Results from an interview study' (2018) 26 *European Journal of Human Genetics* 1572; L Coppola et al 'Biobanking in health care: evolution and future directions' (2019) 17 *Journal of Translational Medicine* 172; I Goold, 'Why Does It Matter How We Regulate the Use of Human Body Parts?' (2014) 40 *Journal of Medical Ethics* 3.

[38] A straightforward case for (intellectual) property rights is made by Epstein (n 34) 159. See also: L Bennett Moses, 'The Problem with Alternatives: The Importance of Property Law in Regulating Excised Human Tissue and In Vitro Human Embryos' in Goold et al (n 16) 197; I Goold and M Quigley, 'Human Biomaterials: The Case for a Property Approach' in Goold et al (n 16)231; S Douglas and I Goold, 'Property in Human Biomaterials: A new Methodology' (2016) 75 *Cambridge Law Journal* 478.

[39] HC Howard, Y Joli, et al, 'Informed consent in the context of pharmacogenomic research: ethical considerations' (2011) 11 *Pharmacogenomics Journal* 155.

[40] R Rao, 'Genes and Spleens: Property, Contract, or Privacy Rights in the Human Body?' (2007) 35 *Journal of Law, Medicine and Ethics* 2; K Greasley, '2; K Gre Rights in the Human Body: Commodification and Objectification' in Goold et al (n 16) 67ff; Pila (n 16) 833ff.

[41] R Brownsword, 'Rights, responsibility and stewardship: Beyond consent' (2009) in Widdows and Mullen (n 16) 99; NC Manson, 'The medium and the message: tissue samples, genetic information and data protection legislation' in Widdows and Mullen (n 16) 15; V Calderai, 'Consenso informato' in *Annali dell'Enciclopedia del Diritto* VIII (2015) 225.

specimens and products obtained from them has prompted the claim for acknowledgement of donor interests against the 'second enclosure movement' led by the pharmaceutical-industrial complex.[42] The analogy with movement at the roots of capital accumulation vividly depicts the reason behind patients' claim to ownership rights over 'their' tissues. The Lockean ideal of property as the foundation of freedom is summoned against colonisation of the world of life. In the distinct but intersected legal framework for the collection and treatment of information obtained from human tissues, 'uncertainty and uneasiness' persist as to the legitimacy of 'broad' or 'open' consent procedures based on requirements for permission limited to extraction, storage and future use of collected biological samples and associated data for unspecified research purposes.[43]

The flip side of the coin is repression of the social dimension of fundamental rights that creeps in when individual self-government is codified into property as an absolute subjective right over a 'thing'. Indeed, acknowledging a general property right on human tissues comes at the cost of cancelling the contexts, ripe with legal qualifications, which steer the ascription of liabilities and rights, with potentially dire implications for medical research. A lock of hair snipped in a barber's shop is a *res derelicta* that can be freely disposed of; a hospital has 'special waste' destined for destruction; in a laboratory is a biological sample, subject to an array of regulations aimed at ensuring safe procurement, storage, and transfer, privacy protection and data safety, legitimate access.[44] The same 'object' corresponds to different legal 'things', depending on their purpose: diagnosis, treatment, research, and so on.

Property rights offer incentives to internalise the costs of economic activities by forcing producers to pay for use of resources.[45] According to mainstream economic analysis of law, there is no limit to what can be owned, provided that it is 'scarce as well as desired'.[46] Much of the contemporary law of biotechnologies leads precisely from the assumption that 'biological constructs extracted from living nature can be patented by anyone ingenious enough to detach them from their physical surroundings and make them useful in commerce or industry'.[47] At the same time, all legal systems limit the extent of what can be deemed an object of individual property rights in the public interest. As a result, the incentive structures in human tissue research vary wildly,[48] depending on whether ownership categories are involved and of what

[42] See J Boyle, 'The Second Enclosure Movement and the Construction of the Public Domain' (2003) 66 *Law and Contemporary Problems* 33.

[43] Hallinan (n 30) 2ff.

[44] K Beier, 'Beyond the dichotomy of individualism and solidarity: Participation in biobank research in Sweden and Norway' in C Lenk et al (n 16) 65; Gottweis and Kaye (n 29).

[45] H Demsetz, 'Toward A Theory of Property Rights' (1967) 57 *American Economic Review* 347; H Demsetz 'Toward a Theory of Property Rights II: The Competition between Private and Collective Ownership' (2002) 31 *Journal of Legal Studies* 653.

[46] R Posner, *Economic Analyses of Law* (Aspen, Wolters Kluwer, 2014) 32ff.

[47] S Jasanoff, 'Taking Life. Private Rights in Public Nature' in KS Rajan (ed), *Lively Capital. Biotechnologies, Ethics and Governance in Global Markets* (Durham, Duke University Press, 2012) 155, 181.

[48] SR Munzer 'Common, Anticommons and Community in Biotechnological Assets' (2009) 10 *Theoretical Inquiries in Law* 271.

kind (private, public, or commons), with far-reaching implications for innovation, fundamental rights and public health.

The argument proposed here reverses the path that leads from the 'thingness' of detached body parts to consent as an act of ownership transfer. Instead of deriving legal rules from an unchecked ontological taxonomy, rights, liabilities and remedies are based on context-laden qualifications grounded on the applicable legal framework and functional analysis. This methodological approach elicits an inquiry into consent specifications in different contexts (A) and its relation to trust (B).

