How to Permit Your Mammoth: Some Legal Implications of "De-Extinction"

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I. INTRODUCTION

Extracting DNA from ancient specimens and using cloning technology to resurrect extinct species has become a staple plot device of popular science fiction novels and films since *Jurassic Park*.[1] But the prospect that extinct animals may live again no longer belongs solely to the realm of science fiction. "De-extinction" is coming closer to reality, as scientists now are experimenting with a number of methods for resurrecting extinct species. No method will bring back the dinosaurs; it has been too long since the Jurassic era for their DNA to survive. It may be possible to "resurrect" more recently extinct species, however, such as the Pyrenean ibex, the passenger pigeon, or possibly even the awe-inspiring woolly mammoth, in the not too distant future.[2]

While some discussion of these exciting developments has appeared in the scientific and popular press, most articles focus on technical and ethical issues: can we do this, and should we?[3] Some have proposed crafting new legal and regulatory regimes to control this anticipated development, looking to other scientific advances posing unknown risks and social implications as models, such as genetically modified organisms[4] and geoengineering, often on an international scale.[5] Should resurrecting species prove to be

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1. MICHAEL CRICHTON, JURASSIC PARK (1990); JURASSIC PARK (Universal Pictures 1993).

2. As discussed in Part II below, most resurrected species would be genetically different from their extinct counterparts, but it may be possible to restore a few species with a genome very close to the original genome.

3. *See, e.g.*, Editorial, *Why Efforts to Bring Extinct Species Back from the Dead Miss the Point*, SCI. AM. (May 27, 2013), http://www.scientificamerican.com/article.cfm?id=why-efforts-bring-extinct-species-back-from-dead-miss-point&page=2; Jacob S. Sherkow & Henry T. Greely, *What If Extinction Is Not Forever?*, 340 SCIENCE 32, 32 (2013) [hereinafter Sherkow & Greely]; Richard Stone, *Fluttering from the Ashes?*, 340 SCI. 19, 19 (2013); Gina Kolata, *So You're Extinct? Scientists Have Gleam In Eye*, N.Y. TIMES Mar. 19, 2013, at A1; Carl Zimmer, *Bringing Them Back to Life: The Revival of an Extinct Species Is no Longer a Fantasy. But Is It a Good Idea?* NAT'L GEOGRAPHIC (Apr. 2013), http://ngm.nationalgeographic.com/2013/04/125-species-revival/zimmer-text.

4. *See, e.g.*, *GM Crops: Promise & Reality*, NATURE (SPECIAL ISSUE) 21 (May 2, 2013); Dorothy Nelkin, Philippe Sands & Richard Stewart, *The International Challenge of Genetically Modified Organism Regulation*, 8 N.Y.U. ENVTL. L.J. 523 (1999).

5. *See, e.g.*, DAVID G. VICTOR, GLOBAL WARMING GRIDLOCK: CREATING MORE EFFECTIVE STRATEGIES FOR PROTECTING THE PLANET (2011); Edward A. Parson & David W. Keith, *End the Deadlock on Governance of Geoengineering Research*, 339 SCI. 1278, 1278 (2013).

feasible, societal concerns and "unknown unknowns"[6] may well lead to the development of a novel regulatory program specific to de-extinction. Nevertheless, many legal tools already exist, developed in other contexts, which could be applied to de-extinction efforts. While recognizing that new approaches are conceivable, this Article explores the implications of de-extinction under existing law.

For purposes of this Article, we treat de-extinction, in some form, as a scientifically reasonable future prospect whose legal implications should be considered in a practical manner. For the most part, we assume that if de-extinction can feasibly be accomplished, someone will undertake the effort if for no other reason than because it would be irresistibly thrilling to do so. *Jurassic Park* itself may be unattainable, but a somewhat more plausible Pleistocene Park, populated with mammoths and aurochs, would generate nearly as much popular excitement. Other motivations for pursuing de-extinction might include the reintroduction of "keystone" species for purposes of reviving whole ecosystems, with substantial environmental benefits.[7] Scientists would have the unprecedented opportunity to study their research subjects as living species. A more prosaic motivation, but not a negligible one, would be purely commercial: parrot fanciers willing to pay a high price for a rare hyacinth macaw presumably would pay a far higher price for a resurrected Carolina parakeet.

Which brings us to the implications of de-extinction under existing law. Would resurrected species be protected by the federal Endangered Species Act (ESA)? If the revived species is actually a genetically modified version of an existing near relative, would it be entitled to ESA protection? How would de-extinction be addressed in an Environmental Impact Statement (EIS) under the National Environmental Policy Act (NEPA) and similar state laws? What would be the environmental impacts of reintroducing such

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6. On "unknown unknowns," see Donald Rumsfeld, U.S. Sec'y of Defense, News Briefing (Feb. 12, 20012), *available at* http://www.defense.gov/Transcripts/Transcript.aspx?TranscriptID=2636 ("[T]here are known knowns; there are things we know we know. We also know there are known unknowns; that is to say we know there are some things we do not know. But there are also unknown unknowns—the ones we don't know we don't know.").

7. There is in fact a Pleistocene Park being developed in Siberia, utilizing living herbivore species such as bison, musk ox and reindeer in an attempt to restore the grassland ecosystem once maintained by foraging mammoths. *See* PLEISTOCENE PARK, http://www.pleistocenepark.ru/en/ (last visited Oct. 31, 2013).

species, revived in the laboratory through genetic technology, into the wild? If the species is a genetically modified organism (GMO), would it be subject to regulation as such? Would its modified gene sequence be patentable (a question that would be of considerable interest to anyone hoping to produce Carolina parakeets for the pet trade)?

In writing this Article, we acknowledge but do not intend to address the serious ethical questions that have been raised regarding de-extinction.[8] Some denounce the idea of de-extinction as yet another instance of humanity's lack of humility. Conversely, others argue that humans have a moral obligation to attempt to bring back at least some of those species we ourselves exterminated, if not perhaps species that died out independently of and long before our advent.[9] Some object that the process of producing a resurrected animal is cruel or harmful to the animal itself.[10] Some are concerned that the ability to revive dead species may undercut conservation efforts for still-living species that are endangered or threatened, detracting from the perceived need to protect them if they are reliably replaceable and eroding society's understanding of what constitutes "nature."[11] The specter of humans "playing God" on this scale—wiping out entire species that inconveniently inhabit some desirable property, then bringing them back at will—is certainly distressing. Concerns also exist about the impact of novel organisms on the integrity of existing

8. *See, e.g.*, Sherkow & Greely, *supra* note 3, at 32-33. The authors outline five categories of risk or objection to bringing back extinct animals: political, moral, animal welfare, public health, and environmental consequences. This Article examines in more detail the application of several legal regimes briefly noted by Sherkow & Greely: the Endangered Species Act, the National Environmental Policy Act, and patent law.

9. But how far back would such a moral obligation reach? Human-caused extinction is not limited to the modern industrial era. Some paleontologists have suggested that hunting was primarily responsible for extinction of megafauna such as mastodons and mammoths. Paul S. Martin, *Prehistoric Overkill: The Global Model*, *in* QUATERNARY EXTINCTIONS: A PREHISTORIC REVOLUTION 354, 354 (Paul S. Martin & Richard G. Klein eds., 1984).

