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Original Article

Patentability and de-extinct animals in Europe: the patented woolly mammoth?

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ABSTRACT

De-extinction is a hot topic within conservation science but the potential patentability of de-extinct animals in Europe has hitherto been unexplored. This article addresses this lacuna, examining the legal, commercial, and ethical implications of patenting de-extinct animals under European patent law. The article is organized into four parts. Part I explores the reasons why patents are relevant and may be applied for in this context. Part II provides an overview of the scientific techniques currently being used in de-extinction projects, setting the foundation for the analysis of patentability which follows. Part III then critically assesses whether recreated animals would qualify as patent eligible subject matter under European patent law. It also investigates the extent to which European patent exclusions such as those on animal varieties, essentially biological processes, and the morality provisions might apply and whether recreated animals would meet the novelty requirement for patentability. Part IV concludes by highlighting the possible ramifications of patenting such animals, elucidating the chasm between the cultural and symbolic significance held by such animals, and their lack of differential treatment in the patent law sphere. It argues that de-extinction reignites questions around the scope of patents, and the role of ethical considerations within patent decision-making which warrant urgent reconsideration.

KEYWORDS: de-extinction, ethics, morality exclusions, OncoMouse, patents, transgenic animals

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I. INTRODUCTION

Ever since the 1993 blockbuster film 'Jurassic Park,' the notion of bringing vanished species back to life has hovered on the boundaries of reality and science fiction, but scientists are now reputedly on the brink of de-extinction.[1] While conservationists argue that this risks persuading lay people that extinction is reversible, technological advances in synthetic biology and genetics have made the revival of extinct species a real scientific possibility, with much of the recent literature in this area shifting from whether we can resurrect extinct species to whether we should. In May 2016, for instance, the International Union for the Conservation of Nature Species Survival Commission released 'Guiding Principles for Creating Proxies of Extinct Species for Conservation Benefit' (2016), while scientists, conservationists and bioethicists, inter alia, have begun to consider the ethics of reviving extinct species,[2] the optimal candidate species for de-extinction,[3] as well as attempting to conduct cost-benefit analyses of both resurrection and reintroduction.[4] The 'nascent discipline' of de-extinction has been the topic of animated debates within the scientific community,[5] but at least one point of consensus has emerged: we are now on the brink of de-extinction. As Donlan puts it, '[t]here are many unknowns surrounding de-extinction. Whether it will happen or not, however, is likely not to be one of them.'[6]

1 Carl Zimmer, *Bringing them back to life*, National Geographic, April 2013, at 28–41; P. Sarchet, *Can We Grow Woolly Mammoths in the Lab? George Church Hopes so,* New Scientist, February 16, 2017, https://www.newscientist.com/article/2121503-can-we-grow-woolly-mammoths-in-the-lab-george-church-hopes-so/; J. Ryan, *Using CRISPR to Resurrect the Dead*, C-Net, June 19, 2019, https://www.cnet.com/features/using-crispr-to-resurrect-the-dead/; B. J. Novak, *De-extinction,* 9(11) Genes 548 (2018). This raises very significant ethical questions in the context of whether such techniques would ever be used to attempt to recreate extinct human species. Such questions are beyond the scope of this current paper, but for a discussion see: Hank Greely, *On Not De-Extincting Homo Neanderthalensis,* https://law.stanford.edu/2013/02/18/lawandbiosciences-2013-02-18-on-not-de-extincting-homo-neanderthalensis/ (accessed February 26, 2020).

2 Corey A. Salsberg, *Resurrecting the Woolly Mammoth: Science, Law, Ethics, Politics, and Religion,* Stan. Tech. L. Rev. 1 (2000); R. Sandler, *The Ethics of Reviving Long Extinct Species*, 28(2) Conserv. Biol. 354–360 (2014); S. Cohen, *The Ethics of De-extinction*, 8(2) NanoEthics 165–178 (2014); P.R. Ehrlich and A.H. Ehrich, *The Case Against De-extinction: It's a Fascinating but Dumb Idea*, 13 E360 (2014); Lucia Martinello, Markku Soksanen and Helena Siipi, *De-extinction: A Novel and Remarkable Case of Bio-objectification*, 55 Croat. Med. J. 423–7 (2014); J. Donlan, *De-extinction in a crisis discipline*, 6(1) FoB 25–8 (2014); B.A. Minteer, *The perils of de-extinction*, 8(1) Minding Nature 11–17 (2015); D.E. Blockstein, *We Cannot Bring Back the Passenger Pigeon: The Ethics of Deception around De-extinction*, 20 Ethics, Policy & Environment 33–7 (2017); P. Kohl, *Using De-extinction to Create Extinct Species Proxies; Natural History not Included,* 20(1) Ethics, Policy & Environment, 15–17 (2017); T.J. Kasperbauer, *Should We Bring Back the Passenger Pigeon? The Ethics of De-extinction*, 20(1) Ethics, Policy & Environment, 1–14 (2017).

3 D.D. Turner, *Biases in the Selection of Candidate Species for De-Extinction*, 20(1) Ethics, Policy & Environment, 21–24 (2017). For the taxonomic bias towards mammals inherent in conservation projects see also: J.A. Clark and R.M. May, *Taxonomic Bias in Conservation Research*, 297 Science, 191–2 (2002).

4 R. Sandler, *De-extinction: Costs, benefits and Ethics*, 1 Nat. Ecol. Evol. 1–2 (2017). Donlan also points out that "[m]oving from a few individuals to a functioning, viable population will probably be the limiting step—presenting a monumental challenge for conservation biologists". See J. Donlan, *De-extinction in a Crisis Discipline*, 6(1) FoB 25–8 (2014).

5 D.J. Richmond, M.S. Sinding and M.T.P. Gilbert, *The Potential and Pitfalls of De-extinction*, 45(1) Zool. Scr. 22–36 (2016).

6 J. Donlan, *De-extinction in a Crisis Discipline*, 6(1) FoB 25–8 (2014); H. Devlin, *Woolly Mammoth on Verge of Resurrection, Scientists Reveal*, The Guardian, February 16, 2017.

Much of the academic literature to date has understandably focused on the science of bringing back extinct species,[7] but 'de-extinction presents us with myriad ethical, legal and regulatory questions.'[8] These include a range of questions around the legal status of de-extinct animals, including potential legal obligations to protect them, and the resulting environmental issues which may arise.[9] Moreover, an important but underexplored question is the extent to which such animals, if successfully recreated, could be commercialized.[10] Watching certain resurrected species, especially 'cool'[11] and 'charismatic megafauna,' is expected to be an exciting diversion for many (indeed, it is often considered, albeit anecdotally, to be a central motivation for de-extinction),[12] but little academic work has focused on the 'non-ecological "instrumental values" that de-extinct species would be likely to have for human beings, most notably, their commercial value.'[13] One avenue to obtain such value from de-extinct animals is via the patent system, and specifically applying for a patent on the revived animal, yet it remains an open question whether such animals would be patentable in the European context, if ongoing de-extinction attempts are successful. In taking this focus, the article explores the legal, commercial, and ethical implications of 'patenting' de-extinct animal species.

This article breaks new ground by exploring the potential European patent law implications of de-extinction in relation to animal life.[14] In doing so, this paper focuses on animal life, as opposed to plant or other organisms, which could also be recreated via de-extinction.[15] The rationale underlying this approach is rooted in the fact that it

7 Beth Shapiro, How to clone a mammoth: the science of de-extinction (2015); M.R. O'Connor, Resurrection Science (2015).

8 John R. Platt, *De-Extinction: Can Cloning Bring Extinct Species Back to Life?*, https://blogs.scientificamerican.com/extinction-countdown/de-extinction-cloning-extinct-species/ (accessed July 26, 2019). See also Gregory E. Kaebnick and Bruce Jennings (eds), *Recreating The Wild: De-Extinction, Technology, And The Ethics Of Conservation*, https://www.thehastingscenter.org/for-media/press-releases/recreating-wild-de-extinction-technology-ethics-conservation/ (accessed February 14, 2020).

9 These include: would de-extinct animals within the EU be classified as "species of Union interest," which, with certain exceptions, are those that are endangered, vulnerable, rare or endemic—all considerations that would appear to apply to a newly revived species? Would such organisms be categorised as so-called "priority species" for which the EU has particular responsibility if their natural range previously fell within the EU's territory? Would these de-extinct animals be subject to the prohibitions on invasive or non-native species, or bound by the strict EU legal regime on genetically modified organisms? How would the existing EU environmental framework—designed to cover living species—be utilized or adapted to cover extinct ones? One of the earliest works exploring these issues is C.A. Salsberg, *Resurrecting the Woolly Mammoth: Science, Law, Ethics, Politics, and Religion*, Stan. Tech. L. Rev. 1 (2000). For a comparative EU/US perspective see: J. Allen, D.M. Doyle, S. McCorristine, and A. McMahon, *De-Extinction, Regulation and Nature Conservation*, 32(2) *Journal of Environmental Law* (2020).

10 Rene X. Valdez, Jennifer Kuzma, Christopher L. Cummings and M. Nils Peterson, *Anticipating Risks, Governance Needs, and Public Perceptions of De-extinction*, 6(2) J. Res. Innov. 221–231 (2019).

11 J.S. Sherkow and H.T. Greely, *What if Extinction is not Forever?*, 340(6128) Science 32–33 (2013).

12 S. Cohen, *The Ethics of De-extinction*, 8(2) NanoEthics 165–178 (2014).

13 J. Welchman, *How Much Is That Mammoth in the Window?*, 20(1) Ethics, Policy & Environment 41–43 (2017).

14 Sherkow and Greely allude to the potential patentability issues in: J.S. Sherkow and H.T. Greely, *What if Extinction is not Forever?* 340(6128) Science 32–33 (2013).

15 For example, for a discussion of de-extinction attempts in the plant context see: Thomas Abeli et al., *Ex Situ Collections and Their Potential for the Restoration of Extinct Plants*, Conserv. Biol. (2020); A.E. Newhouse, L.D. Polin-McGuigan, K.A. Baier, K.E.R. Valletta, W.H. Rottmann, T.J. Tschaplinski, et al., *Transgenic American chestnuts Show Enhanced Blight Resistance and Transmit the Trait to T1 Progeny*, 228 Plant Sci. 88–97 (2014).

is these projects (e.g. particularly the Woolly Mammoth project) that have captured the public imagination and provoked the most scholarly concern to date.[16] For this reason, we wish to explore how applications for patents on such animals in Europe may play out if such megafauna are successfully recreated.

In examining this issue, the article focuses on the European patent law context for two main reasons: first, to date, academic inquiries of the legal implications of de-extinction have focused almost exclusively on domestic law in the USA.[17] This is not to suggest that these studies are less valuable for adopting such an approach—the USA, after all, is one of the traditional centers of conservation power and where key de-extinction projects are ongoing but many of the species that are considered viable candidates for some form of de-extinction are not species whose habitats or migration routes are exclusive to, or even include, the USA.[18] The applicable laws outside the US context are in vital need of investigation if we are to preemptively address the legal issues that could conceivably arise should de-extinction become feasible in the next few years. To date, these aspects of species recreation and particularly the patent implications in Europe have remained unexplored.[19] This article aims to address this lacuna by furnishing a detailed analysis of de-extinction under European patent law.