A. Different Contexts

Informed consent procedures mark the transition from raw materials to biological samples, prompting questions on the legal status of human tissues and donor rights, the feasibility of a common framework for data and samples, and the legitimacy of secondary uses. Across a broad spectrum of applications, the *leitbild* of self-ownership turns an issue of prevention and management of the negative externalities associated with genetic information processing into a veto power over any use of tissues and data not expressly authorised *ex ante* by the donor, unless anonymised, including uses unforeseeable at the time of collection and up to destruction of samples following withdrawal of consent.[49] Quite apart from the epistemic limits of information disclosure,[50] such a broad reading overlooks that: (i) total anonymisation is impossible;[51] (ii) its administrative costs are prohibitive, for much research on secondary data runs through years and decades; (iii) anonymity is undesirable whenever the value of secondary information is a function of first-level information traceability and processing, such as in epidemiological studies on the incidence of diseases across time and space. The idea of self-ownership casts a factitious uniformity over context-sensitive questions, the answers to which depend on the type of specimen collections or biobanks (general hospital biobanks; biobanks intended for research on specific diseases and conditions; population biobanks), data (*stricto sensu* personal and sensitive data, aggregated data, non-sensitive data), and research (epidemiological research, epigenetic studies, research on rare diseases).[52]

Research on rare genetic diseases presents a prima facie compelling case for ascribing quasi-proprietary rights of control to donors personally involved as patients or

[49] Italian Data Protection Authority, Aut 12.12.2013 (www.garanteprivacy.it/web/guest/home/docweb/-/docweb-display/docweb/2818993), following the Council of Europe Recommendation (2006) 4 (Art 15). The right to choose between anonymisation and destruction has been reasserted by the new Recommendation, CM/Rec(2016)6, Art 13.1. See M Macilotti, 'Reshaping Informed Consent in the Biobanking Context' (2012) 19 *European Journal of Health Law* 271.

[50] NC Manson and O O'Neill, *Rethinking Informed Consent* (Cambridge, Cambridge University Press, 2007) 15ff.

[51] JE Lunshof, R Chadwick, DB Vorhaus and GM Church, 'From Genetic Privacy to Open Consent' (2008) 9 *Nature Review Genetics* 406; Macilotti (n 49) 283.

[52] N Black, 'Secondary use of personal data for health and health services research: why identifiable data are essential' (2003) 8 *Journal of Health Services Research and Policy* 36; A Brand et al, 'Biobanking for Public Health' in J Taupitz et al, *Trust in Biobanking. Dealing with Ethical, Legal and Social Issues in an Emerging Field of Biotechnology* (Berlin, Springer, 2012) 3.

parents. Still, property rules may work against their expectations. In the aftermath of *Moore*, attempts by research participants to claim some rights of control and exert some 'voice' option for dissemination of research-generated technologies in the public interest have been dismissed based on an aggressive reading of 'consent' as an act of transfer of property right:[53] 'the property right in blood and tissue samples evaporates once the sample is voluntarily given to a third party'.[54]

These doctrines have encouraged the search for contract-based solutions, where researchers are granted a licence to use the materials in return for donor recognition of the power to share patent decisions and participation in royalties. The agreement between PXE Int, Inc, a non-profit organisation owning a biobank of biological samples and a group of researchers, made it possible to isolate the gene responsible for *Pseudoxanthoma elasticum*, a rare disorder causing degeneration of connective tissue, neglected by the pharmaceutical industry due to its extremely low incidence. New treatments were born.[55] In terms of transaction cost economics, this is a paradigmatic example of a hybrid response (unified contracting) to the inefficient outcome of pure outsourcing systems.[56] On the other hand, contract-based governance is vulnerable to transaction costs and power asymmetries. Conditions of bilateral dependence in research on rare genetic diseases, along with the possibility of organising a disease-defined community into a legal entity owning a biobank, can effectively curb failures of the market for medical treatments[57] and see that donors maintain a robust voice in

[53] See: *Greenberg v Miami Children's Hospital Research Institute Inc* 264 F Supp 2d 1064 (SD Fla 2003) and *Washington University v Catalona* 437 Fed Supp 2d 986 (ED Missouri 2006). In *Greenberg*, the families of children suffering from a rare congenital disease gave tissues, information, and funds to a researcher, with the informal understanding 'that any carrier and prenatal testing developed in connection with the research … would be provided on an affordable and accessible basis, and that … research would remain in the public domain to promote the discovery of more effective prevention techniques and treatments and, eventually, to effectuate a cure'. Following the researcher's decision to transfer the data and samples to another institution and patent the genetic test obtained, the donors assumed the defendant's wrongful interference with the plaintiff's property right in the tissue, as in *Moore* (n 34 and accompanying text). Unlike Moore, however, the *Greenberg* court found that research participants enjoy some limited property rights over their tissues, which should qualify as 'donations to research without any contemporaneous expectations of return'. The *Catalona* court went a step further, by narrowly constructing the meaning of consent as a 'gift' of bodily materials by research participants to research institutions. For critical analyses, see Rao (n 40) 3–5; HA Washington, *Deadly monopolies* (New York, Random House, 2011) 234. Of course, the exit/voice alternative provides a critical analysis framework: see AO Hirschmann, *Exit, Voice, and Loyalty: Responses to Decline in Firms, Organizations, and States* (Cambridge Mass, Harvard University Press, 1970).