10. In general, cloned animals are at risk of mortality due to genetic defects. Phillip Cohen, *Cloned Animals Meet Early Deaths,* NEW SCIENTIST (Feb. 10, 2002), http://www.newscientist.com/article/dn1903-cloned-animals-meet-early-deaths.html#.UjIGZuDZr78.

11. Some commentators see de-extinction as one aspect of the transforming trend of "synthetic biology" and call for greater communication between the synthetic biology community and the biodiversity conservation community. *See* Kent H. Redford et al., *Synthetic Biology and Conservation of Nature: Wicked Problems and Wicked Solutions*, PLOS BIOLOGY, Apr. 2, 2013, http://www.plosbiology.org/article/info%3Adoi%2F10.1371%2Fjournal.pbio.1001530.

ecosystems.[12] These are important questions which are being explored by others, and we note that such concerns may provide the impetus for legal regulation.[13]

This Article proceeds in several parts. Part II introduces the current science of de-extinction and the different methods its proponents are pursuing. The methods are worth reviewing in some detail, since the implications of those methods are significant for legal outcomes. Part III discusses the applicability of the ESA to de-extinct species, whether their artificiality or limited genetic diversity (with only one or a few laboratory-created genotypes) should preclude listing them as endangered and, if not, whether and how they might satisfy the statutory listing criteria. Part IV addresses permitting and evaluation of environmental impacts under NEPA for projects to reintroduce de-extinct species into the wild, by analogy to EISs for reintroductions of living but locally extirpated species into regions that they formerly inhabited and EISs for releases of GMOs into the environment. Part V explores the regulation of resurrected species as GMOs, given that two of the three de-extinction methods being pursued would result in GMOs. Part VI considers the patentability of such GMOs. Part VII summarizes our conclusions.

II. THE SCIENCE AND METHODS OF DE-EXTINCTION

Three methods plausibly could be utilized to resurrect an extinct species: cloning by somatic cell nuclear transfer ("SCNT"), genetic engineering, and artificial selection.[14] We consider these methods in that order because, as explained in more detail below, the first would come closest to truly recreating an extinct species, the second would result in a hybrid of the genomes of an extinct species and a close living relative, and the third would rely entirely on the genotype of a living species to restore a phenotype resembling an extinct species. If ranked according to likelihood of success, however, these methods would be listed in the opposite

12. *Id.*

13. Such questions were extensively discussed at the Stanford Law School conference on De-Extinction. De-Extinction: Ethics, Law & Politics (May 31, 2013) http://www.law.stanford.edu/event/2013/05/31/de-extinction-ethics-law-politics. In addition, "Revive & Restore," a project of the Long Now Foundation, has posted information on several prior conferences at the National Geographic Society and Harvard University. *See Revive & Restore*, LONG NOW FOUND., http://longnow.org/revive/events/ (last visited Dec. 3, 2013) (listing the various conferences held on the consideration of the ethical ramifications and other topics regarding de-extinction).

14. Sherkow & Greely, *supra* note 3, at 32.

order. Artificial selection already appears to be succeeding in at least two instances, producing animals that resemble the quagga, an extinct subspecies of zebra,[15] and the aurochs, an extinct species of wild cattle.[16] Genetic engineering appears reasonably likely to work in some fashion, as discussed below, while SCNT could only succeed, if at all, in those few cases for which the necessary raw material is available.

A. *Somatic Cell Nuclear Transfer*

In the first method, SCNT, the nuclear DNA is eliminated from an egg cell (oocyte) of one organism and replaced with the nuclear DNA of another organism; the egg is then induced to divide and develop into an embryo. The resulting individual will have the nuclear genotype of the donor organism, rather than that of the host egg.[17] For any attempt to clone an extinct species by SCNT, complete and viable nuclear DNA of that species must be available. The best (and perhaps the only) candidates 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. There must also be a closely related living species or subspecies to serve as the egg donor and (for mammal species) surrogate mother for gestation. The DNA program, like a computer program, will not "run" on machines too different from those for which it was designed.[18]

Even the SCNT method, however, would not produce an *exact* duplicate of the original. While the nuclear DNA is obtained from an extinct species, the egg must be a living cell in order to develop into a living embryo. At the least, the mitochondrial genome, contributed by the egg, will be that of the egg donor

15. THE QUAGGA PROJECT SOUTH AFRICA, www.quaggaproject.org (last visited Oct. 31, 2013).

16. THE TAUROS PROGRAMME, www.taurosproject.com (last visited Oct. 31, 2013); *see also* Stephan Farris, *Breeding Ancient Cattle Back from Extinction*, TIME, Feb. 12, 2010.

17. X. Cindy Tian et al., *Cloning Animals by Somatic Cell Nuclear Transfer—Biological Factors*, REPROD. BIOLOGY & ENDOCRINOLOGY 1, 1 (2003), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC521203/.

18. Y. Jiang et al., *Interspecies Somatic Cell Nuclear Transfer Is Dependent on Compatible Mitochondrial DNA and Reprogramming Factors*, PLOS ONE, Apr. 27, 2011, *available at* http://www.plosone.org/article/info:doi/10.1371/journal.pone.0014805. The SCNT method has been used to clone living endangered species. Robert P. Lanza et al., *Cloning of an Endangered Species (*Bos gaurus*) Using Interspecies Nuclear Transfer*, 2 CLONING 79, 79-90 (2000). The researchers transferred nuclear DNA of the guar (an endangered species of cattle) into eggs from closely related domestic cows and implanted the resulting embryos into cows as surrogate mothers. *See id.* at 80-81.

species.[19] Moreover, to continue the computer analogy, running the DNA program on the machine of an egg from a different, though related, species inevitably will alter the expression of the genes in some respects.[20] Thus, clones produced by the SCNT method would closely approximate, but would not truly be, revived members of the extinct species.

In 2009, a team using the SCNT method produced a Pyrenean ibex or *bucardo* (a subspecies of the Spanish ibex, a form of wild goat).[21] The research team used cryopreserved DNA that had been collected from the last surviving female before the subspecies died out in 2000. This material was implanted into eggs from domestic goats and the resulting embryos transferred to Spanish ibex or goat-ibex hybrids for gestation.[22] Out of several hundred attempts, only one fetus survived to term and it died within minutes after birth from lung abnormalities.[23] Nevertheless, this attempt represented the first living birth of an extinct animal.

The Australian gastric-brooding frog is another de-extinction candidate for which well-preserved DNA is available, collected before it became extinct in the 1980s. This species had been closely studied due to its unusual reproductive behavior: females swallowed their own eggs after fertilization and incubated the tadpoles in their stomachs, regurgitating them at maturity. A team headed by Michael Archer is attempting to revive the gastric-brooding frog utilizing SCNT, transferring nuclear DNA from frozen specimens into donor eggs from a related species, the barred frog. This process has produced living embryos, although

19. Consider the human genome as an example: the nuclear genome consists of approximately 3.2 billion nucleotides of DNA contained in twenty-four chromosomes, located within the cell nucleus, while the mitochondrial genome consists of 16,569 nucleotides, multiple copies of which are located in the energy-generating cellular organelles called mitochondria. TERENCE A. BROWN, GENOMES (2d ed. 2002), *available at* http://www.ncbi.nlm.nih.gov/books/NBK21134/. Over eighty percent of the human genome serves some biochemical function, either encoding genes or controlling their expression. The ENCODE Project Consortium, *An Integrated Encyclopedia of DNA Elements in the Human Genome*, 489 NATURE 57, 57-74 (2012).