Secondly, the focus on European patent law was taken because Europe is one of the few patent jurisdictions with express moral exclusions from patentability.[20] Therefore, examining the European context provides a useful site to examine the ethical ramifications of granting patents in the de-extinction context and the extent to which such ethical issues are likely to be considered within patent law. It explores how the current exclusions under European law—which have proved so controversial in the past for transgenic animals—could potentially be interpreted in the de-extinction context.[21]

See also discussion in: Lesley Evans Ogden, *Extinction Is Forever... Or Is It?*, 64(6) BioScience 469–475 (2014).

16 Lucia Martinelli, Markku Oksanen, and Helena Siipi, *De-extinction: a Novel and Remarkable Case of Bio-objectification*, (2014) 55(4) Croat. Med. J. 423–427 (2014).

17 N.F. Carlin, I. Wurman and T. Zakim, *How to Permit Your Mammoth: Some Legal Implications of De-extinction*, 33 Stan. Envtl. L.J. 3–57 (2013); J.S. Sherkow and H.T. Greely, *What if Extinction is not Forever?* 340(6128) Science 32–33 (2013); M.R. Swedlow, *The Woolly-Mammoth in the Room*, 11(3) Wash. J.L. Tech. & Arts 183–196 (2015); H. Tallis and J. Lubchenco, *Working Together: A Call for Inclusive Conservation*, 515 Nature 27–28 (2014). For a notable exception see E. Okuno, *Frankenstein's Mammoth: Anticipating the Global Legal Framework for De-extinction*, 43 Ecology L.Q. 581–634 (2016).

18 E. Okuno, *Frankenstein's Mammoth: Anticipating the Global Legal Framework for De-extinction*, 43 Ecology L.Q. 581–634 (2016).

19 The implications of de-extinction for personal property ownership is beyond the scope of this paper, but the law generally in relation to personal property and animal ownership raises ethical issues which would similarly be applicable in the context of animals created via de-extinction projects. See generally, Erica R. Tatoian, *Animals in the Law: Occupying a Space Between Legal Personhood and Personal Property*, 31 J. E. L. L. 147–166 (2015); Jenny Gray, Zoo Ethics: The Challenges of Compassionate Conservation (2017); Cass Sunstein and Martha C. Nussbaum (eds), Animal Rights: Current Debates and New Directions (2004).

20 These are contained both in Art 53 of the EPC, and also Art 6 of the Biotechnology Directive. By European patent law, we mean the law applicable in the States Parties to the European Patent Convention 1973, as amended. See discussion of these provisions in: Aisling McMahon, *The Morality Provisions in the European Patent System: An Institutional Examination* (PhD Thesis, University of Edinburgh, 2016).

21 One of the most controversial patent applications to date was the patent applied for over a genetically modified mouse, modified to develop cancer for use in medical research (Harvard/Oncomouse, OJ EPO 476 (1990); OJ EPO 589 (1992)) which brought ethical issues related to patents to the fore in Europe. This case, and the issues it raised, led to a questioning of 'patents on life' which came to form part of the

Given that European patent law has express moral exclusions from patentability, concerns posed by patents on de-extinct animals could theoretically (at least on paper) have a greater chance of consideration within the European context. However, the article will argue that given past interpretative practices surrounding such provisions in Europe, without institutional change within patent law, such ethical considerations are unlikely to be significant hurdles to patenting such technology in Europe (contingent, of course, on how the science develops).[22]

This analysis has important practical and theoretical significance. From a practical perspective, the article highlights the main patentability questions within European law that will arise in light of de-extinction projects, aiming to provide an important reference point within the de-extinction debate. At a theoretical level, it identifies aspects of European biotechnological patent law that will require further clarification should de-extinction come to fruition, such as definitional questions surrounding the patentability of cloned animals and transgenic animals not created for medical research purposes. As will be demonstrated, these issues also have broader significance for advanced biotechnologies more generally.

In conducting this analysis, the article is structured as follows: Part I demonstrates why patents are relevant and could be applied for in the context of de-extinction projects; Part II then briefly maps the scientific avenues that are being used in de-extinction projects setting the foundation for the legal analysis which follows; Part III provides a detailed assessment of the potential patentability of de-extinct animals, examining questions of patent eligible subject matter; the potential applications of the exclusions from patentability under Art 53 EPC to animals created in the de-extinction context; and whether such animals would meet the patent novelty requirement.[23] Part IV concludes by highlighting the possible effects, and positive/negative ramifications, of patenting such animals and elucidates the chasm between the cultural and symbolic significance held by such animals, and their lack of differential treatment in the patent law sphere.

II. DE-EXTINCTION: THE RELEVANCE OF PATENTS?

Arguably, there are four main reasons why patents may be sought in the context of de-extinction projects. First, de-extinction experiments are 'expensive' and thus far

broader debate on the patentability of biotech inventions during the drafting of the European Biotechnology Directive. See: G. Porter, *The Drafting History of the European Biotechnology Directive,* in Embryonic Stem Cell Patents in Europe: European Law and Ethics (A. Plomer and P. Torremans eds., 2009), 14. See also discussion in: D. Beyleveld and R. Brownsword, Mice, Morality and Patents (1993); A. Warren-Jones, Patenting RDNA: Human and Animal Biotechnology in the United Kingdom and Europe (2001); E. Armitage and I. Davies, Patents and Morality in Perspective (1994); B. Sherman and L. Bentley, *The Question of Patenting Life,* in Perspectives on Intellectual Property: Intellectual Property and Ethics Volume 4 (L. Bently and S.M. Maniatis eds., 1998).

22 The institutional dimension of the application of the morality provisions is discussed, by one of us, in Aisling McMahon, *The Morality Provisions in the European Patent System: An Institutional Examination* (PhD Thesis, University of Edinburgh, 2016).

23 The paper focuses primarily on the novelty requirement of patent law, because based on current scientific methods this may be the most difficult hurdle for such patent applications over de-extinct animals to overcome.

'dependent on private charitable investment.'[24] The 'New York Times,' for instance, estimates the mammoth project to cost around 10 million dollars,[25] while one prominent biologist, albeit conceding that no one actually knows the precise cost, speculated that it would cost 'probably tens of millions of dollars.'[26] Moreover, the cost of de-extinction will inevitably vary by species, while the pace of de-extinction progress will largely depend on the resources that its proponents are able to attract.[27] Given the 'significant investment,'[28] it is plausible that those who succeed in recreating extinct species may wish to patent their recreations in order to leverage investment to the projects in the first instance. Within the European context, patents can be applied for through the European Patent Office (EPO) by using one application to claim a patent in multiple European Patent Convention (EPC) Contracting States, and having such protection may be presented as being 'essential to maintain and encourage investment' in such projects.[29] Indeed, there is a distinct possibility that the potential for future patents could be used to attract investment to such projects and provide an avenue to recoup expenditure.[30]

Secondly, having patent protection could also act as an incentive for some individuals/companies undertaking this work given the considerable financial benefits that could realistically accrue if patents were granted on recreated animals. Patents are often seen as 'the most important way in which researchers can protect the income that might come from ideas or technologies they have developed.'[31] A patent allows the patent holder to exclude others from using an invention without their permission (via a patent license) albeit only for a limited period of time (patent duration is generally 20 years).[32] Thus, if such animals were patented, the patent holder would have the potential to generate exclusivity around the animal for the period of the patent grant. This, in effect, means that others could not use (arguably including sell/display, etc.) the patented resurrected animal without permission from the patent holder. Such permission would be in the form of a license from the patent holder and generally licenses are granted in return for monetary compensation. Given the potential demand for such animals and the charismatic nature of many extinct animals (such as the cultural significance of the

24 W.M. Adams, *Geographies of Conservation I: De-extinction and Precision Conservation*, 41(4) Prog. Hum. Geog. 534–545 (2017).

25 Nicholas Wade, *Regenerating a Mammoth for $10 Million*, New York Times, November 19, 2008.

26 J.R. Bennett, R. Maloney, T. Steves, P. Seddon and H.P. Possinghyam, *Spending Limited Resources on De-extinction Could Lead to Net Biodiversity Loss*, 1 Nat. Ecol. & Evol. 1–4 (2017). For the considerable costs involved see also: Ronald Sandler, *De-extinction: Costs, Benefits and Ethics,* 1 Nat. Ecol. & Evol. 105 (2017) and Gwenllian Iacona, Richard F. Maloney, Iadine Chades, Joseph R. Bennett, Philip J. Seddon and Hugh P. Possingham, *Prioritizing Revived Species: What are the Conservation Management Implications of De-extinction*, 31(5) Functional Ecology 1041–1048 (2017).

27 J. Donlan, *De-extinction in a Crisis Discipline*, 6(1) FoB 25–8 (2014).

28 Beth Shapiro, How to clone a mammoth: the science of de-extinction (2015).

29 Richard Binns and Bryan Driscoll, *The European Directive on the Legal Protection of Biotechnological Inventions,* 8(12) Expert Opin. Ther. Pat. 1729–1735 (1998).

30 Beth Shapiro, How to clone a mammoth: the science of de-extinction (2015).

31 Angad Singh, Sharanabasava Hallihosur and Lastha Rangen, *Changing Landscape in Biotechnology Patenting*, 31 World Pat. Inf. 219–225 (2009).

32 On the role of patents to dictate uses of an invention see: Aisling McMahon, 'Biotechnology, Health and Patents as Private Governance Tools: The Good, the Bad and the Potential for Ugly?' 3 Intellectual Property Quarterly (2020).

woolly mammoth), the patent holder in such a scenario would be in a position to charge considerable prices for licensing.

Thirdly, and relatedly, as noted, having a patent creates an exclusive right which could be used to limit the number of animals created and thereby could help increase the animal's exclusivity and value. One prospective outcome of the outlay in capital is that newly non-extinct species (or animals created via genetic engineering to look like such extinct species) will be displayed for profit in private zoos or parks as part of the nature tourism industry.[33] Indeed, Carlin et al. argue that 'exclusive rights to exhibit resurrected species in a Jurassic or Pleistocene Park could provide a revenue stream to recover past costs or fund de-extinction efforts for additional species.'[34] Establishing a breeding population confined to zoos and preserves would alleviate concerns about reintroducing such animals into the wild,[35] protecting them from poachers, not to mention the potential impact on the ecosystem,[36] but there would also be the associated cost of housing the animals once they are created.[37] Zoos, however, are a multimillion pound business and 'if you were the zoo that had that one Woolly mammoth or saber-toothed cat, these costs might just be worth it.'[38] Even Tori Herridge, a paleobiologist at the National History Museum in London, who considers the whole idea to be 'ethically flawed' admits that 'it will make a huge amount of money for the person who clones—and maybe patents—the woolly mammoth' and, despite all her protests, she acknowledges that: 'I'd pay to see one if it was there, wouldn't you?'[39]

More broadly, if one motivation behind resurrecting these species is to generate valuable patents and ticket sales to amusement parks and zoos, then protecting the exclusive rights to exhibit such resurrected species would appear to provide the ideal revenue stream to recover past costs or to fund de-extinction efforts for additional species,[40] or to incentivize those with commercial interests to invest in this area. Moreover, (although no de-extinction project proponent has yet announced an attempt to exploit this potential opportunity), there is the possibility that de-extinct organisms could be sold as outright commercial products, for example as exotic pets.[41] Another

33 W.M. Adams, *Geographies of Conservation I: De-extinction and Precision Conservation*, 41(4) Prog. Hum. Geog. 534–545 (2017); P.M. Whittle, E.J. Stewart and D. Fisher, *Re-creation Tourism: De-extinction and its Implications for Nature-Based Recreation*, 18 (10) C. I. T. 908–912 (2015).