[54] *Greenberg v Miami Children's Hospital* (n 53) 1075.

[55] DE Winickoff, 'Partnership in UK Biobank: A Third Way for Genomic Governance?' (2007) 35 *Journal of Law, Medicine and Ethics*, 450: 'PXE International has become a well-known model for the way it has leveraged its control of the biobank qua biocapital in order to achieve collective goals'.

[56] OE Williamson, 'The Theory of the Firm as a Governance Structure: From Choice to Contract' (2002) 16 *Journal of Economic Perspectives* 171.

[57] They can but need not. The capacity of private ordering to correct failures of the market for advanced therapies depends on the construction of consent as an act of transferral of the rights of control over human tissues, whose success in turn depends on the characteristics of the transaction. See EW Williams and R Coase, 'The Regulated Industries: Discussion' (1964) 54 *The American Economic Review* 192, 195: 'Contemplation of an optimal system … has directed economists' attention away from the main question, which is how alternative arrangements will actually work in practice. … It is no accident that in the literature … we find a category market failure but no category government failure. Until we realize that we are choosing between social arrangements which are all more or less failures, we are not likely to make much headway'.

managerial choices. Conversely, unilateral dependence and high organisational costs in research on high-incidence diseases highlight the limits of property and contract as techniques to promote and protect access to knowledge.[58]

B. Trust

Of the conditions for pursuit of knowledge, trust is possibly the most valuable, likely the most vulnerable,[59] most of all if the conditions for choosing *ex ante* are weak.[60] A privacy-obsessed approach to the government of biomedical research sees trust in the light of procedures for processing and circulating anonymised or pseudo-anonymised data and biological samples, unconcerned by the fact that anonymity, to the extent that it can[61] and must be safeguarded, is irrelevant to donor interest *qua* citizen to participate actively in scientific research.[62] Indeed, the 'rhetoric of anonymity'[63] obscures the circumstance that consent may safeguard interests other than privacy, such as the aspiration to bring values and convictions into public space, including the right to 'share in scientific advancement and its benefits'.[64]

The measure to which these aspirations can be realised depends on the idea of self-determination: as either a value with roots in the right to privacy or as an instrument for exercising civil, political and economic rights. Adhesion to the first model implies that donor values must be binding on researchers. This seemingly obvious conclusion is problematic whenever donor wishes are dictated by prejudice or superstition. Donors may oppose specific uses of their tissues based on scientifically inconsistent beliefs, such as the harmfulness of vaccines or hostility toward minorities or social

[58] Munzer (n 48) 282.

[59] O O'Neill, *Autonomy and Trust in Bioethics* (Cambridge, Cambridge University Press, 2002). S Lo Iacono and B Sonmez, 'The Effect of Trusting and Trustworthy Environments on the Provision of Public Goods' (2021) *European Sociological Review* 155.

[60] For an empirical analysis of different models of consent in different types of research see S Wallace, S Lazor and BM Knoppers, 'What is in a Clause? A Comparison of Clauses from Population Biobank and Disease Biobank Consent Materials' in Dabrock, Taupitz and Ried (n 52) 119.

[61] HT Greely, 'The uneasy ethical and legal underpinnings of large-scale genomic biobanks' (2007) 8 *Annual Review of Genomics and Human Genetics* 343; MC Tallacchini, 'Rhetoric of Anonymity and Property Rights in Human Biological Materials (HBMs)' (2005) 7 *Law and the Human Genome Review* 153, 164ff; JE Lunshof et al (n 51) 410: 'No promises of anonymity, privacy or confidentiality are made. The leading moral principle is veracity – telling the truth – which should precede autonomy'.

[62] S Rodotà, *Tecnologie e diritti* (Bologna, Il Mulino 1995) 29; MC Tallacchini, 'A Participatory Space Beyond the 'Autonomy Versus Property' Dichotomy' in D Mascalzoni et al, *The Ethics, Law and Governance of Biobanking* (Dordrecht, Springer, 2015) 21, 22: 'In many ways, privacy has become more a constructed 'myth' than a perceived need, a screen to protect the interests of the market more than those of the individual. Privacy can, in fact, be transformed into an obstacle, an undesired and paternalistic protective barrier, while showing one's face and name can, in some circumstances, be important for individuals'; B Prainsack and A Buyx, 'A Solidarity-Based Approach to the Governance of Research Biobanks' (2013) 21 *Medical Law Review* 71.

[63] Tallacchini (n 61) 163: 'As a legal standard, anonymisation of data is not simply the recognition that an effective procedure of encryption has been performed, but much more a legal fiction: it aims at hiding all remaining interest of the subject-of the-data with regard to biological materials.'

[64] Art 27.1 Universal Declaration on Human Rights. The 'right to science' is emphasised by E Vayena and J Tasioulas, 'The dynamics of big data and human rights: the case of scientific research' (2016) 374 *Philosophical Transactions of the Royal Society* A 374:20160129.

groups. Deference for individual choices cannot go so far as to warrant discriminatory biases and irrational beliefs without encroaching upon fundamental scientific and constitutional values. Bar the freedom to refuse or withdraw consent, donor control over the nature and purposes of research should be limited to general criteria linked to broad ethical, political and religious directives, with scant concession to idiosyncratic motivations.