20. Stefan Hiendleder et al., *Mitochondria and the Success of Somatic Cell Nuclear Transfer Cloning: From Nuclear-Mitochondrial Interactions to Mitochondrial Complementation and Mitochondrial DNA Recombination*, 17 REPROD., FERTILITY & DEV. 69, 69-83 (2005); Y. Jiang et al., *supra* note 18.

21. J. Folch et al., *First Birth of an Animal from an Extinct Subspecies (*Capra pyrenaica pyrenaica*) by Cloning*, 71 THERIOGENOLOGY 1026, 1026 (2009), *available at* http://www.ncbi.nlm.nih.gov/pubmed/19167744. For an account in the popular science press, see generally Zimmer, *supra* note 3.

22. Folch et al., *supra* note 21, at 1028.

23. *Id.* at 1029-30.

they survived for only a few days.[24]

Although no adult Pyrenean ibex or gastric-brooding frog has yet been produced, there is some prospect of eventually doing so, due to the availability of complete nuclear DNA collected prior to their extinction and preserved under laboratory conditions. This is likely to be the case for few extinct species, however.[25] A recent article in *National Geographic* somewhat fancifully suggests that SCNT could be used to recreate a woolly mammoth, assuming that scientists can extract sufficiently intact nuclear DNA from frozen mammoth tissue discovered in Siberia:

> [R]esearchers will need to transfer the nucleus into an elephant egg that has had its own nucleus removed. This will require harvesting eggs from an elephant [(the mammoth's closest living relative)]—a feat no one has yet accomplished. If the DNA inside the nucleus is well preserved enough to take control of the egg, it just might start dividing into a mammoth embryo. If the scientists can get past that hurdle, they still have the formidable task of transplanting the embryo into an elephant's womb. Then . . . they will need patience. If all goes well, it will still be almost two years before they can see if the elephant will give birth to a healthy mammoth.[26]

The availability of sufficiently intact nuclear DNA is a major

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24. *Scientists Produce Cloned Embryos of Extinct Frog*, SCI. DAILY (Mar. 15, 2013), http://www.sciencedaily.com/releases/2013/03/130315151044.htm.

25. There may be future opportunities for de-extinction by SCNT utilizing material from "frozen zoo" collections, such as the Frozen Zoo in San Diego, *see Frozen Zoo*, SAN DIEGO ZOO, WILDLIFE CONSERVANCY, http://www.sandiegozooglobal.org/what_we_do_banking_genetic_ resources/frozen_zoo (last visited Oct. 31, 2013), and the Frozen Ark in London, *see* THE FROZEN ARK, http://www.frozenark.org (last visited Oct. 31, 2013). These facilities maintain collections of DNA from living endangered species, preserved in liquid nitrogen, in order to restore genetic diversity in the event that some local populations are extirpated and the surviving, but shrinking, populations are at risk from excessive inbreeding. However, in such cases, there are still living eggs available, from the same species, on which to run the DNA program. The genome introduced by SCNT would be that of an extinct population of the same species as the egg, rather than from a different, extinct species. While de-extinction is not the goal of these projects, should any species preserved in frozen zoos ultimately become extinct, this material would be available for attempts to revive them. It should be noted that, like de-extinction projects, frozen zoo projects and other efforts to clone endangered species that are difficult to breed in captivity have been criticized as reducing the impetus to tackle the underlying problems endangering the species. *See Cloning Endangered Species and Undermining Conservation*, AM. ANTI-VIVISECTION SOC'Y, http://www.aavs.org/site/c.bkLTKfOSLhK6E/b.6470141/k.4A47/Cloning_Endangered_ Species_and_Undermining_Conservation.htm#.UVHaRIl5mc0 (last visited Oct. 31, 2013).

26. Zimmer, *supra* note 3.

assumption, however. DNA decays rapidly after death, and a ten thousand-year-old mammoth corpse dug up from the Siberian tundra is a much less likely source of viable material for SCNT than a decade-old vial stored in an ultra-cold laboratory freezer.[27]

Another significant problem is that the program is being run on the wrong machine: the host egg may be unable to make sufficient sense of the introduced DNA to produce viable individuals. The extinction of the species has eliminated the source of eggs which could have done so, as well as (for mammal species) the females which could have gestated such embryos successfully to term. As a result, it may well be that, as with the ibex and the frog experiments to date, the embryos will never survive. If so, this method of de-extinction, though theoretically plausible, could prove impossible in practice.

B. *Genetic Engineering*

The second method of de-extinction is genetic engineering. For many extinct species, extensive but more fragmentary genetic material is widely available. Old museum specimens will not yield intact cell nuclei.[28] There is not enough of a readable DNA program left to run by itself; however, a sufficient number of specimens may yield sufficient fragments to assemble a partial gene sequence. That information would then be utilized, not directly to resurrect an extinct species from its genome, but to transform *another* species into what we shall call a "facsimile" of the extinct species. Using modern "gene-splicing" techniques,[29] the genome of a related species could be modified to incorporate sequences from the extinct species. By selecting specific genes that code for traits that distinguish the two species, and inserting those genes from the extinct species into the living relative, the resulting hybrids would come to resemble the extinct form.

No extinct species has yet been recreated by this form of

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27. Jeremy J. Austin et al., *Paleontology in a Molecular World: The Search for Authentic Ancient DNA*, 12 TRENDS IN ECOLOGY & EVOLUTION 303, 303 (1997); *see also* Webb Miller et al., *Sequencing the Nuclear Genome of the Extinct Wooly Mammoth*, 456 NATURE 387, 387-90 (2008) (reporting the extraction and sequencing of 3.3 billion bases of nuclear DNA sequence from wooly mammoth specimens, which was used to estimate the evolutionary divergence between the mammoth and the African elephant).

28. Mary Higby Schweitzer et al., *Soft Tissue and Cellular Preservation in Vertebrate Skeletal Elements from the Cretaceous to the Present*, 274 PROC. ROYAL SOC'Y B 183, 183-97 (2007).

29. Richard Stone, *Fluttering from the Ashes?*, 340 SCI. 19, 19 (2013).

genetic engineering. Revive & Restore, a project of the Long Now Foundation, is sponsoring an effort to revive the passenger pigeon by this method using its living relative, the band-tailed pigeon.[30] Portions of the nuclear and mitochondrial genomes of the passenger pigeon have already been sequenced, for the purpose of analyzing their evolutionary history.[31] Working for the Revive & Restore project, Ben Novak has sequenced roughly half the species' genome from three taxidermy specimens from Troy, New York.[32] If the genes coding for passenger pigeons traits can be spliced into the band-tailed pigeon genome (a step that the project has not yet begun), the eventual result should be band-tailed pigeons that look very much like passenger pigeons. The Revive & Restore project hopes eventually to release its resurrected passenger pigeons to the wild.