34 N.F. Carlin, I. Wurman and T. Zakim, *How to Permit Your Mammoth: Some Legal Implications of De-extinction*, 33 Stan. Envtl. L.J. 3–57 (2013).

35 See: J. Allen, D.M. Doyle, S. McCorristine, and A. McMahon, *De-Extinction, Regulation and Nature Conservation*, 32(2) *Journal of Environmental Law* (2020).

36 S. Novella, *De-extinction*, http://theness.com/neurologicablog/index. php/de-extinction/(accessed May 16, 2017).

37 J. Welsh, *Scientists Want to Bring 24 Animals Back from Extinction*, http://www.businessinsider.com/24-animals-for-de-extinction-2013-3?IR=T (accessed May 3, 2019).

38 *Id.*

39 T. Herridge, *Mammoths are a Huge Part of My Life. But Cloning Them is Wrong*, https://www.theguardian.com/commentisfree/2014/nov/18/mammoth-cloning-wrong-save-endangered-elephants (accessed May 7, 2019).

40 N.F. Carlin, I. Wurman and T. Zakim, *How to Permit Your Mammoth: Some Legal Implications of De-extinction*, 33 Stan. Envtl. L.J. 48 (2014).

41 Jasper Fforde series 'Thursday Next' is based on an imagined future time where the main protagonist has a pet dodo, and resurrection of extinct species generally is more common. See: Jasper Fforde, The Eyre Affair: A Thursday Next Novel (2003) which is the first book in this series.

possibility, memorably imagined in Julia Leigh's novel 'The Hunter' (1999),[42] is that biotechnology firms compete to be the first to find relevant DNA and recreate a presumed extinct species or animals resembling an extinct species. Likewise, such attempts may be strengthened by having intellectual property rights over the recreated animal or isolated genes that derive from it.

If commercially motivated, the patentee could leverage the rarity of the animal to increase its monetary value for the exotic pet or food trade.[43] The market for exotic wild cats, fish, monkeys, reptiles, birds, and other exotic pets (excluding black market trade which is estimated to be worth between 8 and 20 billion euro worldwide) is highly 'lucrative,'[44] while the 'hyper-rare can have a tremendous allure for some food adventurers.'[45] This, of course, suggests potentially profitable secondary markets that might 'justify the economic outlay, but an ethical justification it is not.'[46]

Fourthly, given the controversial nature of such projects, it is at least plausible that ethically minded scientists or teams working on de-extinction attempts may wish to patent the recreated animal to give them control over its use. The patent could be used to stop others using the patented technology in a way not intended by the patent holder—at least for the duration of patent grant—who could refuse licenses for use or attach conditions on licenses for use.[47]

In short, there are many reasons why those involved in de-extinction projects may seek patents, including inter alia raising finance to support the research, recouping costs, or if groups are commercially motivated, generating a valuable income stream. However, it is conceivable that ethical objections to patents in this context will arise. Many people feel strongly that 'it is wrong to genetically engineer animals and doubly wrong that there should be a financial incentive to do so by the carrot of a monopoly.'[48] The extent to which a resurrected animal would be treated as a commodity (which could arise if patents were applicable over or related to the de-extinct animal) raises deep philosophical and ethical questions. To date, there is not a clear answer on whether such animals would be patentable in Europe. However, what is conclusive is that the

42 Made into a movie in 2011.

43 Britt Wray, Rise of the Necrofauna: The Science, Ethics, and Risks of De-Extinction (2017). For a critical review of the book see Jeffrey V. Yule and John Wolfe, *Rise of the Necrofauna: The Science, Ethics, and Risks of De-Extinction: Review,* 93 Q. R. B. 388–389 (2018).

44 L. Slater, *Wild Obsession*, http://ngm.nationalgeographic.com/2014/04/exotic-pets/slater-text (accessed April 26, 2017); R. Duffy, EU Trade Policy and the Wildlife Trade (2017).

45 L. Heldke, Exotic Appetites: Ruminations of a Food Adventurer (2003). The idea of endangered animals being sold as exotic/rare foods, for high prices and marketed as such is suggested in the film, The Freshman (1990), where characters are told high prices are charged "for the privilege of eating the very last of a species."

46 T. Herridge, *Mammoths are a Huge Part of my Life. BUT Cloning Them is Wrong*, https://www.theguardian.com/commentisfree/2014/nov/18/mammoth-cloning-wrong-save-endangered-elephants (accessed May 7, 2019).

47 There is evidence of patents being used for instance to stop patented CRISPR technology being used for gene drives, etc., see J. Sherkow, *Patent protection for CRISPR: an ELSI review,* 4(3) J. L. Biosci. 565–576 (2017); See also: Aisling McMahon, *Biotechnology, Patents and Licensing for 'Ethical Use': A Regulatory Opportunity?* (Working Paper 2020).

48 D. Thomas and G.A. Richards, *The Importance of the Morality Exception under the European Patent Convention: The Oncomouse Case Continues*, 26(3) EIPR 97–104 (2004); Aisling McMahon, *The Morality Provisions in the European Patent System: An Institutional Examination* (PhD Thesis, University of Edinburgh, 2016); Peter Drahos, "Biotechnology Patents, Markets and Morality" 21 E.I.P.R. 441 (1999); and Oliver Mills, *Biotechnological Inventions: Moral Restraints and Patent Law* (2010).

science is developing to make de-extinction possible, which makes it imperative to address this question before the reality of de-extinct animals, and patent applications relating to them, arise.

As noted, much of the scholarly discussion around de-extinction and patent law has focused on the USA, where some legal scholars are confident that de-extinct species will be patentable, but significantly there is no morality provision in the US patenting regime.[49] The EPO, by contrast, (at least in theory) takes ethical considerations into account when granting patents and, as will be seen, morality and ordre public type objections could arise in Europe (Article 53(a) of the EPC contains a general exclusion from patentability on the grounds of ordre public and morality, replicated in Art 6 of the Biotechnology Directive 98/44 EC) when applications are filed for de-extinct animals and de-extinction processes.[50] Such ethical objections, as will be demonstrated, may be similar to those raised against transgenic animals in the past and will arguably include the rights of animals as sentient beings, animal welfare, ecological, and health concerns,[51] as well as potential objection based on the argument that de-extinction in the animal context could lead the way to the recreation of an extinct human species.[52]

Prior to delving into such ethical questions and the applicable European patent law, the next section outlines the basic science used in current de-extinction attempts. This forms the necessary foundation for the subsequent legal analysis.[53]

III. THE BASIC SCIENCE OF DE-EXTINCTION

A range of techniques can be used to try and bring back extinct animals, three of which are most likely to succeed,[54] namely: selective breeding (or back-breeding); genome

49 D. Thomas and G.A. Richards, *The Importance of the Morality Exception Under the European Patent Convention: The Oncomouse Case Continues*, 26(3) EIPR 97–104 (2004); M. Oksanen and T. Vuorisalo, *De-extinct Species as Wildlife*, 3 Trace 4–27 (2017).

50 Article 6 contains a general morality provision and also specific categories of inventions excluded from patentability under Art 6(2), discussed later in this section.

51 R. Sandler, *The Ethics of Reviving Long Extinct Species*, 28(2) Conserv. Biol. 354–360 (2014). For animal rights and welfare concerns more specifically see Rene X. Valdez, Jennifer Kuzma, Christopher L. Cummings and M. Nils Peterson, *Anticipating Risks, Governance Needs, and Public Perceptions of De-extinction*, 6(2) *Journal of Responsible Innovation* 211–231 (2019).

52 R.E. Green and Others, *A Draft Sequence of the Neanderthal Genome*, 328 Science 710–722 (2010); S. Cottrell, J.L. Jensen and S.L. Peck, *Resuscitation and Resurrection: the Ethics of Cloning Cheetahs, Mammoths, and Neanderthals*, 10(3) LSSP 1–17 (2014); Hank Greely, *On Not De-extincting Homo Neanderthalensis*, https://www.thehastingscenter.org/publications-resources/special-reports-2/recreating-wild-de-extinction-technology-ethics-conservation/ (accessed February 14, 2020). For a discussion on patentability and novel beings which raises some analogous issues, see: Aisling McMahon, 'Patents and Control: Ethics and the Patentability of Novel Beings and Advanced Biotechnologies in Europe' 30(3) Cambridge Quarterly of Healthcare Ethics (2021) (forthcoming).

53 This is correct at time of writing February 2020.

54 A very useful overview is provided by: J.S. Sherkow and H.T. Greely, *What If Extinction Is Not Forever?*, 340 Science 32 available at https://nature.berkeley.edu/garbelottoat/wp-content/uploads/sherkow-and-greely-2014-1.pdf; See also: W M. Adams, *Geographies of Conservation 1: De-extinction and Precision Conservation*, 41(4) Prog. Hum. Geog. 534–545 (2017).

editing; and cloning.[55] These methods have been referred to as the most 'plausible'[56] avenues for achieving de-extinction. The first of these categories—selective breeding—requires more minimal human intervention, whilst the latter categories require significant human intervention. It is useful at this juncture to briefly set out the basics of each of these techniques.

First, back-breeding or selective breeding can be used when closely related descendants to the extinct species have survived. These contemporary relatives 'are selectively bred for those characteristics that defined the extinct species.'[57] In this instance, 'the experimenter selects and breeds pairs of individual animals that have some characteristics resembling those of the extinct species, and repeats the process with their offspring until, after a number of generations, offspring are produced that more closely resemble the extinct form.'[58] An example of this is the auroch project in Europe, which has been using such techniques since 2008. Aurochs are the ancestors to domestic cows, and the Tauros Program back-breeds cows with the closest DNA similarity to the original aurochs in an attempt to bring them back as a 'functional wild animal.'[59] This process can be assisted by genome sequencing methods, which may be used to guide 'back-breeding with genome sequences from samples of the extinct species.'[60] However, this technique would not be universally applicable to all extinct species because it would only have the potential to operate in cases where 'the genetic variations of the extinct species survive in the descendant species.'[61]

Secondly, cloning of an extinct animal could be used but only if one could obtain DNA from the extinct animal. As Swedlow points out 'part of the difficulty of cloning extinct animals is the fact that DNA typically undergoes some level of decay, depending on how long the species has been extinct.'[62] This technique for de-extinction has been attempted in the past, for example, with the Pyrenean ibex, where somatic cell nuclear transfer was used on cryorpreserved tissue from the last known of this subspecies, in an endeavor to resurrect it.[63] However, despite several attempts 'only one fetus survived

55 Iterative evolution is another way in which extinct animals may be 'resurrected'—this is a natural process of de-extinction which occurred for example in the context of the white throated rail—whereby species can reappear naturally by evolution overtime e.g. if the threat to the environment which caused extinction subsides.