From yet another perspective, uncertainty as to future uses of biological samples, the limits of anonymisation procedures, and the need for traceability can be effectively addressed by complementing open consent procedures with objective measures of protection (for instance, independent evaluation, supervisory bodies representing donors and publicity of results). What is often depicted as a quintessentially personal expression of individual sovereignty seems more like a process of multi-party communication grounded in the impersonal nature of knowledge and aimed at managing the crises of cooperation that stem from uncertainties, cognitive biases, organisational dysfunctions and professionals' habits.[65] The scientific and normative bases of cooperation between researchers and donors should not be left to the consideration, goodwill and civil commitment of individuals and civil society organisations. Rather, it is a question of citizenship that touches upon 'revision of the contract between science and society'[66] and, as such, must be addressed, *de jure condendo*, with institutional change.

IV. PROPERTY IN THE BODY. AN EVOLUTIONARY APPROACH

This section sketches out a theory of donor consent within the framework of an anti-naturalistic understanding of the objects of property rights – in a nutshell: from an act of disposal of property interests over a 'thing' existing *in rerum natura* to a stage within the process of mutual construction of rights and things.[67]

The tendency to identify what is perceived by the senses and can be recalled to the mind by 'the operation of reflection' as an 'object' is an epistemic obstacle to acknowledgement of the historical nature of legal qualifications,[68] with ripple effects on the idea of distributive justice. In the general legal meaning of the word, a 'good' or an 'asset' is a (tangible or intangible) 'thing', subject to estimation *à prix d'argent* (*cf* Article 2284 French Civil Code and Article 2740 Italian Civil Code). As the items included in the general class of goods change across space and time, the proportion between what is due to each person and what is left to the distribution of wealth and talents varies accordingly. This means that analysis of the determinants of distributive

[65] M Graziadei, 'Il consenso informato e i suoi limiti' in S Rodotà and P Zatti (eds), *Trattato di biodiritto* IV *I diritti in medicina* (Milano, Giuffrè, 2011) 191, 219ff.

[66] MC Tallacchini, 'Democrazia come terapia: la governance tra medicina e società' (2006) 22 *Notizie di Politeia* 15.

[67] See P Femia, 'Il campione biologico come oggetto di diritti. Bene giuridico e processi di valorizzazione' in D Farace (ed) *Lo statuto etico-giuridico dei campioni biologici umani* (Roma, Nuova Editrice Universitaria, 2016) 149.

[68] I Kant, *Critique of Judgment* (trans JH Bernard) (New York, Hafner, 1951) §40. The notion of *obstacle épistemologique* was developed by G Bachelard, *La formation de l'esprit scientifique: contribution à une psychanalyse de la connaissance objective* (Paris, Librairie philosophique J Vrin, 1938).

choices goes up a notch: from selection and ascription of entitlements over an asset to institution of the asset and limits to its exploitation. In other words, the problem of distributive justice (and the core of dissent) does not concern primarily the conditions for markets to produce fair, as well as efficient, results, but the choice between: (i) things open to (more or less regulated forms of) market allocation; (ii) things excluded from the market, but still open to non-market allocation systems; (iii) things subject to a regime of market-inalienability.

Since the 1970s, these choices have been driven by the convergence of supply-side economic policies and technological innovation, radiating worldwide from its US epicentre.[69] The result is an incessant flow of new, efficient proprietary assets,[70] obtained from 'enclosure' of the public domain and the commodification of things formerly excluded from appropriation,[71] including human and non-human genome,[72] reproductive capacities,[73] information extracted from any (social or natural) phenomenon or (public or private) activity observable through sensors or realized through networked terminals.[74]

Production of biotechnological assets then 'sees' the body as a natural resource. As the millennial history of trades in corpses and relics for medical and devotional markets suggests, the human body has never been entirely *extra commercium*.[75] Nevertheless, these transactions occurred in a grey area, verging on impiety and proscription, whilst the contemporary demand for biological tissues is set within the secularised framework of the knowledge economy.[76] The association established by continental Civil Codes between property rights and *res corporalis* (*cf* §90 BGB; Article 810 Italian Civil Code Article 544 French Civil Code) fits this *gestalt*,[77] with minimal adjustments required by relation of the thing to the donor.[78] By contrast, in

[69] U Mattei, 'Circolazione dei modelli giuridici', in *Annali dell'Enciclopedia del diritto*, I (Milano, Giuffrè, 2008) 173.

[70] Demsetz (n 45).

[71] Boyle (nn 28 and 42); BM Frischmann, 'Evaluating the Demsetzian Trend in Copyright Law' (2007) 3 *Review of Law and Economics* 649; A Gambaro, 'Dai beni immobili ai beni virtuali' (2009) in *XXI Secoloi*, www.treccani.it/enciclopedia/dai-beni-immobili-ai-beni-virtuali_%28XXI-Secolo%29.

[72] Kieff (n 16); Hoppe (n 16); JL Roberts, 'Progressive Genetic Ownership' (2018) 93 *Notre Dame Law Review* 1105; GS Alexander, EM Peñalver, JW Singer and LS Underkuffler, 'A Statement of Progressive Property' (2009) *Cornell Law Faculty Publications* 11.

[73] V Calderai, 'Breaking out of the Regulatory Delusion. The Ban to Surrogacy and the Foundations of European Constitutionalism' (2020) 20 *Global Jurist* 1.

[74] S Zuboff, 'Big other: Surveillance Capitalism and the Prospects of an Information Civilization' (2015) 30 *Journal of Information Technology* 75; S Zuboff, 'Surveillance Capitalism and the Challenge of Collective Action' (2019) 28 *New Labor Forum* 10.