Even so, the hybrids will still be band-tailed pigeons, albeit genetically modified band-tails. The point at which this project will have "brought back the passenger pigeon" will be when, in the subjective judgment of the researchers, the genetically engineered birds sufficiently resemble passenger pigeons in appearance that the researchers are ready to declare victory. Moreover, there is little reason to expect that the hybrids would behave like passenger pigeons, massing in enormous flocks, if released into the wild. Gene sequences may be selected for splicing into the band-tail genome to produce distinctive aspects of the passenger pigeon's appearance; however, it may be difficult to impossible to identify the gene sequences responsible for distinctive aspects of passenger pigeon behavior. Moreover, in many bird species, social behavior is largely learned,[33] but young gene-spliced band-tails would have no passenger pigeon adults to learn from.[34] None of which is to say

30. *See* Ben Novak, *DNA Sequencing Starts on "Passenger Pigeon 1871"*, LONG NOW FOUND., http://longnow.org/revive/de-extinction/2013/sequencing-starts-on-passenger-pigeon-1871/ (last visited Oct. 31, 2013).

31. Tara L. Fulton et al., *Nuclear DNA from the Extinct Passenger Pigeon (*Ectopistes migratorius*) Confirms a Single Origin of New World Pigeons*, 194 ANNALS OF ANATOMY 52, 52-57 (2012).

32. Stone, *supra* note 29, at 19.

33. *See generally* SOCIAL LEARNING IN ANIMALS: THE ROOTS OF CULTURE (Cecilia Heyes & Bennett Galef, Jr. eds., 1996).

34. This can also be an issue for living endangered species. Juvenile whooping cranes, originating from a captive breeding program with no experienced elders to learn from, must be taught migration routes by following humans in ultralight aircraft. Thomas Mueller et al., *Social Learning of Migratory Performance*, 341 SCI. 999, 99 (2013) (finding no evidence of a significant genetic effect on the route of the young birds' first southward fall migration).

that passenger pigeon facsimiles created from band-tailed pigeons, or ivory-billed woodpecker facsimiles created from pileated woodpeckers, would not be a fascinating addition to the world, providing the best available opportunity for *de facto* resurrection of vanished species. But they would not truly be the same species as the extinct originals; the extinction clock would not turn back.

The key 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. With approximately 1500 passenger pigeon specimens in collections around the world, genetic material is not lacking for this species.[35] The problem of running the program on the wrong machine also should be less severe; the great majority of the genetically modified band-tails' DNA would, after all, be that of a band-tailed pigeon, a program which should easily be read and run in developing band-tail embryos. The addition of some amount of foreign passenger pigeon DNA may not prove fatal. Nevertheless, the question remains, exactly which passenger pigeon DNA sequences, and how many of them, must be added before the project proponents are satisfied that they have produced a bird that sufficiently resembles their goal. It is possible that the genes for the desired traits cannot be identified and successfully introduced or the resulting birds may not survive to adulthood or, if they do, may not be fertile.

C. *Artificial Selection and "Back-Breeding"*

The third method is artificial selection by selective breeding of individuals of a living species. The experimenter selects and breeds pairs of individuals that have some characteristics resembling those of the extinct species, and repeats the process with their offspring until, after some number of generations, offspring are produced that more closely resemble the extinct form. The key advantage of selective breeding is that it is far more likely to succeed than the laboratory methods of de-extinction, assuming that the source population has the right sort of genetic variation and the breeder has sufficient patience.[36] Again, the object is to produce progeny

35. Stone, *supra* note 29, at 19.

36. In fact, this is how evolution by natural selection works, though without human intervention and over a far longer timescale. Darwin's observations of artificial selection of pigeons and other domestic animals were crucial to his formulation of the theory of evolution by natural selection. *See generally* CHARLES DARWIN, ON THE ORIGIN OF SPECIES BY MEANS OF NATURAL SELECTION, OR THE PRESERVATION OF FAVOURED RACES IN THE STRUGGLE FOR LIFE (Harvard University Press 1964) (1859).

that sufficiently resemble the breeders' goal that they are ready to declare victory. The power of selective breeding to alter the physical forms of organisms can be seen in the enormous range of variation exhibited by domestic dogs: from Shi Tzus to mastiffs, all with modified versions of the ancestral gray wolf genome.[37] Compared to the degree of modification necessary to transform a gray wolf into a Shi Tzu, selectively breeding gray wolf progeny into a semblance of the extinct dire wolf would be a modest task.[38]

The resulting dire wolf facsimiles, however, would remain members of a living species, the gray wolf, modified by selective breeding. Humans have not yet succeeded in producing a new species by artificial selection. Even domestic dogs, despite their extreme variation, all are considered to be a subspecies (*Canis lupus familiaris*) of the gray wolf (*Canis lupus*).[39] Similarly, dire wolf facsimiles and other products of de-extinction by artificial selection would belong to the source species, rather than the same species as the extinct model or a new species.

One form of artificial selection is "back-breeding," referring to the possibility that the living, direct descendants of a recently extinct species, separated by relatively little evolutionary time, may still carry much of the ancestral species' genome.[40] If so, selective breeding among the lines of descendants featuring the most "primitive" traits potentially could create a line whose genome consists of those ancestral traits, more closely approximating the recreation of the extinct genotype. Back-breeding may or may not also utilize genetic technology. If gene sequences characteristic of an extinct species can be identified in individuals of a living descendant, those individuals can be selected for breeding. Alternatively, individuals that resemble the ancestral species may be selected for breeding the old-fashioned way, by appearance. In addition, selective breeding may also be pursued with species that

37. Elaine A. Ostrander & Robert K. Wayne, *The Canine Genome*, 15 GENOME RES. 1706, 1708 (2005).

38. The dire wolf was only about twenty-five percent more massive than the gray wolf, with slightly shorter and sturdier legs and stronger jaws. William Anyonge & Chris Roman, *New Body Mass Estimates for* Canis dirus*, the Extinct Pleistocene Dire Wolf*, 26 J. VERTEBRATE PALEONTOLOGY 209, 210 (2006). Fans of the dire wolves in George R. R. Martin's fantasy novel A GAME OF THRONES (1996), take note.

39. P. Myers et al., THE ANIMAL DIVERSITY WEB (ONLINE) (2013), http://animaldiversity.ummz.umich.edu/accounts/Canis_lupus_familiaris/classification/#Canis_lupus_familiaris (last visited Oct. 31, 2013).

40. Christian Gamborg et al., *Domestication: Ethics at the Intersection of Landscape Restoration and Animal Welfare*, 19 ENVTL. VALUES 57, 57-58 (2010).

are similar to, but not direct descendants of, the extinct target species.

As noted above, two selective breeding projects that have reported some successes involve the quagga, a striking extinct subspecies of zebra which had stripes only on the front of its body, and the aurochs, the extinct ancestor of modern cattle. The Quagga Project has produced foals resembling the quagga's characteristic stripe pattern by selectively breeding plains zebras. In that case, individual zebras are chosen for breeding simply based on their coloration, with existing variation among plains zebras providing the raw material to produce quagga facsimiles.[41] The Tauros Programme is back-breeding extant breeds of cattle considered to represent "primitive" characteristics, seeking to recreate a phenotype resembling the ancestral aurochs.[42] The researchers plan to identify DNA sequences in living cattle breeds that match those found in aurochs specimens, in order to select the appropriate breeds for hybridizing.