56 Shlomo Cohen, *The Ethics of De-Extinction*, 8 Nanoethics 165–178 (2014).

57 Heather Browning, *Won't Somebody Please Think of the Mammoths? De-extinction and Animal Welfare,* 31 J. Agr. Environ. Ethic. 785–803 (2018).

58 Norman F. Carlin, Ilan Wurman and Tamara Zakim, *How to Permit Your Mammoth: Some Legal Implications of "De-Extinction"*, 33(1) Stan. Envtl. L. J. 3–57 (2013).

59 Rewilding Europe, *The Aurochs: Europe's defining animal,* https://rewildingeurope.com/rewilding-in-action/wildlife-comeback/tauros/ (accessed February 26, 2020).

60 J.S. Sherkow and H.T. Greely, *What If Extinction Is Not Forever?,* 340 Science 32 (2013).

61 *Id.*

62 Miriam Ricanne Swedlow, *The Woolly-Mammoth in the Room: The Patentability of Animals Brought Back from Extinction Through Cloning and Genetic Engineering*, 11(3) Wash. J. L. Tech.& Arts 183–196 (2015). See also Gwenllian Iacona, Richard F. Maloney, Iadine Chades, Joseph R. Bennett, Philip J. Seddon and Hugh P. Possingham, *Prioritizing Revived Species: What are the Conservation Management Implications of De-extinction,* 31(5) Functional Ecology 1041–1048 (2017).

63 Raul E. Pina-Aguilar, Janet Lopez-Saucedo, Richard Sheffield, Lilia I. Ruiz-Galaz, Jose de J. Barroso-Padilla and Antonio Gutiérrez Antonio, *Revival of Extinct Species Using Nuclear Transfer: Hope for the Mammoth, True for the Pyrenean Ibex, but is it Time for "Conservation Cloning"?,* 11(3) Cloning and Stem Cells 341

to term, and it died minutes after birth from lung abnormalities.'[64] These obstacles were also highlighted by Carlin et al. who argue that 'the best (and perhaps the only) candidates [for cloning] are species which became extinct very recently, from which DNA specimens were collected from living individuals prior to extinction, and then frozen and maintained in the laboratory.'[65] Thus, in short, to date cloning has been scientifically problematic in this context as it is only possible if there are viable cell nuclei available, and currently this will 'likely be the case in only a few very recent extinctions.'[66]

Finally, genetic engineering could be used to resurrect an extinct species. Modern genetic engineering, including whole genome sequencing techniques, could be used to create hybrid species.[67] However, this task is 'hugely complex' with highly 'technical challenges' involved in the process.[68] Sherkow and Greely point out, for instance, that if sufficient DNA samples were available from an extinct species to allow high quality whole genome sequencing then DNA from a similar species could be edited to match the extinct species genomic sequences. The authors use the following example: if an extinct species such as a passenger pigeon could be sequenced, then one could seek to edit, for example, a bandtailed pigeon to make the genomic sequence of the extinct animal. The result, if successful, would be to create a bird which is a hybrid of a passenger pigeon and a bandtailed pigeon.[69] Sherkow and Greely state that '[b]y using targeted replacement of genomic sequence across several loci, much of the extinct genome could be reconstructed within several generations.'[70] An advantage of this method is that 'it is likelier to succeed, at least for those species where sufficient specimens and sufficiently close surviving relatives exist.'[71]

Notably, and importantly for the question of patentability, '[n]either the back-breeding nor genetic engineering approaches would yield an animal that had exactly the same genome as any member of the extinct species for many years, if ever.'[72] Thus, the animal created would be distinct to the animal which once existed in nature, and the similarity with the extinct animal would vary depending on how far the back-breeding progressed, and the level of genome editing carried out. Both techniques

(2009); Ricardo García-González and Antoni Margalida, *The Arguments against Cloning the Pyrenean Wild Goat*, 28(6) Conserv. Biol. 1445 (2014).

64 J. Folch et al., *First Birth of an Animal from an Extinct Subspecies (Capra pyrenaica pyrenaica) by cloning*, 71(6) Theriogenology 1026–1034 (2009). As cited by J.S. Sherkow and H.T. Greely, *What if Extinction is not Forever?*, 340(6128) Science 32–33 (2013).

65 N F. Carlin, Ilan Wurman and Tamara Zakim, *How to Permit Your Mammoth: Some Legal Implications of "De-Extinction"*, 33(1) Stan. Environ. Law J. 3–57 (2013).

66 J.S. Sherkow and H.T. Greely, *What if Extinction is not Forever?*, 340(6128) Science 32–33 (2013).

67 CRISPR Cas9 techniques are also seen as holding promise in such contexts, see: Beth Shapiro, *Mammoth 2.0: Will Genome Engineering Resurrect Extinct Species?*, 16(228) Genome Biology 1–3 (2015); Britt Wray, *CRISPR May Prove Useful in De-extinction Efforts*, https://www.the-scientist.com/reading-frames/crispr-may-prove-useful-in-de-extinction-efforts-30992 (accessed July 26, 2019).

68 W.M. Adams, *Geographies of Conservation 1: De-extinction and Precision Conservation*, 41(4) Prog. Hum. Geog. 534–545 (2017).

69 J.S. Sherkow and H.T. Greely, *What if Extinction is not Forever?*, 340(6128) Science 32–33 (2013).

70 *Id*, citing H.H. Wang et al., *Genome-Scale Promoter Engineering by Coselection MAGE*, 9(6) Nat. Methods 591–3 (2012).

71 Norman F. Carlin, Ilan Wurman and Tamara Zakim, *How to Permit Your Mammoth: Some Legal Implications of "De-Extinction,"* 33(1) Stan. Envtl. Law J. 3–57 (2013).

72 J.S. Sherkow and H.T. Greely, *What if Extinction is not Forever?*, 340(6128) Science 32 (2013).

would produce an animal distinct to that which existed previously, and hence it would, arguably, not be a previously naturally occurring animal as such. The cloning approach, if viable nuclei were available, would produce an animal which was the 'genomic twin to one member of the extinct species—but only one.'[73] In other words, cloning would produce a genomic replica of the donor animal (whose DNA was used to produce the clone), but this is not representative of all animals in that species. Moreover, aside from genomic differences as Sherkow and Greely point out, '[t] he revived individuals would not have the same epigenetic makeup, microbiome, environment, or even "culture" as their extinct predecessors.'[74] Thus, even in the cloned context, if one looked outside the question of genomic make up per se, the animals recreated (if such techniques are successful) would be different from those which once existed in nature based on epigenetic, environmental factors, etc. Bearing in mind these characteristics, the article now turns to consider whether animals revived from extinction using such techniques could be patentable under current European patent laws.

IV. PATENTS AND DE-EXTINCTION: AN ASSESSMENT OF PATENTABILITY IN EUROPE

Three main questions arise in the context of the potential patentability of animals created via de-extinction projects under European patent law: (i) would a de-extinct animal be patent eligible subject matter? (ii) relatedly, would any of the exceptions to patentability apply? (iii) would such an invention fulfill the basic patent criteria, and specifically the novelty requirement?[75] Considering each of these issues, in turn, sheds light on the possible patentability of de-extinct animals in Europe. However, as will be seen, much will depend on the scientific technologies that are developed and used to recreate such animals. The patentability questions and answers may thus shift based on these underlying techniques and the types of animals which result.

A. Would a Recreated Woolly Mammoth be Patent Eligible Subject Matter: An Invention or Discovery?

In the European context, the main applicable regional patent law instruments are the EPC 1973 which applies in 38 European States including all EU Member States; and the Biotechnology Directive 98/44EC, which applies in EU Member States, and which was adopted as supplementary interpretation for the EPC.[76] Art 52(1) EPC provides that:

73 *Id*.

74 *Id,* Sherkow and Greely at 32.

75 We focus on novelty here, given that this could potentially be the greatest hurdle from a theoretical perspective (given such animals in theory are being recreated and some might argue existed previously) faced under the basic patentability criteria for the recreated animal. The criteria of inventive step will depend on the scientific process used at the time and this, at least for the first animals created, would most likely be met. Industrial application will also conceivably be met.

76 Implementing regulations, rule 28 was adopted to incorporate art.6, Biotechnology Directive into the EPC framework. For a discussion, see: Aisling McMahon, *An Institutional Examination of the Implications of the Unitary Patent Package for the Morality Provisions: A Fragmented Future too Far?* 48 Int. Rev. Intellect. Prop. Compet. Law 42 (2016).

> European patents shall be granted for any inventions, *in all fields of technology*, provided that they are new, involve an inventive step and are susceptible of industrial application.[77]

Similarly, Article 27(1) of the TRIPS Agreement applicable in all World Trade Organization Contracting States, provides that: '... patents shall be available for any inventions, whether products or processes, *in all fields of technology*, provided that they are new, involve an inventive step and are capable of industrial application.'[78] Thus, in principle at least, if all fields of technology are patentable, and given that the term 'technology' has been interpreted broadly, animals created via de-extinction endeavors may be patentable.

Having said this, only 'inventions' are patentable, and Art 52(2) EPC and Art 27(2) TRIPS provide that 'discoveries, as such' are not patentable. Nonetheless, the term discovery has been interpreted broadly, while discoveries 'as such' are not patentable if they already exist in nature. However, an invention may be patentable if produced by technical intervention even if it exists in nature. A useful example in this context are patents related to human genes, although genes themselves in the human body are not patentable in Europe, genes that are isolated from the body and which can be demonstrated to carry out a particular function are still patentable in Europe. This is even though the genes isolated are identical in chemical composition to the element in the body.[79] Such isolated genes are patentable even if they mirror the structure of the substance found in the body, as 'the processes used to isolate that element are technical processes.'[80] In such cases, it would not be possible to identify the isolated gene (which does not exist in isolated form in nature) without human intervention and for that reason the isolated gene is patentable.[81] Bently and Sherman note that the same rationale underlies the patentability of 'transgenic plants or animals, which by definition do not exist in nature.'[82] Indeed, in 'Harvard/OncoMouse,'[83] it was held that 'transgenic animals of the present invention having an artificially inserted oncogene do not exist in nature as such but are the result of a technical intervention by man.' Hence, transgenic animals were not excluded from patentability in Europe on the basis of arguments relating to whether they were discoveries.

If a similar reasoning were applied to de-extinct animals one could make a strong argument for patentability depending on the technique used for de-extinction. In the context of animals created via genetic engineering techniques—which involves the creation of transgenic animals using genes from both the extinct and similar animals—

77 Emphasis added.

78 Emphasis added.

79 The patentability of such isolated genes in Europe has been confirmed by Art 5(2) of the Biotechnology Directive and Recital 21 and 22 of the Directive.

80 L. Bently and B. Sherman, Intellectual Property Law (2014) 473 which cites: S. Stercckx, *Some Ethically Problematic Aspects of the Proposal for a Directive on the Legal Protection of Biotechnological Inventions*, 20(4) EIPR 124–5 (1998); and S. Crespi, *Biotechnology Patents: The Wicked Animal Must Defend Itself*, 17(9) EIPR 431 (1995). This position has also been expressly confirmed by the EPO in the decision in *Howard Florey/Relaxin* EPOR 541[1995] which related to the patentability of the hormone Relaxin.