[75] R Richardson, *Death, Dissection and the Destitute* (Chicago, University of Chicago Press, 1987) 54ff and PJ Geary, *Furta Sacra. Thefts of Relics in the Central Middle Ages* (Princeton, Princeton University Press 1990) 44ff (with an interesting reference to the trafficking of works of art).

[76] Rajan (n 17).

[77] Schünemann (n 24) 58. A sophisticated version of this insight is embedded in Art 5 It cc, whose 'atti di disposizione del corpo umano' slavishly draws out the ownership paradigm, as the 'external projection of a right' through which 'the subjection of the res to this power of the subject is expressed'. The German category of *Verfügungsgeschäfte* thus lends legal clothing to a metaphysics of the body as a portion of geometric space, identified in relation to its physical properties (*res extensa*), somewhat mysteriously linked with a spiritual subject (*res cogitans*). See C Castronovo, 'Il negozio giuridico dal patrimonio alla persona' (2009) 12 *Europa e diritto privato* 87.

[78] Halàsz (n 24).

common law jurisdictions, the centuries-old barrier against property interests in the human body cracked from the end of the twentieth century to the benefit of researchers and research funders.[79]

In both Civil Law and Common Law traditions, individuation by detachment provides the hook to attach human tissues to the world of natural 'things'. The time-honoured rules on fruits (*cf* Articles 820–21 Italian Civil Code, §953 BGB) and occupancy (*cf* Article 923 Italian Civil Code, §§958–58 BGB) have thus been bent to suit ascription of property rights to donors[80] and researchers[81] (in the latter case upon interpolation of voluntary relinquishment via donor consent).[82] Yet, at the same time, to be perceived as a resource the human body must go through a procedure of naturalisation or dehumanisation; it must be thought of as a 'thing' to qualify as an 'asset', an object of property interests.

In a seminal study, Yan Thomas has shown the role of procedure in the institution of things in Roman law.[83] A thing 'existed' for the law insofar as it was ritually or procedurally apprehended to be valued. Contemporary consent requirements work just the same: not so much as an act of disposal (*verfügungsakt*) but as a rite of passage, a performative act that imparts a positive qualification – a value – to something that otherwise would be only negatively qualified as 'hazardous waste' and destroyed.[84]

[79] *Moore v Regents of the University of California* (n 34). In a much-criticised decision, the Court of Appeal of England and Wales ordered the hospital where some patients had deposited their semen before undergoing treatment that could have led to infertility to pay damages, following the destruction of the sample, finding an infringement of a property right: *Yearworth and Others v North Bristol NHS Trust* [2009] 2 All ER 986 (CA). Interestingly, the plaintiffs had cited a well-known decision by the *Bundesgerichtshof*, based on identical facts, in support of a claim for damages for personal injuries (BGH, 9.11.1993, (1994) *Neue Juristische Wochenschrift* (NJW), 127, annotated by A Laufs and E Reiling, 'Schmerzensgeld wegen schuldhafter Verletzung tiefgefrorenen Spermas? (1994) *Neue Juristische Wochenschrift (NJW)* 775ff). In that case, the Bundesgerichtshof upheld a claim for compensation for non-pecuniary damages (§253, former §847) for injury to physical integrity (§823) based on the functional unity between the semen and the body. SHE Harmon and G Laurie, 'Yearworth v. North Bristol NHS Trust: Property, Principles, Precedents and Paradigms' (2010) 69 *CLJ* 476, 491: 'The rather uninspired and uninspiring advancement of the property paradigm in Yearworth suggests that property was only used as a convenient vehicle through which to achieve a certain outcome. But the property model could lead to numerous harms, including exploitation and the dehumanisation of patients and people more generally'.

[80] Roth (n 16) 58ff. Italian scholars mainly reject this solution: CM Bianca, *Diritto Civile, 1, La norma giuridica. I soggetti* (Milano, Giuffrè 1978) 163.

[81] *Moore v Regents of the University of California* (n 34) 144; *Washington University v Catalona* (n 54) 999ff.

[82] *Washington v Catalona* (n 54).

[83] Thomas (n 2) 1431.

[84] The European regulatory framework is currently defined by Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives OJ L312/3 (as amended by the Commission Regulation (EU) 1357/2014 of 18 December 2014 replacing Annex III to Directive 2008/98/EC of the European Parliament and of the Council on waste and repealing certain Directives OJ L369/89) and by Commission decision 2000/532/EC of 3 May 2000 replacing Decision 94/3/EC establishing a list of wastes pursuant to Article 1(a) of Council Directive 75/442/EEC on waste and Council Decision 94/904/EC establishing a list of hazardous waste pursuant to Article 1(4) of Council Directive 91/689/EEC on hazardous waste (notified under document number C(2000) 1147) (Text with EEA relevance) OJ L 226/3 (European List of Waste). Human tissues are identified (under Commission decision 2000/532/EC) by codes 180102 and 180103 (respectively body parts and organs including blood bags and blood preserves' and 'waste whose collection and disposal is subject to special requirements in view of the prevention of infection') of the List. See also Human Tissue Act 2004, s 44: material taken during

The lens of metaphysical dualism and sovereignty of the will conceals contexts that channel the meaning of consent. A sample of gametes stored in a fertility centre can be different 'things', depending on whether the sample comes from an anonymous donor or a patient before treatment that could lead to sterility.[85] The same 'object' – say an umbilical cord – is not the same 'thing' depending (a) on whether its collection was authorised, and (b) its destination (stem cell transplant, research or autologous implantation). These examples can be generalised. Legal 'things' are logical mediums, inhabitants of Popper's World 3:[86] qualifications and nexus of qualifications functional to identification and ascription of rights, liabilities and remedies. The autonomy of law from ontology is such that the same piece of matter originates different 'things', with different legal statuses, depending on their functions.