D. *Implications of De-Extinction Methodologies*

At this point it is worth noting that we have been grossly oversimplifying the biological species concept.[43] First, *all* species contain considerable genetic variation among their members. Second, the demarcation between species is to some extent arbitrary. In theory, a species is defined by reproductive isolation, i.e., all of its members are capable of breeding with one another and producing fertile offspring, while members of two different species either cannot interbreed or produce infertile offspring.[44] At lower taxonomic levels such as subspecies, there is no such objective criterion. Subspecies are identified based on locally adapted traits but are fertile; if they do interbreed, the local variations will gradually disappear.[45] Even at the species level, however, genetic variation forms a continuum. The category of

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41. THE QUAGGA PROJECT SOUTH AFRICA, *supra* note 15. Living plains zebras are not the descendants of quaggas, so this is not an example of back-breeding.

42. THE TAUROS PROGRAMME, *supra* note 16.

43. For an elucidation of the biological species concept by one of its key originators, see ERNST MAYR, THE GROWTH OF BIOLOGICAL THOUGHT: DIVERSITY, EVOLUTION AND INHERITANCE (1982); *see also* Kevin DeQueiroz, *Ernst Mayr and the Modern Concept of Species*, 102 PROC. OF THE NAT'L ACAD. OF SCI. 6600, 6600-07 (2005).

44. DeQueiroz, *supra* note 43, at 6601.

45. *Gene Flow and the Limits to Natural Selection*, 17 TRENDS IN ECOLOGY & EVOLUTION 183, 184 (2002).

"species" is not really objectively determined, but exists for our convenience of reference. A species is the name we give to a class of individuals exhibiting a certain range of genetic and phenotypic variation.[46]

When we speak of resurrecting a species by SCNT or genetic engineering, we mean extracting nuclei or DNA fragments from one or a few individuals, representing a tiny subset of the former species' range of variation.[47] Thus, in no sense would SCNT or genetic engineering restore an entire extinct species (i.e., its entire original range of variation), only a limited number of individual genotypes. On the other hand, just as an endangered species is still a species if only a few individuals survive, the limited number of genotypes produced by these methods would be the only living representatives from within the former range of variation, which we call a species.[48]

The key points to take away from this discussion, and which will be relevant for the legal analysis which follows, are these: No "resurrected" species would be an *exact* copy of the original extinct species. With all methods, the results will to some degree be *facsimiles* or *likenesses* of the original species. Even with SCNT, the egg (with its mitochondrial DNA) and, if the organism is a mammal, the uterus, would be provided by a different, living donor species. The results of genetic engineering and artificial selection, both starting with a living species that is either genetically modified or selectively bred to resemble an extinct one, are probably best considered either as modified versions of the living species or as something altogether new—but not as extinct species truly brought back from the dead. In the remainder of this Article, we will use the term "facsimile" to refer generally to such individuals which may more or less resemble, but are not exact copies of, their extinct counterparts. For purposes of the law, it may make most sense to treat such facsimiles both as *new* creations altogether (thus implicating patent law, for example) yet also as *recreations*, in a sense. They would not represent the true revival of

46. *See supra* note 43 and accompanying text.

47. Although the 1500 extant passenger pigeon specimens represent a negligible fraction of their former billions, a sample size that large would capture nearly all of the species' genetic variation. However, the pigeon de-extinction project will utilize DNA from a handful of individuals, not all 1500. *See* Stone, *supra* note 29, at 19.

48. Artificial selection is a different case, since it begins with all of the genetic variation in the individuals from the source populations. The range of genetic variation in the resulting new breed would represent a combination of subsets from the source breeds.

an extinct species, but nonetheless would be living representatives of at least a portion of the range of genetic variation that once constituted that species.

A final point that should be emphasized is that the ultimate objective of de-extinction efforts is not to produce laboratory curiosities, but to restore lost species to independent existence in nature. No de-extinction proponent has yet admitted a desire to produce mammoths solely for zoos or Carolina parakeets solely as pets. Rather, the aim of these efforts is to create, release, and reestablish self-sustaining breeding populations in the wild. It is with that goal as the context that we examine the potential applicability of environmental laws such as the Endangered Species Act and the National Environmental Policy Act. Although these laws apply to captive (and even dead) specimens and experimental populations, their fundamental purpose is to protect and enhance the survival of species in the wild.

There are, of course, two essential prior stages in a de-extinction project: first, creation of the resurrected organisms in the laboratory (for de-extinction attempts by SCNT or genetic engineering); and, second, production of a sufficiently large population in captivity necessary to begin introducing offspring into the wild. We address some of the issues raised by these initial stages where appropriate throughout the Article. In most cases, however, the applicable legal requirements will not be substantially different from those for other, more conventional forms of laboratory and captive breeding programs.[49] Accordingly, this Article focuses largely on the more novel legal implications of projects that undertake to return extinct species to the natural environment.

III. THE ENDANGERED SPECIES ACT

The federal Endangered Species Act (ESA) imposes a variety of protections and procedures on activities affecting an "endangered species," defined as "any species which is in danger of extinction

49. *See generally* GUS A. KOEHLER, BIOINDUSTRY: A DESCRIPTION OF CALIFORNIA'S BIOINDUSTRY AND SUMMARY OF THE PUBLIC ISSUES AFFECTING ITS DEVELOPMENT ch. 3 (1996), *available at* http://www.library.ca.gov/crb/96/07/BIOT_CH3.html (discussing the many overlapping federal, state, and local requirements for biotechnology laboratories, including hazardous and toxic materials regulations, fire and safety codes, air pollution regulations, and zoning and land use issues). In addition, the Animal Welfare Act, 7 U.S.C. §§ 2131-59 (2012), governs the ethical maintenance of laboratory animals used for research.

throughout all or a significant portion of its range."[50] These protections and procedures do not apply to any species—and would not apply to a resurrected species—unless the species is listed as endangered by the U.S. Fish and Wildlife Service (FWS) or the National Marine Fisheries Service (NMFS).[51] In this section, we first briefly discuss the ways that the ESA, if and as applicable, could both benefit and complicate attempts to resurrect extinct species and reintroduce them to the wild. The remainder of this section considers the more basic issue of whether and how de-extinct species may be listed as endangered in the first place.