81 L. Bently and B. Sherman, Intellectual Property Law (2014), 474. This European position differs from the law in the US and Australia where isolated genes have been interpreted by courts as being akin to a discovery or product of nature, and hence not patentable.

82 *Id.*

83 OJ EPO 473 [2003] (Opposition Division).

this would create a hybrid animal. The animal created would be distinct from both the extinct animal and the similar existing animal, thereby forming a new hybrid animal created by human intervention. Such an animal could not be viewed as existing in nature, and instead would be a transgenic animal. This would, arguably, not fall foul of the exclusion of discoveries from patentability as it would not be the same as existing animals in nature. Similar arguments could also apply to back-breeding as the animal created is not the same as that which existed in nature. Back-breeding, however, involves a natural biological process to recreate the animal and hence could fall within other exclusions from patentability considered below.

Finally, extinct animals recreated via cloning are somewhat trickier when it comes to determining whether they would be a discovery or an invention. On the one hand, existing DNA would be used to recreate a previously existing animal once found in nature. On the other hand, that animal no longer exists in nature and substantial human intervention would be required to recreate it. Thus, it is at least questionable whether it would be seen as a naturally occurring animal, as the animal no longer exists in nature. Put otherwise, an argument could be made that, even if cloned, it could still be patentable if one recreated an extinct animal. Furthermore, the cloned animal would be genetically identical to one animal, the previously existing now extinct animal, but would differ in terms of epigenetic make up, etc., to that animal as noted above. One could also argue that the de-extinct animal, even if it replicated what previously existed in nature, is not a discovery as it does not currently exist in nature, so one could not discover it in nature. Thus, for a cloned extinct animal to be patentable, much would turn on how a patent office interpreted the temporal aspect of 'existing in nature.'

In Europe, patents were previously obtained relating to 'Dolly the Sheep,' which covered both the cloning method and any cloned animals produced as a result.[84] In contrast, the patentability of the cloned sheep was rejected by the US Court of Appeals for the Federal District which held that animals created by cloning could not be patent eligible as such animals were an exact genetic replica of the donor animal. In other words, in the USA, 'Dolly's genetic identity to her donor parent' rendered her 'unpatentable'[85] and arguments that differences in mitochondrial DNA or environmental influences could make a cloned animal patent eligible were also rejected.[86] The reasoning in the US decision was that the cloned sheep was 'an exact replica of another sheep' and therefore 'does not possess markedly different characteristics than any [farm animals] found in nature.'[87] However, it is questionable—even in the US context—whether a different line of reasoning would apply to de-extinct animals as

84 See for example European patent No. 0,849, 990, GB patent No. 2,318,578 and GB patent No. 2,331,751., as cited in Anna Hally, *Patenting Natural Products in the US and Europe– the Divide Grows*, https://frkelly.com/patenting-natural-products-us-europe-divide-grows (accessed July 26, 2019).

85 Roslin Institute (Edinburgh) 750 F 3d 1333 (8 May 2014) 1337.

86 *Id*, 1338, as cited by Matthias Herdegen, The International Law of Biotechnology: Human Rights, Trade, Patents and the Environment (2018), 161; For a discussion of the potential effects of the decision of *Alice Corp. v. CLS Bank International* 134 S. Ct. 2347 (2014) (where the US Supreme Court set out the test and standard for determining whether an invention falls within statutory patentable subject matter) may have had on how the US court would have decided on the subject matter eligibility of the cloned animal patent had the Roslin case been decided after the decision in Alice, see: Dan Burk, *Dolly and Alice*, 2(3) Journal of Law and the Biosciences 606–626 (2015).

87 In Re Roslin Institute (Edinburgh), 750 F.3d 1333, 1337 (2014).

these do not currently exist in nature. Moreover, given that patents were previously granted in Europe for cloned animals, it is plausible that cloned de-extinct animals (if successfully created) would be deemed patent eligible subject matter, and could be patentable provided they met other patent criteria in Europe.

In short, considering all of the above techniques, the issue of whether de-extinct animals would be patent eligible or fall foul of the exclusion for discoveries will hinge on factors such as: the techniques used to bring the animal back from extinction, the characteristics of the animal resulting, the temporal definition of what it means to 'exist in nature' as interpreted by the EPO, and the extent of technical or human intervention required in this regard. Furthermore, if objections to patentability arose where cloning techniques were used to recreate an extinct animal based on the fact that the animal created was identical to that which previously existed in nature and this became a key decider of patentability (as happened in the US Dolly the sheep context, but which is unlikely in Europe if previous practice is followed) this obstacle to patentability for de-extinct animals could be addressed by avoiding cloning techniques in de-extinction attempts. For commercial purposes, if patentability is to be determined based on whether the animal was identical to that which once existed in nature or not, it could potentially lead to a focus on techniques using genetic engineering to ensure sufficient modifications to the DNA in order to secure patentability. In other words, the likelihood of strategizing around patentability and patent claim drafting is high given the potential financial rewards involved. Much, however, will depend on how the EPO draws a line on such issues when, and if, they arise.

B. De-extinction and the Exclusions to Patentability

Two of the exclusions from patentability under Art 53 EPC may also be of relevance to patentability and de-extinction, namely: Art 53(a) the so-called morality provision which states that patents shall not be granted for 'inventions the commercial exploitation of which would be contrary to "ordre public" or "morality"' and Art 53(b) that excludes patents on 'plant or animal varieties or essentially biological processes for the production of plants or animals.' It is useful to consider each of these exclusions, in turn, to assess whether they could potentially apply to exclude patents on animals created via de-extinction projects.

In terms of the structure of this section, we deal with these two exclusions in reverse order here looking first at the Art 53(b), which relates to exclusions on animal varieties and essentially biological processes, and then at the Art 53(a) morality provision. The reason for this is because the question of whether animals created via de-extinction fall within the animal variety or essentially biological processes exclusions is a definitional question. If such animals were to fall within this definition they would be excluded from patentability without the need to consider other provisions such as the Art 53(a) morality provision which requires a broader examination of the moral/ethical issues to which animals created via de-extinction may give rise.

Exclusion Against Animal Varieties and Essentially Biological Processes: Art 53(b) EPC

The excluded categories of subject matter under Art 53(b) involve two exclusions from patentability which may be relevant for de-extinction: exclusions on animal varieties,

and exclusions on essentially biological processes for the production of animals or plants.

C. Animal Varieties

Anything falling under the definition of an 'animal variety' is excluded from patentability under Art 53(b) EPC. The changes that have occurred in biotechnology have made this provision more complex to apply over time.[88] There is no definition of animal variety per se in the EPC, but it has been interpreted in some cases, and importantly it does not exclude patents on animals as such.[89] For example, in the OncoMouse decision, the EPO Examining Division held that an animal variety was either a species or a subunit of a species. A difficulty was identified in that the terms used in English (animal varieties) and French (races animals) versions of the EPC meaning subunit of species, and the German version of EPC ('Tierarten' meaning species) differed. For the purposes of the 'OncoMouse' decision, it was not necessary to decide on the authoritative term as the claims in that case referred to mammals, which were neither a species nor subunit of a species.[90]

The meaning of 'animal variety' was considered again by the TBA the in 'Harvard/-Transgenic Animals'[91] case but it sidestepped a decision on which of the linguistic options to prefer, as the claim in the case for transgenic rodents was a taxonomic category higher than species, variety and race. Hence, the patent could not be excluded by French, English, or German versions of Art 53(b) EPC. Nonetheless, the TBA did say in the course of its decision that the fact that the three official texts of the EPC used different taxonomic categories had the potential to 'lead to the absurd result that the outcome of an Article 53(b) objection depended on the language of the case.'[92] In essence, species is a higher taxonomic category so it would exclude more than variety or race. For patent applicants to be safe in terms of patentability, a claim should not fall within the definition of species, variety, or race given such linguistic differences.

Furthermore, the Technical Board of Appeal (TBA) in the OncoMouse case held that the exclusion under Art 53(b) on patenting animal varieties did not constitute an exclusion on patents for animals in general. Indeed, the TBA held that the exclusion which acted as an exception to patentability should be construed narrowly.[93]

In terms of de-extinction, this would again depend on the type of technology that is used. It would also depend on how similar the animal created was to the original existing species. Using genetic engineering to recreate an extinct animal would lead to a hybrid transgenic animal (based on current techniques) which is not the same as the actual extinct animal or species. Whether this recreated animal could be seen as a species in its own right is questionable, and in any case, it would be a man-made species if it was. If it fell within the definition of species this 'could' fall foul of the animal variety

88 L. Bently and B. Sherman, Intellectual Property Law (2014), 500. The provision was at the time of the drafting of EPC in 1973 a more straightforward one to apply.

89 See EPO guidance available at https://www.epo.org/law-practice/legal-texts/html/caselaw/2016/e/clrib32.htm.

90 L. Bently and B. Sherman, Intellectual Property Law (2014), 500.

91 T315/03 OJ EPO 15 [2006].

92 *Id*, TBA [60], as cited in L. Bently and B. Sherman, Intellectual Property Law (2014), 501.

93 *Harvard/OncoMouse* EPOR 525 [1991], as cited in L. Bently and B. Sherman, Intellectual Property Law (2014), 500.

exclusion but: (i) it is unlikely to fall within this definition, (ii) careful patent drafting could be used to get around this, and (iii) uncertainty remains on this provision given the differences in the English, French, and German language versions of the EPC.

Cloning, on the other hand, would lead to an animal genetically identical to one that previously existed, but only identical to the donor animal from which it was cloned. Notwithstanding questions surrounding the patentability of cloned animals, the patent holder could claim for that cloned animal and not for the species, race, or variety in general, as the cloned animal would not be representative of a race/species, etc.

Finally, back-breeding techniques involve selective breeding over generations to try to recreate similar animals to the original and it is highly unlikely that such animals created would be considered a species/race/variety and thus fall foul of this provision.

Overall, the exclusion against patents on animal varieties itself is uncertain but given the possibility of de-extinct animals in the near future it may give rise to important practical questions on this terminology which would benefit from greater scrutiny in the interim. Arguably, much will depend on the types of technologies used, the nature of the patent claim and of the animal produced as to whether it would be patentable or not.

D. Essentially Biological Processes

The exclusion against patents on essentially biological processes is contained in Art 53(b) EPC and was also confirmed by Art 4(1)(b) of the Biotechnology Directive. The exclusion is relevant to methods of breeding, and hence may be applicable to the back-breeding methods of de-extinction. To take just one example, the EPO guidelines set out that a method of cross breeding, interbreeding, or selectively breeding 'say horses involving merely bringing together these animals or their gametes having certain characteristics would be essentially biological and therefore unpatentable.'[94] Moreover, Bently and Sherman noted that even if one added 'an additional feature of a technical nature, such as the use of genetic molecular markers to select either parent or progeny,' the situation would remain unchanged.[95] This suggests that processes for back-breeding (i.e. using methods which seek to map the genome of the extinct animal to get closer to creating a similar animal) would not be patentable.