This insight is backed up by the observation that in all jurisdictions human tissues do not qualify as ownership by the simple fact of detachment, independently from ascription of rights, obligations and remedies ordinarily associated with property rights. Following this rule of recognition, human raw materials obtained in medical settings have neither exchange value (they cannot be sold) nor use value (except for diagnosis and therapy). By this double exclusion from the market and from direct exploitation, no public or private entities – not even donors – qualify strictly speaking as owners: no one can claim *uti dominus* possession; exercise the faculties of use, management, economic exploitation, disposition, exclusion; bring actions inherent in the *ius sequelae*, be expropriated, and so on, until precious little is left in the 'bundle'.[87] By the same token, consent cannot work as a transfer of property rights that *ex hypothesi* do not yet exist. Instead, we can observe that the general function of consent, authorising otherwise unlawful conduct,[88] is complemented by the destination of human tissues to research within the frame of 'appropriate consent procedures' (Article 22 ECHB) to bring into legal 'existence' certain things 'd'origine et à finalité humaine'.[89]

By contrast, human tissues stored in research facilities following donor consent do qualify as 'things', 'objects' of property interests. To understand what kind of 'things' researchers are dealing with, it is worth pausing a moment: are they the same things extracted from the body? Important clues come from language. The word 'specimen', commonly used by researchers, designates an artefact: selected, classified, stored to be used as a source of information, along with other specimens.[90]

the course of medical treatment is surplus tissue and can be treated as waste; Code de la santé publique, Art R1135-11: 'Les pièces anatomiques d'origine humaine destinées à l'abandon doivent être incinérées'; Decr Pres Repubblica n 254-2003, Art 10.

[85] See n 79.

[86] The world of abstract intellectual creations: Popper (n 25) 106ff.

[87] W Hohfeld, 'Fundamental Legal Conceptions as Applied in Judicial Reasoning' in WA Cook (ed), *Fundamental Legal Conceptions as Applied in Judicial Reasoning and Other Legal Essays by Wesley Newcomb Hohfeld* (New Haven, Yale University Press, 1920); A Honoré, 'Ownership' in AG Guest (ed), *Oxford Essays in Jurisprudence: A Collaborative Work* (Oxford, Oxford University Press, 1961) 107; ST Munzer, 'A Bundle Theorist Holds On to His Collection of Sticks' (2011) *Economics Journal Watch* 265; JL Contreras, 'The False Promise of Data Ownership' (2019) 94 *NYU Law Review* 624.

[88] Calderai (n 41).

[89] Hermitte (n 16).

[90] Manson (n 41) 15.

Depending on whether the emphasis is on the material or the informational dimension, human specimens are classified as non-excludable and non-rival goods, their normative status constantly teetering between the poles of (public or private) ownership and commons. Yet, as the time and work required for development of knowledge enter the picture, the assimilation of human specimens to the material support of genetic data is wanting in its implication that the information is somewhere in the sample, just like the apologue on justice in 'The Merchant of Venice' in the play.[91] Semiotically, the difference is the same that occurs between knowledge from symbolic communication (*signum artificiale*) and knowledge from experience (*signum naturale*). Whereas the former applies a code shared within a community, the latter proceeds inductively from observations. Unlike information communicated through conventional language and intentionally reproduced in a medium, genetic information requires scientific knowledge, technical skills, and a great deal of analysis, classification, and association with other information in order to be realised.[92] To say that the data are in the samples is like saying that the statue is in a block of marble.

Some corollaries follow from here: (i) unlike data, samples not (yet) analysed are potential information: 'produced and stored for epistemic purposes';[93] (ii) therefore, the regime of personal data protection should apply only to data; (iii) normative classifications based on data 'sources' are epistemically baseless: there is no such thing as inherently personal and sensitive data, but all data can be personal and sensitive in relation to the purposes for which they are collected and the uses to which they are put; (iv) since the uses that can be obtained from individual specimens are limited, potential knowledge is expressed by collections of specimens and data, along with sharing and connecting different collections.[94]

The latter feature supports the choice of biobanks as the basic unit of analysis. Biobanks are *universitates iuris*: pools of different items considered as a whole based on their purpose or destination. To an extent, the relevance of destination downplays the ownership issue. Public or private, non-profit or for-profit, management powers and exclusionary rights are framed in the public interest, so that a biobank can fulfil its purpose and operate as a medical research infrastructure, with powers and responsibilities instrumental to exercise of the functions of 'stewards' and 'trusted mediators' among different stakeholders.[95] The description of biobanks as research infrastructures is supported by the gradual convergence of European national legislation

[91] Manson and O'Neill (n 51).

[92] Manson (n 41) 31.

[93] Munzer (n 48) 271.

[94] G Laurie et al, 'Genetic databases. Assessing the benefits and the impact on human and patient rights. A World Health Organisation Report' (2004) 11 *European Journal of Health Law* 87, 92.