Foremost among the protections of the ESA is the "take" prohibition: it is illegal to "take" an endangered species, except in compliance with an "incidental take permit" (which must include provisions to minimize and mitigate the impacts of the taking) or other authorization.[52] It is also illegal to import or export an endangered species; possess, sell or transport an unlawfully taken endangered species in commercial activity; engage in interstate or foreign commerce in endangered species; or violate any of the regulations implementing the ESA.[53] In addition to these prohibitions, federal agencies have affirmative obligations to help ensure the survival of listed species. FWS and NMFS must designate critical habitat[54] and develop and implement recovery plans for the species.[55] Other federal agencies must consult with FWS and NMFS to insure that the actions they authorize, fund, or carry out are not likely to jeopardize the species' continued existence, or destroy or adversely modify its critical habitat.[56]

Species may be listed as endangered based on a number of factors, including habitat loss, overexploitation, disease or predation, inadequate protection by other regulatory mechanisms, or other natural or artificial factors.[57] The listing process may be

50. 16 U.S.C. § 1532(6) (2012). The ESA also protects "threatened" species, defined as "any species which is likely to become endangered within the foreseeable future throughout all or a significant portion of its range." *Id.* § 1532(19).

51. *Id.* § 1533.

52. *Id.* §§ 1538(a)(1), 1539(a)(1). "Take" is defined as "harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct." *Id.* § 1532(18). Permits to take endangered species for scientific purposes, enhancement of propagation, or survival may be obtained under 50 C.F.R. § 17.22.

53. 16 U.S.C. § 1538(a)(1) (2012).

54. *Id.* § 1533(a)(3).

55. *Id.* § 1533(f).

56. *Id.* § 1536(a)(2).

57. *Id.* § 1533(a)(1).

initiated by FWS or NMFS, or by petition to FWS or NMFS by any person.[58] Accordingly, once a de-extinction project has reached the stage of reintroducing a breeding group of resurrected individuals into the wild, we assume that the project proponents or other environmental advocates may petition to list them as endangered. One may ask why de-extinction researchers would seek such listing, voluntarily subjecting themselves to the permit requirements and other restrictions of the ESA. A listing petition would serve several purposes, seeking directly to protect and help grow the nascent population, and indirectly to promote further de-extinction efforts by drawing attention to the project and bringing in potential public and private support. More fundamentally, obtaining ESA protection for a species that has been newly restored to life would serve the central purpose of the ESA: to provide for the conservation and recovery of species that otherwise would be lost.

A mechanism already exists under the ESA for the reintroduction of experimental populations of endangered species in parts of their former range from which they have been eradicated, which also could be utilized for reintroductions of resurrected species into the wild. This section was added to the ESA in order to provide a degree of regulatory flexibility for management of reintroduced experimental populations, which otherwise might be hindered by the strict protections of the ESA, and also to address concerns of states and local landowners that reintroductions might conflict with established practices of hunting, fishing, livestock grazing, and agriculture.[59]

Special regulations are established for managing experimental

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58. *Id.* Any person may also petition FWS or NMFS to designate critical habitat. 50 C.F.R. § 424.10 (2013). This provision could be utilized to seek critical habitat protection for portions of an extinct species' former range that are essential to its conservation and management. 16 U.S.C. § 1533(b)(2) (2012). A critical habitat petition for the passenger pigeon could be unprecedented in geographic scope, as the species was once distributed in vast flocks throughout North America east of the Rocky Mountains. *See* A. W. SCHORGER, THE PASSENGER PIGEON 257 (1955).

59. 16 U.S.C. § 1539(j) (2012); *see* Endangered and Threatened Wildlife and Plants; Proposed Revision to the Nonessential Experimental Population of the Mexican Wolf, 78 Fed. Reg. 35,719, 35,731 (proposed June 13, 2013) (to be codified at 50 C.F.R. pt. 17) ("Congress enacted the provisions of [16 U.S.C. § 1539(j)] to mitigate fears that reestablishing populations of threatened or endangered species into the wild would negatively impact landowners and other private parties. Congress also recognized that flexible rules could encourage recovery partners to actively assist in the reestablishment and hosting of such populations on their lands . . . ."); *see also* Holly Doremus, *Restoring Endangered Species: The Importance of Being Wild*, 23 HARV. ENVTL. L. REV. 1, 21-25. (1999).

populations.[60] They may be classed as "essential" if their loss would likely reduce the chances of the species' survival in the wild; all other experimental populations are deemed nonessential[61] and receive reduced protection under the ESA, unless they are located within a national park or refuge.[62] Resurrected species would pose a unique case. On the one hand, it would seem they must necessarily be "essential" if considered members (and sole representatives) of the extinct species. If, however, they are considered members of a living species modified to resemble an extinct relative, they would be nonessential to the survival of that living species. For the reasons discussed above, the latter seems to be the more reasonable interpretation for facsimiles produced by the proposed de-extinction methodologies.

A key requirement for reintroduction of an experimental population is that the release location must be "wholly separate geographically from the nonexperimental populations of the same species" in order to avoid interbreeding between the experimental and wild populations.[63] Again, resurrected species produced by any of the three methods would pose a unique case. Since there are no surviving wild populations for the experimental population to interbreed with, they could be located anywhere within the extinct species' historic range. Conversely, passenger pigeons that were genetically engineered from band-tailed pigeons might breed with wild band-tailed pigeons, or artificially selected quaggas might breed with plains zebras, potentially spreading the facsimile's altered traits into populations of the species from which it was derived. Since band-tailed pigeons and plains zebras are not endangered, however, such hybridizing would not pose an ESA issue (though it would constitute a NEPA issue, as discussed in Part IV below).

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60. 50 C.F.R. § 17.81(c) (2013); *see also, e.g.*, *id.* §§ 17.84(c)-(v) (listing special rules for vertebrates, including the red wolf, the southern sea otter, the whooping crane, the gray wolf, the California condor, the Mexican wolf, and the Sonoran pronghorn).

61. *Id.* § 17.80(b).

62. 16 U.S.C. § 1539(j)(C)(i) (2012). To date, FWS has classified all reintroduced experimental populations as nonessential. Doremus, *supra* note 59, at 38.

63. 16 U.S.C. § 1539(j)(2012). Similarly, a permit under 50 C.F.R. § 17.22 is ordinarily required to transfer individuals from an existing donor population of an endangered species into an experimental population. However, there would be no need for such a permit for introducing a resurrected species from the laboratory, when no wild donor population exists.

A. *Applicability of the ESA*

Before a resurrected species may be listed or an experimental population may be established under the ESA, the fundamental question is whether such species can come within the reach of the statute in the first place. Needless to say, the ESA was intended to protect living endangered species. The drafters of the ESA, which was adopted in 1973, could not have anticipated the prospect of de-extinction with twenty-first century genetic technology.[64] Thus, de-extinction presents a classic case of dynamic statutory interpretation, which arises out of a "need for practical accommodation of the [statutory] directive to new circumstances."[65] An "original expected application" approach to statutory interpretation arguably would preclude the statute's applicability to de-extinct species. However, most originalists do not adhere to this approach even in constitutional cases, let alone in statutory cases.[66]

Furthermore, both a textualist and a purposive analysis of the statute seem to demand inclusion of de-extinct species within its scope. On its face the text of the ESA applies to all species that qualify as endangered, with nothing to preclude applicability to those that scientists may be able to resurrect. The central purpose of the statute is to identify, protect, and promote the recovery of precisely those species facing the greatest risk. None has faced greater risk than a species that actually has gone extinct.