However, this would differ in instances of de-extinction, which involved genetic engineering. As Bently and Sherman note the matter would change in the case of a process in which a gene was inserted by genetic engineering which would then be potentially patentable.[96] Thus, for a process to fall outside the exclusion under Art 53(b) for essentially biological processes, there must be a 'technical step which by itself introduced or modified a trait in the genome.'[97]

Moreover, even if the process to create the de-extinct animal was an essentially biological process, it was debatable until recently whether this would lead to the

94 EPO Guidelines for Examination, G. 5.4.2, as cited in L. Bently and B. Sherman, Intellectual Property Law (2014), 511.

95 L. Bently and B. Sherman, Intellectual Property Law (2014), 511.

96 L. Bently and B. Sherman, Intellectual Property Law (2014), 512.

97 State of Israel/Tomatoes II, T 1242/06 (31 May 2012) [43] as cited in L. Bently and B. Sherman, Intellectual Property Law (2014), 512.

product (animal created) being unpatentable per se. This has been a matter of recent controversy in the plant context in Europe.

Looking to the law as it pertains to plants can provide insights to the likely position in relation to animals. This area has been subject to several recent European decisions, and the law was arguably in a state of flux until May 2020, as conflicting statements on the law applicable under the EPC as applied by the EPO, and the Biotechnology Directive 98/44 EC as applied by the EU were evident.[98]

The controversy in this context can be traced to the case of 'State of Israel/Tomatoes II,'[99] which following a decision on the exclusion of essentially biological processes for the creation of the tomatoes in question (the patent itself was originally for a method of breeding tomato plants to produce plants with reduced water content, which involved several steps including crossing, collecting, growing, and selection of the plants), an application was then made for the claims limited to the products produced by the excluded processes. An argument was made that the products created should also be excluded from patentability because if the patent was granted on the product it would make the exclusion against methods for essentially biological processes ineffective. The reasoning held that the product claims give an absolute right to the product, which would mean that the patent holder could exclude or stop others from making or using the patented product, and would mean the patent holder could 'prevent others from using the essentially biological plant breeding methods.'[100] The TBA stated that:

> Disregarding the process exclusion in the examination of product claims would have the general consequence that, for many plant breeding inventions, patent applicants and owners could easily overcome the process exclusion of Article 53(b) EPC by relying on product claims providing a broad protection which encompasses that which would have been provided by an excluded process claim.[101]

In other words, allowing a patent on the product created by the essentially biological process would defeat the purpose of the exclusion in the EPC, as if the patent applied, then the patent holder could simply draft the claim for the product (leaving aside a claim to the process) and if the product patent was granted it would have the effect of also allowing the patent holder to stop others using the biological process for making that product. The TBA stated that it had serious concerns that if the patent was granted it would undermine or frustrate the legislator's intention in framing the process exclusion and referred questions on this to the EPO Enlarged Board of Appeal (EBA) for consideration.

98 There is an overlap of Contracting States Parties to the Directive (all EU States) and the EPC (all EU States and 11 other non-EU States), and hence this interpretative divergence is potentially problematic, and will thus need to be addressed, particularly as the EPO (which has as its primary legal instrument the EPC, and the Directive as supplementary interpretation) assesses patentability for applicants applying for patents in EU countries using the EPO route. On the jurisdictional overlaps under the 'European' patent system see: A. McMahon, *An Institutional Examination of the Implications of the Unitary Patent Package for the Morality Provisions: A Fragmented Future too FAR?* 48(1) Int. Rev. Intellect. Prop. Compet. Law 42–70 (2017).

99 T 1242/06 (31 ay 2012) [43] as cited in L. Bently and B. Sherman, Intellectual Property Law (2014), 512.

100 L. Bently and B. Sherman, Intellectual Property Law (2014) 512.

101 State of Israel/Tomatoes II, T 124/06 (31 May 2012), [47].

A decision was issued by the EBA on these questions and additional questions added by the Broccoli II case in March 2015 in G 2/12 (Tomatoes II) and G 2/13 (Broccoli II). Perhaps surprisingly, this decision found that 'plants or seeds obtained through such excluded processes are – in contrast to individual plant varieties patentable.'[102] The EPO EBA ruled that 'plant products such as fruits, seeds and parts of plants are patentable even if they are obtained through essentially biological breeding methods involving crossing and selection.'

However, following this EPO decision, the European Commission on 3rd November 2016 issued Notice 2016/C 411/03 which pertained to Art 4 of the Biotechnology Directive (this is the corresponding Directive provision which excludes essentially biological processes from patentability under the Directive) where it stated that in its view animals and plants derived from essentially biological processes should not be patentable.[103] Subsequently, the EPO issued a notice on 29 June 2017, confirming that it would deny patents for plants/animals exclusively derived from essentially biological processes,[104] and Rule 28 EPC was amended with the addition of a paragraph which stated that the exclusion under Rule 28 applied to animals or plants that were exclusively derived from an essentially biological process. If this were the law applicable, animals derived via back-breeding under de-extinction projects could not be patentable.

However, in a further development the decision of the EPO's TBA in T 1063/18 related to protection of a pepper plant in December 2018 is relevant. The TBA held that the amendment of Rule 28(2) was contrary to Art 53(b) EPC as interpreted by the Enlarged Board of the EPO, and that the EPC should prevail[105]—in other words products derived from essentially biological processes might still be patentable under the EPC. This finding, however, left the law applicable under the Directive and EPC potentially divergent, and the law appeared to be somewhat uncertain. In February 2019, the EPO Committee on Patent Law held a meeting to discuss this issue with representatives of the EPO Contracting States and the EC Commission as observer were present, discussing the need for legal certainty on the issue and the possibility of obtaining an opinion from the EPO Enlarged Board was discussed.[106] The issue was subsequently referred for consideration to the Enlarged Board of the EPO which

102 Timo Minssen, *The Impact of Broccoli II and Tomato II on European Patents in Conventional breeding, GMO's and Synthtic Biology: A Grand Finale of a Juicy Patents tale?*, http://blog.petrieflom.law.harvard.edu/2015/06/17/the-impact-of-broccoli-ii-tomatoes-ii-on-european-patents-in-conventional-breeding-gmos-and-synthetic-biology-the-grand-finale-of-a-juicy-patents-tale/ (accessed July 26, 2019).

103 Commission Notice on certain articles of Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions (2016/C 411/03) where it stated at page 7 that "The Commission takes the view that the EU legislator's intention when adopting Directive 98/44/EC was to exclude from patentability products (plants/animals and plant/animal parts) that are obtained by means of essentially biological processes". It further stated that: "It is worth underlining that the same reasoning applies to animals. Even if, strictly speaking, there is no intellectual property right covering animal varieties at EU level, the same exception applies to animal varieties, namely that neither animal varieties nor essentially biological processes for the production of animals can be patented. The same approach—i.e. exclusion from patentability—should thus apply to animals that are directly obtained from essentially biological processes".

104 See P. England, *Essentially Biological Processes and Their Products—What is Patentable?*, https://www.lexology.com/library/detail.aspx?g=083676e0-2c66-4f28-8163-3e8c0eb9bd27 (accessed July 26, 2019).

105 *Id.*

106 European Patent Office, *EPO Member States Discuss Patentability of Plants Obtained by Essentially Biological Processes*, https://www.epo.org/news-issues/news/2019/20190220.html (accessed July 29, 2019).

clarified the law in this area.[107] In May 2020, the decision of the Enlarged Board made it clear that the exclusion of patents on essentially biological processes for the production of animals or plants under Art 53(b) EPC, included an exclusion on patentability for any plants or animals derived from such processes.[108] Hence, de-extinct animals created via back breeding would now appear unpatentable in Europe.

Morality Provisions and De-extinction

The morality provision contained in Art 53(a) EPC provides that patents shall not be granted for inventions where their 'commercial exploitation is against ordre public or morality.' The terms ordre public and morality are not defined within the EPC. The provisions in the EPC are supplemented by the morality provisions in the Biotechnology Directive 98/44EC. Art 6(1) of the Directive repeats the general morality provision evident in the EPC, and Art 6(2) provides a list of four categories of inventions that are expressly excluded from patentability on the basis of morality, namely:

> (i) processes for cloning human beings, (ii) processes for modifying the germ line genetic identity of human beings, (iii) uses of human embryos for industrial or commercial purposes, (iv) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

Following the adoption of the Directive in 1998, the European Patent Organisation voluntarily adopted the specific list of exclusions contained in Art 6(2) of the Biotechnology Directive into the EPC on 16 June 1999. This was achieved through a decision of the Administrative Council amending the Implementing Regulations.[109] Furthermore, Regulation 26(1) of the Implementing Regulations states that the Directive should be used as a supplementary means of interpretation for patents on biotechnological inventions. Thus, these four exclusions are supplementary interpretation for the EPC in determining the effect of the morality exclusion on the patentability of inventions.

Multiple ethical objections to the patentability of de-extinct animals could be raised under the general morality provision and arguably also under Art 6(2)(d) based on the potential suffering to recreated animals. Prior to examining the likely objections, this section briefly examines the main relevant existing EPO cases. Particular focus is placed on cases involving transgenic animals from which analogies can be drawn in the de-extinction context. This section considers the potential objections that are likely in the context of (i) the general morality provision, and (ii) the specific exclusion under Art 6(2)(d) of the Directive, to the patentability of animals created via de-extinction attempts.

107 G 3/19 (Pepper), Opinion of the Enlarged Board of Appeal European Patent Office, 14th May 2020.

108 However, as the Directive is supplementary interpretation for the EPC, and the EPO is the grant body for European patents, this poses considerable difficulties and will require further clarification of the law by the EU and EPO.

109 The mechanism for adopting these provisions has been criticized as democratically deficient, see I. Schneider, *Governing the Patent System in EUROPE: the EPO's Supranational Autonomy and its Need for a Regulatory Perspective,* 36(8) Science and Public Policy 619, 623 (2009). For a full discussion of these issues see: Aisling McMahon, *The Morality Provisions in the European Patent System: An Institutional Examination* (PhD Thesis, University of Edinburgh, 2016).

E. De-extinction, Animals and the General Morality Provisions

At the outset, it can be noted that generally the morality provisions have been interpreted by the EPO in a relatively light touch manner and patents are rarely excluded on the basis of such provisions. Instead the EPO generally eschews broader ethical issues and is reluctant to engage with questions of morality/ethics as they pertain to patentability.[110] For instance, the general morality provision was invoked to challenge gene patents prior to the Directive in 'Howard Florey/Relaxin,'[111] but the EPO stated that whether:

> . . . human genes should be patented is a controversial issue on which many persons have strong opinions . . . [T] he EPO is not the right institution to decide on fundamental ethical questions.

This indicates, as one of us has argued elsewhere, an institutional reluctance to engage with patents on this basis which, as will be seen, is replicated in later decisions of the EPO.[112] It also suggests that it is very unlikely that this provision could be successfully used to deny patents in the de-extinction context.