[95] This implies, as a minimum, adoption of measures aimed at granting access to researchers on a non-discriminatory basis while ensuring safe and efficient use of samples and information: see A Boggio, 'Population Biobanks' Governance: a Case Study of Knowledge Commons, in KJ Strandburg et al (n 16) 102, 106; The Deutscher Ethikrat, *Humanbiobanken für die Forschung* (Berlin, Deutscher Ethikrat, 2010); M Macilotti, *Le biobanche di ricerca. Studio comparato sulla "zona grigia" tra privacy e proprietà* (Trento, Università di Trento, 2013) 14.

towards integration in national healthcare and research systems.[96] The destination to the public interest is stronger if biobanks are entrusted to (public or private) entities operating as 'service units'[97] on a non-profit basis within national health systems, whereas it thins out if biobanks are owned by private bodies offering products and services on the market. However, even in this case obligations of registration and accreditation, control by administrative agencies, protocols for managing samples and data, and auditing procedures realise a substantive adjustment of property rights in the public interest.

The merit of sharing knowledge justifies management of biobanks as medical knowledge commons,[98] regardless of their allocation to public or private entities. The commons-based approach to biobanking does not imply nationalisation of genetic resources extracted from citizens' bodies,[99] as in the unfortunate Icelandic Medical Database Act and Biobank Act (1998), any more than it subscribes to expropriation of private biobanks. Separating the problem of destination from the problem of allocation cuts across the division between public and private ownership, highlighting the regulatory significance of management strategies. If a resource is an infrastructure whose purpose is the sharing of knowledge as a catalyst of innovation, that strategy must be built on non-discriminatory access.[100] As biological specimens are rival and excludable assets, trade-offs are required between openness and the need to limit resource depletion through overuse and misuse. This goal is fulfilled by legal regimes based on the principle of the broadest possible qualified access to samples and data. The backbone of such regimes, as far as concerns the legal status of human tissues, consists of legal and administrative procedures of independent research evaluation and compliance with (objective and subjective) individual rights and measures to protect societal interests.[101]

At the end of the supply chain, biotechnological products obtained from human tissues can be divided into intermediate and final products. In the wake of the doctrine pinned down by the US Supreme Court since the 1980s, the transition from 'things' subject to a regime of market-inalienability to 'things' subject to full-blown market regimes is controlled by §101 Patent Act, based on the principle of the novelty of the invention compared to substances existing in nature.[102] Accordingly, discoveries

[96] Gottweis and Kaye (n 29) 40ff.

[97] See the definition of the Italian National Committee for Biosafety and Biotechnology, 'Guidelines for the certification of Biobanks': 'service units, without direct profit, organised in technical units with quality, order and destination criteria, aimed at collecting and preserving human biological material and data related to it, for the purpose of medical research' (my translation).

[98] Boggio (n 95).

[99] Rao (n 40) 6ff.

[100] BM Frischmann, *Infrastructure. The Social Value of Shared Resources* (New York, Oxford University Press, 2012) 7ff.

[101] In this perspective, the proposal to substitute the equivocal denomination 'biobanks' with 'bioarchives: collections of public knowledge sources on the non-pecuniary value of life' is thus justified. See Femia (n 67) 190.

[102] *Diamond v Chakrabarty* 447 US 303 (1980); *Association for Molecular Pathology et al v Myriad Genetics, Inc, et al*, 569 US 12-398 (2013); *Mayo Collaborative Services v Prometheus Laboratories, Inc*, 566 US 10-1150 (2012).

that do not involve bio-engineering intervention,[103] including non-manipulated gene sequences,[104] are not eligible for patents.

This outcome was but a foregone conclusion. The patentability of isolated and purified DNA sequences had been a pillar of the 'global government of knowledge' established by the US Patent and Trademark Office and the European Patent Office,[105] echoed by Directive 98/44/EC on biotechnological inventions (Articles 3.2 and 5.2). By emphasising the functional dimension of innovation, the European Court of Justice assuaged the harsher effects of intellectual property, with the result of exempting scientific discoveries from patent rights.[106]

Criticisms of the expansion of intellectual property rights in this sector address the 'tragic scarcity' effects[107] of a mechanism that makes investment conditional upon the price system and collective action problems generated by the fragmentation of property rights at an early stage of research (anticommons).[108] Against this backdrop, the requirement of informed donor consent for filing a patent application if the invention involves human biological materials (Recital 26 Directive 44/98/EC) is the perfect *notion à consensus*: uplifting and useless,[109] it adds a new veto right without limiting the unfair distributive effects of intellectual property rights.[110]

[103] *Diamond v Chakrabarty* (n 102) 310 (distinguishing from *Funk Bro Seeds Co v Kalo Inoculant Co*, 333 US 127, 1948). Granting a patent in these cases would upset the balance between 'incentives that lead to creation, invention, and discovery' and 'imped[ing] the flow of information that might permit, indeed spur, invention'.

[104] *Association for Molecular Pathology et al v Myriad Genetics* (n 102): 'Myriad did not create or alter either the genetic information encoded in the BCRA1 and BCRA2 genes or the genetic structure of the DNA. It found an important and useful gene, but groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the §101 inquiry'.