One plausible objection to ESA applicability would be that a de-extinct species—more accurately, a facsimile of an extinct species—is inherently artificial, the product of human manipulation in the laboratory or breeding facility. Indeed, to produce the closest approximation of the original extinct species, by SCNT, the most extreme manipulation would be required. We are not aware of anyone proposing ESA listing, for example, for any of the genetically modified organisms (GMOs) that already exist. As one federal judge noted recently, "The development and use of genetically engineered animals for food and ornamental purposes has become a fast-growing industry in recent years."[67]

64. The ESA's drafters potentially could have considered the possibility of artificial selection to produce facsimiles of extinct species. Apparently no one thought of it.

65. WILLIAM N. ESKRIDGE JR., DYNAMIC STATUTORY INTERPRETATION 176 (1994).

66. *See* Richard H. Fallon Jr., *Are Originalist Constitutional Theories Principles, or Are They Rationalizations for Conservatism?*, 34 HARV. J.L. PUB. POL'Y 5, 9-11 (2011).

67. Int'l Ctr. for Tech. Assessment v. Leavitt, 468 F. Supp. 2d 200, 202 (D.D.C. 2007).

Consider GMO crops, genetically engineered for disease-, pest- or pesticide-resistance; or consider the GloFish, a GMO zebrafish into which the gene for a fluorescent protein, originating in a species of jellyfish, has been inserted.[68] These organisms were never intended for release into the wild, though that does not prevent accidental releases from occurring.[69] Suppose that GMO plants or GloFish were to escape, begin breeding and become established, but suffer threats that could cause their extinction (suppose that the plants did not prove as pest-resistant as planned, or that the unlucky GloFish attracted nocturnal predators). The text of the statute might seem to justify ESA listing, but, in our view, it should not be forthcoming in such cases, because the ESA was not intended to provide protection for new organisms invented by human beings *ab initio*.[70]

To reconcile the lack of ESA coverage for GloFish with ESA coverage for de-extinct species, a key distinction may be that the latter (or the species they are intended to recreate) once existed in nature, and that the proponents of de-extinction hope and expect eventually to reintroduce them into the wild. That is precisely the point of resurrecting them. By contrast, GMOs engineered as food or pets never existed before and were never *intended* to be introduced and established in the wild, even though they may be released accidentally.[71] Where the release and reestablishment of self-sustaining breeding populations is the ultimate goal, the artificiality of their origins arguably should not bar ESA protection. Nevertheless, application to a fundamentally artificial organism would be a novel interpretation of the statute.[72]

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68. *Id.*

69. Escaping GMO organisms have become an issue for litigation. In *Monsanto Co. v. Geertson Seed Farms*, 130 S. Ct. 2743 (2010), a plaintiff challenged the deregulation of Roundup Ready alfalfa, an herbicide-resistant GMO, due to concerns about genetic contamination of its own non-GMO alfalfa crop by cross-pollination.

70. Aside from the artificiality of novel GMOs such as the GloFish, their specific but limited genetic distinctiveness might not qualify them as "species" or "distinct population segments" under the ESA. *See infra* Part III.B.

71. If and when someone does announce a project to revive extinct species solely for captivity—such as mammoths for zoos or Carolina parakeets as pets—perhaps these instances should be classed with GloFish and other domesticated exotica as ineligible for ESA listing.

72. There is another policy reason that human genetic manipulation of a species should not be an automatic bar to ESA coverage: it may become necessary to genetically engineer living endangered species using material from "frozen zoos," in order to restore genetic diversity to dwindling populations threatened by inbreeding and prevent the species from becoming extinct. *See supra* note 25 and accompanying text. Presumably doing so should not endanger their ESA listing status.

There is at least one example of a GMO plant created for release into the wild because its non-GMO original has been nearly wiped out by disease: the American chestnut tree. Once, the chestnut constituted twenty-five to fifty percent of the forest trees in the heart of its range in the eastern United States.[73] By 1940, however, between fifty and ninety-nine percent of mature trees were killed by the chestnut blight, a fungus introduced from Asia.[74] In recent years, efforts at cross-breeding with Chinese chestnuts and genetic engineering have produced blight-resistant chestnuts which share fifteen-sixteenths of the American genotype.[75] Since 2006, more than 100,000 of these trees have been planted across nineteen states.[76] The chestnut has not been listed as endangered because numerous sprouts remain; the blight strikes only after the trees attain a certain size. However, if the American chestnut were a listed species, it is unlikely that the effort to save the species by hybridization with the Chinese chestnut would have been deterred by objections that artificial genetic manipulation might deprive them of ESA protection.[77]

Moreover, a broader concept of "artificiality" has already been addressed in applying the ESA to organisms that have *not* been genetically engineered but were bred in captivity—specifically, to hatchery fish. In 1993, NMFS adopted an interim policy on the ESA status of captive-reared Pacific salmon, produced from eggs and sperm collected from wild-caught salmon, raised in hatchery

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73. Robert B. McKinstry, Jr., *Ecosystem Restoration and Federal Land Policy: Reexamination in Light of the American Chestnut Restoration Effort*, *in* RESTORATION OF AMERICAN CHESTNUT TO FOREST LANDS: PROCEEDINGS OF A CONFERENCE AND WORKSHOP 173, 174-75 (Kim C. Steiner & John E. Carlson eds., 2006).

74. *Id.* at 175.

75. *Id.* at 175-76.

76. Heather Haddon, *Hopes for Chestnut Revival Growing*, WALL ST. J. (Aug. 19, 2012), http://online.wsj.com/news/articles/SB10000872396390444233104577593571278706402.

77. A similar example at the subspecies level is provided by the Florida panther, an endangered subspecies of cougar. In 1995, with few individuals remaining and those suffering genetic defects from inbreeding, FWS introduced eight cougars from a Texas population into Florida. By 2010, the population had grown to about one hundred animals and genetic studies demonstrated that the hybrids were healthier than those with the pure Florida panther genotype. *See* Christine Dell'Amore, *Hybrid Panthers Helping Rare Cat Rebound in Florida*, NAT'L GEO. DAILY NEWS, (Sept. 24, 2010), http://news.nationalgeographic.com/news/2010/09/100924-science-florida-panthers-texas-hybrids-endangered-animals/. It is unclear whether any purebred Florida panthers remain at this point; even if so, it may not be long before the pure genotype no longer exists. Yet, despite the replacement of "natural" Florida panthers with "artificial" hybrids, the Florida panther remains on the endangered species list.

facilities, and released to join the wild population.[78] In the interim policy, NMFS concluded that "in general, [hatchery] fish will not be included as part of the listed species."[79] However, after the interim policy was challenged successfully,[80] NMFS changed course and adopted a final policy in 2005 that included hatchery fish when evaluating population stability.[81] Applying the new policy, NMFS reevaluated populations of steelhead (a form of salmon) in the Upper Columbia River, Washington, and downgraded their status from endangered to threatened.[82] Opponents of the decision sued, arguing that NMFS had improperly inflated the numbers of the "natural" populations by adding "artificial" hatchery fish. The Ninth Circuit rejected that claim, upholding both the final policy and the listing decision as consistent with the ESA and entitled to judicial deference.[83] Thus, the artificial origin of the hatchery fish did not exclude them *per se* from the scope of the ESA.[84] On the contrary, the court held, "[c]onsistent with the plain language of the statute, the Hatchery Listing Policy conducts a status review of the entire 'species'—no more, and no less."[85]

B. *Eligibility for ESA Listing*

Assuming then that application of the ESA to de-extinct species is not precluded either by a strict interpretation of legislative intent or by aversion to listing GMOs or "artificial" organisms, could resurrected species in fact qualify for ESA listing by the

78. *See generally* Interim Policy on Artificial Propagation of Pacific Salmon Under the Endangered Species Act, 58 Fed. Reg. 17,573 (Apr. 5, 1993).