The context of de-extinction is analogous to patentability claims over transgenic animals. Indeed, methods of genetic engineering used to create some extinct animals (or animals similar to these) are essentially a means to create transgenic animals and hence fall squarely within this context. The EPO has allowed patents on transgenic animals in the past, but adopts a balancing test where suffering is likely to occur to the animal, and it is this test that determines patentability. One of the most controversial decisions in this regard is the 'OncoMouse' decision,[113] which pertained to the patentability of a genetically modified mouse which was modified to make it more susceptible to developing cancer for the purpose of use as an animal model in research. The TBA in the case held that the application of Art 53(a) would 'seem to depend mainly on careful weighing up of the suffering of animals and possible risks to the environment on the one hand, and the invention's usefulness to mankind on the other.'[114] The matter was remitted to the Examining Division which granted the patent, finding that the benefit to mankind (finding a cure for cancer) was significant, and it played down the suffering to animals created stating that the invention would mean that less healthy mice would be needed to be used and destroyed due to the invention. The EPO in the case did not accept objections based on the idea of patents on life, or patents on sentient animals, so these would also arguably be unlikely to be decisive in the de-extinction context.

110 A. McMahon, *Gene Patents and the Marginalisation of Ethics,* 41(10) EIPR 608–620 (2019).

111 EPOR 541[1995].

112 Aisling McMahon, *The Morality Provisions in the European Patent System: An Institutional Examination* (PhD Thesis, University of Edinburgh, 2016). See also: Leland Stanford EPOR 2 [2002]; Harvard/OncoMouse; OJ EPO 473 [2003]; OJ EPO 246 [2005]; University of Utah Research Foundation T0666/05, Technical Board of Appeal, 13 November 2008. For decisions of the EPO involving embryonic stem cells, decided under Art 6(2) the specific morality provisions which apply a definitional test and hence show a change in position see: Wisconsin Alumni Research Foundation (WARF) (G002/06), Decision of the Enlarged Board of Appeal of 25 November 2008TECHNION/Culturing stem cells EPOR 23 [2014]; ASTERIAS/Embryonic stem cells EPOR 9 [2015].

113 OJ EPO 451 [1989] (Exam); TBA decision T19/90 OJ EPO 490 [1990] TBA.

114 OJ EPO 490 [1990] [5].

The test set out in the OncoMouse decision was subsequently applied in Upjohn's patent case which related to a mouse which was modified to lead it to lose its hair. However, here the EPO held, in weighing up benefits and suffering, that the mouse would not be patentable and the process was immoral. The scope of Art 53(a) as it applies to transgenic animals was also considered in the later decision in Transgenic Animals,[115] which confirmed the application of the utilitarian test adopted by the TBA in OncoMouse. The TBA stated that the question of ordre public or morality did not refer to the morality of the act of genetically engineering the mouse per se. Instead the morality provision was concerned with the publication/exploitation of the OncoMouse or method.[116] The TBA held that the balancing test allowed a range of factors to be considered including 'harm to the environment, possible uses of non-animal alternatives, possible threats to human evolution,' etc.[117]

In the above cases, the invention for which a patent was applied for related to the medical/cosmetic application of the mouse, and generated suffering to the transgenic animal created by making it either susceptible to cancer (OncoMouse) or to hair loss (Upjohns). This differs from the context of recreating extinct animals, and although suffering could result to the animal created under de-extinction attempts (for instance if the techniques being used for creation were not sufficiently effective),[118] it would be unlikely that the animal would be created solely for medical research purposes, and thus the suffering to the animal would not be as self-evident as it was in these previous cases. It is questionable, therefore, whether the balancing test would be engaged as the suffering to the animal may not be borne out at all (depending on how such projects develop). Potentially, if de-extinct animals were created, and patent claims and challenges brought, this could push the EPO to reconsider the application of the morality provisions in such cases and may give rise to a new test. Alternatively, if a balancing test were applied given the anticipated lack of suffering to the animal, it may make the morality exclusion easier to surpass in this context.

In terms of potential broader objections, patent claims related to animals produced from de-extinction methods could raise four main ethical concerns, similar to the OncoMouse case, upon which a challenge could be mounted on the basis of the general morality provision in Art 6(1) of the Directive or Art 53(a) EPC. First, 'environment/ecological concerns': objections could be raised based on the potential risk to the environment of introducing an extinct animal or something similar to an extinct animal back into an ecosystem, and the potential damage this could do to that ecosystem. If such animals were created they might be kept in isolation to avoid this risk, but there is still the possibility of escape and of the animal breeding with existing animals thereby changing the ecosystem. Resurrected species could, inter alia, create irreversible problems in contemporary environments and for native species that have evolved in the absence of the vanished biota.[119] Moreover, claims could be raised from a human rights perspective that introducing such animals could severely adversely

115 Harvard/Transgenic Animals T 315/03 OJ EPO 15 [2006] (TBA).

116 L. Bently and B. Sherman, Intellectual Property Law (2014), 520. Note the EPC no longer refers to publication.

117 L. Bently and B. Sherman, Intellectual Property Law (2014), 520.

118 C. Zimmer, *Bringing Them Back to Life*, 223(4) National Geographic 28–41 (2013).

119 B.A. Minteer, *Is it right to reverse extinction?*, 509(7500) Nature 261 (2014).

impact on human rights to life or health (depending on the environmental threat posed). The EPO in the past has confirmed that Art 53(a) consideration of ordre public incorporates a consideration of fundamental human rights,[120] although cases denying patents on the basis of human rights implications under the general morality provisions are scant.[121] Thus, in the absence of a change in interpretative stance by the EPO, it is unlikely that patents on de-extinct animals would be denied on a human rights type challenge. Moreover, were such a challenge to be engaged with seriously by the EPO, any challenger would have to demonstrate the potential environmental impacts and how these would potentially impinge on human rights. This could open the door for broader human rights challenges in other patent contexts (such as access to medicines, etc.) which the EPO has not engaged with to date and arguably would be unlikely to welcome.

Secondly, 'animal welfare concerns': objections could arise in particular in the cases of genetically engineered animals, including the creation of hybrid animals, if it required living animals to be engineered in order to recreate such animals given that they are 'moral patients.'[122] There are clear ethical questions about the making and use of living animals in de-extinction attempts,[123] including 'concerns about the welfare of cell donors and surrogates used to reproduce de-extinct animals.'[124] Moreover, the animals created by genetic engineering could experience suffering (depending on the effects of the genetic engineering). These concerns would then have to be juxtaposed against whether the patent will be of benefit to humankind (e.g. developing de-extinction technologies could further human health and reproductive science). Thus, in the context of de-extinction, the same sort of balancing exercise that was done in the Harvard/OncoMouse case—'weighing up' between the utility to humankind as against the environmental hazards and the detriment to animals—is likely to be relevant.

Thirdly, 'animal rights objections': similar to early decisions on the patentability of transgenic animals, if patents were applied for on de-extinct animals it could raise concerns on the appropriateness of granting patents on sentient animals. There are also concerns that 'the ability to revive dead species may undercut conservation efforts for still-living species that are endangered or threatened,'[125] thereby impacting on the

120 See Case T0149/11 of 24 January 2013, *Method and Device for Processing a Slaughtered Animal or Part Thereof in a Slaughterhouse*, para 2.5. However, to date, the EPO's consideration of human rights issues in the context of the morality provisions has been limited. See generally, Aisling McMahon, *The Morality Provisions in the European Patent System: An Institutional Examination* (PhD Thesis, University of Edinburgh, 2016).

121 See, Aisling McMahon, *The Morality Provisions in the European Patent System: An Institutional Examination* (PhD Thesis, University of Edinburgh, 2016); A. McMahon, *Gene Patents and the Marginalisation of Ethics,* 41(10) EIPR 608–620 (2019).

122 W. M. Adams, *Geographies of Conservation 1: De-Extinction and Precision Conservation*, 41(4) Prog. Hum. Geog. 534–545 (2017).

123 C. Friese and C. Marris, *Making De-extinction Mundane?*, 12(3) PLoS biology 1–3 (2014); V. Gewin, *Laws Lag Behind Science in De-extinction Debate*, http://blogs.discovermagazine.com/crux/2013/06/05/laws-lag-behind-science-in-de-extinctiondebate/#.WVSVcDOZOgQ (accessed May 24, 2017); S. Cohen, *The Ethics of De-extinction*, 8(2) NanoEthics 165–178 (2014); W. M. Adams, *Geographies of Conservation 1: De-extinction and Precision Conservation*, 41(4) Prog. Hum. Geog. 534–545 (2017).

124 C. Friese and C. Marris, *Making De-Extinction Mundane?,* 12(3) PLoS Biology 1–3 (2014).

125 N.F. Carlin, I. Wurman and T. Zakim, *How to Permit Your Mammoth: Some Legal Implications of "De-Extinction"*, 33(1) Stanf. Envtl. L. J. 3–57 (2013).

rights of current animals. By contrast, one of the benefits of de-extinction as a process is that it 'allows for preservation and re-establishment of ecosystems in danger of or already lost to extinction.'[126] The concept of de-extinction may also 'increase public support for conservation.'[127] Browning, for instance, identified ecological, restorative, and scientific benefits of de-extinction to mankind, including 'the improved quality of ecosystems with restoration of keystone species' and 'leading to advancement of knowledge and technology.'[128]

Fourthly, objections may arise around 'who (if anyone) should hold patents and the special nature of extinct animals': if it is possible to recreate extinct animals or animals similar to extinct animals, it could be argued that such animals should not be the sole domain of patent holders or subject to their control via patent. Instead, it is arguable that such animals should be free from patents given their 'special' nature and significance to humans generally.

Whilst ethical objections could conceivably be highly contested and debated should patent applications be made in relation to de-extinct animals in Europe, the past practice of the EPO on the general morality provisions has shown a strong reluctance to engage with moral objections to deny patentability. The strongest argument may rest on the potential effects to the environment. However, if this was used to deny patents to such transgenic animals created in the de-extinction sphere it may be difficult to distinguish this from transgenic animals more generally. This, in turn, could jeopardize the patentability of transgenic animals generally which the EPO may be reluctant to do.[129] One argument which could differentiate de-extinction from other contexts is that it may be intended to place de-extinct animals in the wild again, which is not generally the case with other patented high profile transgenic animals like 'OncoMouse.'[130] Moreover, the EPO has already allowed patents on transgenic animals thus animal rights arguments and arguments based on the special nature of extinct animals are unlikely to be successful. Furthermore, animal welfare concerns could possibly lead to the denial of patents, but only if the potential suffering of animals could be shown.[131] If it was possible to show this, then a balancing test would come into play, and the level of benefits to humankind would need to be demonstrated. Unlike 'OncoMouse,' the benefit of extinct animals is less obvious, a main benefit could conceivably be related to the aesthetic (i.e. to be used for viewing purposes), although it may also be argued that techniques used to create them could be used in agriculture or in reproductive medicine and hence have ancillary benefits.[132] Usefulness to humankind could also be

126 M.R. Swedlow, *The Woolly-Mammoth in the Room: The Patentability of Animals Brought Back from Extinction Through Cloning and Genetic Engineering*, 11(3) Wash. J. L. Tech.& Arts 183–196 (2015).

127 W. M. Adams, *Geographies of Conservation 1: De-Extinction and Precision Conservation*, 41(4) Prog. Hum. Geog. 534–545 (2017).

128 H. Browning, *Won't Somebody Please Think of the Mammoths? De-Extinction and Animal Welfare*, 31 J. Agr. Environ. Ethic. 785–803 (2018).