[105] Acting on an aggressive interpretation of international trade agreements. See P Drahos, *The Global Governance of Knowledge: Patent Offices and their Clients* (Cambridge, Cambridge University Press, 2010); G van Overwalle, 'Biotechnological Patents: Global Standards, European Approaches and National Accents' in D Wüger and T Cottier (eds), *Genetic Engineering and the World Trade System* (Cambridge, Cambridge University Press, 2008) 77ff.

[106] Case C-428/08, *Monsanto Technology LLC v Cefetra BV and others* ECLI:EU:C:2010:402. In a case that pitted Monsanto against two companies importing food products obtained from genetically modified organisms in breach of the patent, the Court made the application of Art 9 of the Directive (patent protection extends to all material 'in which the product is incorporated and in which the genetic information is contained and performs its function') conditional on the circumstance that the genetic information 'at the time of the alleged infringement, performs the function described in the patent application'. Importation of the product from a country that does not apply patent protection was then deemed lawful because the genetic sequence was inert and no longer performed the function described in the patent application.

[107] G Calabresi and P Bobbit, *Tragic Choices* (New York, Norton, 1978) 129ff.

[108] Above, section III.A and nn 57 and 58. See Heller and Eisenberg (n 27). Rebecca Eisenberg later partially corrected her thesis in light of empirical analyses: R Eisenberg, 'Noncompliance, Nonenforcement, Nonproblem? Rethinking the Anticommons in Biomedical Research' (2008) 45 *Houston Law Review* 1059, 1062; R Eisenberg, 'Patent Costs and Unlicensed Use of Patented Inventions' (2011) 78 *University of Chicago Law Review* 53 (the 'tragedy of the anticommons' depends not only on the excessive number of upstream patents but also on the restrictions introduced by the licensing system).

[109] At least in the general terms in which it has been transposed by Italian legislation: see Art 170-bis Cod Proprietà Industriale.

[110] Quite apart from enforcement and compliance difficulties originating from bilateral information costs: see JA Bovenberg, 'Moore's Law and the Taxman: Some Thesis on the Regulation of Property in Human Tissue' in M Steinmann, P Sýkora and U Wiesing (eds), *Altruism reconsidered: exploring new approaches to property in human tissue* (Farnham, Ashgate, 2009) 164. The examples of private biobanks born from disease-defined communities suggest that the success of such initiatives crucially hinges on an institutional design tailored to the transactions: above, section III.A and nn 55, 56.

Similarities across the Atlantic should not keep us from considering the impact of institutional alternatives on biotechnological innovation. Whereas US law looks at the raw material/specimens/product sequence through the lens of contract and property rights, European legal systems use the lens of public policy. The difference lies in the burden required to overcome the presumption of availability of a resource in the public domain or, conversely, to trigger patent protection in the face of an alleged infringement, particularly in the light of today's complex networked models of genetic and epigenetic interaction.[111] Under conditions of uncertainty, the general interest in sharing knowledge and including natural resources in the public domain provides quite different assumptions. In terms of information, exclusive control is evil unless it can be proven to be good.

V. CONCLUDING REMARKS

This chapter has critically examined the *Leitbild* of donor consent to medical research based on human tissues as an act of transfer of rights akin to property or possession, established on the asymmetric dualism between persons and things. The capture of the human body into that old dichotomy fits well with neoliberal intuitions of moral agency and the relentless extraction of capital value from 'bare life' in the knowledge economy. However, this stands at variance with understanding the body as an integral dimension of personhood and personal freedom in modern constitutions and declarations of rights.

The argument advanced through these pages represents donor consent as a performative act, whereby the law institutes human biological materials. The almost paradoxical double qualification attached to human tissues – medical waste and valuable resource – suggests that their assimilation to raw matter and means of production entails a threshold of indeterminacy between *persona* and *res* structurally similar to the 'sovereign ban' that in a well-known interpretation of biopolitics marks the law primaeval relationship to natural life.[112] No longer living matter but still not *res*, human tissues are abandoned to destruction unless they can be turned into exchangeable commodities and internalised into the value chain of the biomedical industry. Yet, in liberal societies the power to redeem matter from destruction is entrusted to donor consent to preserve our commitment to human dignity and the inviolability of embodied personhood.

Some implications of this insight align with reframing human specimens collected for research as communal or collective property. However, the categorisation here proposed does away with the need to justify the transition of human tissues from private to communal ownership, as tissues collected for research are *ab imis* attracted to the public dimension in consideration of the general interest in development of knowledge, regardless of the private or public nature of the legal entities who bear the responsibilities for their management. In this light, communal ownership or

[111] Munzer (n 48) 286ff.
[112] G Agamben, *Homo Sacer. Il potere sovrano e la nuda vita* (Torino, Einaudi, 1995) 34ff.

Commons means no more and no less than an approach to resource management 'by which a resource is shared within a community'.[113]

From a reconsideration of the time-honoured category of detached body parts, three corollaries follow: (i) Informed consent should be re-examined to limit donor control over research activities and outputs to broad ethical, political and religious considerations; (ii) secondary uses of samples and data for research purposes not expressly authorised *ex ante* by donors should be allowed without the necessity for a new consent procedure, nor should withdrawal of consent to data processing imply destruction of biological samples (bar previous *inter partes* commitments to that effect) or compensation (bar remuneration for any inconvenience suffered); (iii) legal research in this field should focus on risk management and protection against exploitation of clinical labour,[114] rather than ever elusive strategies to control 'bare life'.

[113] Frischmann (n 100) ix.
[114] Cooper and Waldby (n 16).