129 As this may have impacts in the agri/biotech contexts, including impacting upon the certainty of patents in such fields, with a direct impact in patents applied for, and hence potential for patent renewals for the EPO.

130 Stewart Brand, *The Case for De-Extinction: Why We Should Bring Back the Woolly Mammoth*, Yale Environment 360 (2014).

131 Jenny Gray, Zoo Ethics: The Challenges of Compassionate Conservation (2017), 112.

132 For a discussion of the patenting of living organisms in an agricultural context see Magnus Finckenhagen, Scope of Process Patents in Farm Animal Production: Exclusive Rights to Patents on Farm Animal Breeding Methods and Relevant Exemptions on the Patentability of Such Inventions (2014).

interpreted broadly by the EPO as an interest in seeing the return of extinct animals for evolutionary study, public viewing, etc. Nonetheless, whilst such arguments might support patents on the processes of creating transgenic extinct animals, they may be weaker in the context of patent claims on the animals created (should suffering to such animals arise). Overall, however, much will depend on the technologies used in de-extinction attempts and the resulting nature of animals created.

F. De-extinction, Animals and Art 6(2)(d): Specific Morality Exclusions

Alongside the general morality provisions, one of the specific exclusions under the morality provision is of potential relevance in this context, namely: Art 6(2)(d) of the Biotechnology Directive which excludes processes for '[m]odifying the genetic identity of animals which are likely to cause them suffering without any substantial benefit to man or animal, and also animals resulting from such processes.' As noted above, the specific exclusions under Art 6(2) were adopted as supplementary interpretation for the EPC system and therefore used by the EPO when assessing patentability. The EPO has demonstrated a different interpretative approach to deny patents where technologies fall within the definition of these provisions. This has been most controversial in the context of patents on 'uses of embryos for industrial and commercial purposes.'[133] Besides, Art 6(2)(d) requires one to prove suffering of the animal, and whether there was a benefit to man or animal, and arguably the provision would only apply if the modifications would cause suffering which would need to be clearly demonstrated. In de-extinction contexts one is creating an animal which otherwise would not exist and no suffering may be intended to be experienced by the animal as a result of the process. If suffering were to arise to existing animals by the process then this may be considered to fall under this category, or if the process used to create the de-extinct animal encompassed suffering, it would apply. That said, the nature of suffering, if any, in the de-extinction context, is questionable and would depend on the technology used.

G. Reflection on Application of the Morality Provisions & De-Extinction

In short, the light touch application of the general morality provisions to date in Europe, the reluctance of the EPO to engage critically with this provision, together with the potential knock-on effects on the patentability of transgenic animals generally if the EPO used the provision to deny patents in the de-extinction context (depending on the technology used) suggests these provisions (if current interpretative patterns prevail within the EPO) are unlikely to exclude patents in the de-extinction field. Moreover, the specific exclusions under Art 6(2)(d) of the Directive embody a definitional test. If applications fall within the definition of the exclusion they are automatically excluded, but a key factor in this context would be how suffering is construed and the extent of the suffering, if any, to the de-extinct animal created.

133 Case C-34/10 Brüstle v Greenpeace eV, Judgment of the Court (Grand Chamber), 18th October, 2011, [2011] E.C.R. I-9821; Case C-364/13 International Stem Cell Corporation v Comptroller General for Patents, December 18, 2014. For EPO decisions on embryonic stem cells, see: Case T1079/03 Edinburgh University (Unreported) [2003] OD EP 94913174.2; Case T522/04 California Institute of Technology (CIT) (Unreported) [2003] ED EP 93921175.1; WARF, note 54; TECHNION/Culturing stem cells [2014] EPOR 23; ASTERIAS/Embryonic stem cells [2015] EPOR 9. As discussed in: Aisling McMahon, *The Morality Provisions in the European Patent System: An Institutional Examination* (PhD Thesis, University of Edinburgh, 2016).

H. De-extinction and Patent Criteria: What's so Novel?

Finally, even if a de-extinct animal was not deemed unpatentable based on the above patent exclusions in Europe, as with other inventions, to be patentable it would have to be shown to meet the criteria for patentability, namely inventive step, novelty and industrial application. Of these, novelty could pose the most difficulties. Even if de-extinct species qualify as patentable subject matter, they might not fulfill the novelty requirement as espoused in the EPC. Indeed, at an abstract level, de-extinction and novelty may at first glance seem to be mutually incompatible concepts. An invention, after all, is only considered to be new if it does not form part of the 'state of the art' (i.e. the invention must not be made available to the public in any way, in any part of the world, at any time before the priority date), while the whole purpose of de-extinction is to bring back an extinct species that previously existed in nature.[134] Nonetheless, this issue, as with others in the patenting and de-extinction context, will ultimately depend on the techniques used and whether there are significant differences between the extinct species and the synthesized versions.[135] For example, proponents justifying de-extinct species as patent eligible subject matter may argue that scientists have created de novo an entirely new life form that is a doppelganger rather than an exact genomic replica of the extinct species,[136] and thus that it should meet the patent novelty requirement.[137] By contrast, opponents in certain instances may emphasize the fact that the resurrected species is identical to the (formerly) naturally occurring extinct original and that a true clone of that species cannot be novel given that such animals were 'available to the public' prior to extinction.[138] Although de-extinct animals per se may well in appropriate cases amount to a patentable invention, patent examiners may have to decide whether it is the 'surface similarity or the underlying genetic distinctiveness' that is fundamental to determining whether the resurrected species is novel or not.[139]

If resurrected species are exact replicas of extinct originals, those originals may be considered as 'prior art.'[140] However, as has been seen, the technologies used (bar cloning) do not create identical animals to that which existed previously. In particular, genetic engineering creates a new animal which is a hybrid of the similar animal and extinct animal, with a mixture of DNA from both. Again, regarding the question of patentability criteria, much will depend on how the technology evolves and is used to create such animals.

134 M.R. Swedlow, *The Woolly-Mammoth in the Room*, 11(3) Wash. J.L. Tech. & Arts 183–196 (2015).

135 B.A. Minteer, *Is it Right to Reverse Extinction?*, 509(7500) Nature 261 (2014).

136 S. Cohen, *The Ethics of De-extinction*, 8(2) NanoEthics 165–178 (2014).

137 Hagglund argues that the doctrine of "lost arts" could be used to skirt the novelty requirement in the US. See Mark L Rohrbaugh, *The Patenting of Extinct Organisms: Revival of Lost Arts*, 25 AIPLA Q.J. 371 (1997). See also: Ryan Hagglund, *Patentability of Cloned Extinct Animals*, 15 Geo. Mason L. Rev. 319, 404 (2008). For an opposing view see Darren M. Jiron, *Patentability of Extinct Organisms Regenerated through Cloning*, 6 VA. J.L. & Tech. 33 (2001). For the doctrine of "lost arts" more generally see Alan L. Durham, *Lost Art and The Public Domain*, 49 Arizona State Law Journal 1257–1300 (2017).

138 W.M. Adams, *Geographies of Conservation 1: De-extinction and Precision Conservation*, 41(4) Prog. Hum. Geog. 534–545 (2017).

139 N.F. Carlin, Ilan Wurman and Tamara Zakim, *How to Permit Your Mammoth: Some Legal Implications of "De-extinction"*, 33(1) Stanf. Envtl. Law J. 3–57, 51 (2013).

140 N.F. Carlin, Ilan Wurman and Tamara Zakim, *How to Permit Your Mammoth: Some Legal Implications of "De-extinction,"* 33(1) Stanf. Envtl. Law J. 3–57, 58 (2013).

V. CONCLUSION: DE-EXTINCTION AND THE POTENTIAL EFFECTS OF PATENTABILITY: A TALE OF CAUTION OR HOPE?

The potential patentability of de-extinct animals reignites broader questions surrounding the scope of what is and is not patentable in Europe. It also brings to the fore questions on the role of ethics in the patenting of advanced biotechnologies. Such questions require careful consideration so that we can preemptively address the challenges that could arise. The question of patentability is not a trivial one and has significant implications for such technologies. If patents were granted on such de-extinct animals the nature of a patent is that it allows the patent holder to decide how the invention under patent (the recreated animal) is used, by whom and for what purposes (for the duration of patent grant).[141]

This, in turn, could affect how such animals are used, and how they are developed downstream. It could also be used to increase prices of viewing/using such animals and therefore raises broader access issues. Moreover, given the cultural significance of many extinct animals such as the extinct woolly mammoth or dinosaurs, it is questionable if placing such recreated (albeit non-identical) animals under patent would be appropriate—is this an over commodification of animals that have a greater cultural significance? Furthermore, from a broader standpoint, one of the foundational theories of patents is that they act as an incentive for inventions. However, given the potential environmental implications of de-extinct animals, is it appropriate to incentivize such inventions via patent? To what extent should patents be given to technologies which have questionable and potentially harmful effects on contemporary ecosystems and humankind? More fundamentally, the question of patents in the de-extinction context raises again the issues of what role patent law has in a broader innovation landscape—given the potential for patents to drive or encourage innovation should such drivers be removed if uncertainty continues around the benefits of such technologies? Should patent agencies such as the EPO consult and act in tandem with other bodies such as environmental agencies when questions like this come before them?

On the other hand, it is also plausible that patents could be used in a way which embeds ethical standards at the post-grant stage. For instance, as one of us argues elsewhere, conditions could be placed on patents which only allow use of the invention for specific purposes, or prohibits specific uses.[142] This type of approach has been evident with the ethical licensing restrictions used under some patented CRISPR-gene editing technologies,[143] but it remains to be seen how widespread such approaches will become and how they will be employed in practice. Moreover, if there is no patent, then the patent holder(s) has no control over how the recreated animal is used by others—giving patent holder(s) a patent allows some control over downstream uses—but the broader question is whether it is appropriate that the patent holder would have such authority over the recreated animal?

141 See discussion on the nature of patents in: Aisling McMahon, 'Biotechnology, Health and Patents as Private Governance: The Good, the Bad, and the Potential for Ugly?' 3 Intellectual Property Quarterly (2020).

142 Aisling McMahon, *Biotechnology, Patents and Licensing for 'Ethical' Use: A Regulatory Opportunity?* (Working Paper, 2020). This research was funded by the Irish Research Council, *New Foundations* Scheme (2018).

143 See discussion in J. Sherkow, *Patent Protection for CRISPR: an ELSI Review,* 4(3) Journal of Law and the Biosciences 565–576 (2017); See also: Aisling McMahon, ibid.

Overall, the expected arrival of de-extinct animals and the patent applications that will conceivably follow, raises a deeper question on whether the patent system as currently constructed and interpreted, is the appropriate vehicle to 'protect' such inventions. 'Raising the dead,' it appears, raises 'a raft of legal and regulatory uncertainties.'[144]

SUPPLEMENTARY DATA

Supplementary data mentioned in the text are available to subscribers in *JLBIOS* online.

144 V. Gewin, *Laws Lag Behind Science in De-extinction Debate*, http://blogs.discovermagazine.com/crux/2013/06/05/laws-lag-behind-science-in-de-extinction-debate/#.WVSVcDOZOgQ (accessed May 24, 2017).