79. *Id.* at 17,575.

80. Alsea Valley Alliance v. Evans, 161 F. Supp. 2d 1154, 1161 (D. Or. 2001).

81. Policy on the Consideration of Hatchery-Origin Fish in Endangered Species Act Listing Determinations for Pacific Salmon and Steelhead, 70 Fed. Reg. 37,204, 37,215 (June 28, 2005).

82. Final Listing Determinations for Ten Distinct Population Segments of West Coast Steelhead, 71 Fed. Reg. 834, 834 (Jan. 5, 2006) (codified at 50 C.F.R. pts. 223 & 224).

83. Trout Unlimited v. Lohn, 559 F.3d 946, 957 (9th Cir. 2009).

84. For a detailed discussion of the background and issues regarding the policy change and the downgrading of the Columbia River steelhead listing, see Andrew Long, *Defining the "Nature" Protected by the Endangered Species Act: Lessons from Hatchery Salmon*, 15 N.Y.U. ENVTL. L.J. 420 (2007).

85. *Trout Unlimited*, 559 F.3d at 957. As for the downgrading of steelhead to threatened status, the court concluded that the petitioner and NMFS were "engaged in a good faith disagreement that is supported by science on both sides; indeed, the amicus brief filed in this case argues that there is no scientific consensus concerning the relationship between hatchery and natural fish." *Id.* at 956. Under those circumstances, the court deferred to NMFS as the expert regulatory agency charged with making listing decisions.

statute's terms? To spell those out in more detail, a species may be listed as endangered based on: "(A) the present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence."[86]

The claim may be made that having only recently returned from extinction, the resurrected species remains in danger of it. Its initially small population size, if nothing else, would appear to affect the species' prospect of continued existence sufficiently to satisfy factor (E). Resurrected individuals initially confined to the laboratory or breeding facility could not be said to have a "habitat or range" per factor (A). But once released into the wild (which, as noted above, is the basic aim of de-extinction projects), any of the factors could come into play, depending on the species and the circumstances: habitat at risk, overutilization, disease or predation, insufficient regulatory protection, or other factors. For example, fungal disease and over-collection for scientific purposes have been suggested as causes of the gastric-brooding frog's extinction.[87] Resurrected and reintroduced into their original habitat, the frogs likely would face the same fungal disease. If, unlike the gastric-brooding frog, the species became extinct long ago, much of its former habitat may have been lost to human activity and development. Meanwhile, its food supply may also have disappeared, its remaining habitat may have been colonized by other species occupying the same ecological niche, or novel predators, diseases, and parasites may since have developed or been introduced. Climate change could also be a factor, both anthropogenic and natural (*e.g.,* the range potentially available to woolly mammoths has shrunk considerably since the Ice Age). Moreover, newly resurrected species presumably would be unprotected by existing regulatory mechanisms, absent ESA listing.

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86. 16 U.S.C. § 1533(a)(1) (2012). Such threats *to* a resurrected species could provide the basis for listing under the ESA. Conversely, threats *from* a resurrected species would be considered under NEPA. S*ee infra* Part IV.A.

87. *See* Convention on International Trade in Endangered Species of Wild Fauna and Flora [hereinafter CITES], Sixteenth Meeting of the Conference of the Parties, Consideration of Proposals for Amendment of Appendices I and II, Mar. 3-15, 2013, *available at* http://www.cites.org/eng/cop/16/prop/index.php (suggesting that fungal disease was the most likely culprit and proposing to de-list the gastric-brooding frog from protection under the CITES trade convention, on the ground that there is no trade in this extinct species).

Finally, all de-extinct organisms will be threatened by a crucial "other natural or manmade factor": even as their numbers increase, their low genetic diversity, originating from one or a few individuals created in the laboratory or by selective breeding, will put them at serious long-term risk of accumulating genetic defects as the result of inbreeding.

Assuming that such facts support designating resurrected organisms as "endangered," would they constitute a "species" for purposes of the ESA? The statute's definition of "species" provides that lower taxonomic units are also treated as species under the act: "'species' includes any subspecies of fish or wildlife or plants, and any distinct population segment of any species of vertebrate fish or wildlife which interbreeds when mature."[88] The term "species" itself is, however, effectively undefined.[89]

As a threshold issue, some have questioned whether a single resurrected genotype (whether in a single individual or in a number of clones created from a single genotype) by SCNT or genetic engineering can constitute a "species."[90] For purposes of the ESA, the answer is yes. FWS has listed a species of plant, the Franciscan manzanita, which consists of a single known individual. This species had last been seen in 1947 and was thought to be extinct for over six decades, when a biologist spotted a single manzanita growing in the wild in San Francisco in 2009 (as it

88. 16 U.S.C. § 1532(15) (2012).

89. In 1996, FWS and NMFS proposed a policy for ESA listing of "intercrosses" which might have provided a model for treatment of de-extinct species produced by genetic engineering or artificial selection. Endangered and Threatened Wildlife and Plants; Proposed Policy and Proposed Rule on the Treatment of Intercrosses and Intercross Progeny, 61 Fed. Reg. 4710 (1996) (Feb. 7, 1996) (proposed to be codified at 50 C.F.R. pt. 424). The proposed policy defined an "intercross" as a hybrid between an endangered and a non-endangered species, including both cases of natural inter-breeding between related species and intentional hybridization to restore genetic diversity to inbred species such as the cheetah. *See id.* at 4710-11. Such intercrosses would have been eligible for ESA listing if the progeny more closely resembled the endangered parent species than an intermediate between the two parental species. *Id.* at 4711. Intercrosses produced in captivity would have been eligible for ESA listing if they were produced as part of an approved recovery plan, in order to compensate for lost genetic viability in the listed parent species due to human activity. *Id.* at 4711-12. In such cases, ESA protection could apply to the intercrosses both while in captivity and after release to the wild. *Id.* at 4712. As for GMOs, the proposed policy provided that "organisms resulting from genetic engineering experiments that use genetic material from listed species" could be listed themselves only if "such organisms are produced for the purpose of recovery of the listed species in accordance with an approved recovery plan." *Id.* The proposed policy was never finalized.

90. Sherkow & Greely, *supra* note 3, at 32. This issue would not apply to facsimiles created by artificial selection, such as aurochs, which would have greater genetic diversity.

happened, in the path of the Presidio Parkway project; the plant has since been relocated).[91] In effect, the manzanita's rediscovery is a "natural" case of de-extinction. In September 2012, FWS listed the species as endangered and published a proposed rule to designate several hundred acres of parks and open space in San Francisco as its critical habitat.[92] Additional individuals propagated from cuttings of the single Franciscan manzanita are being cultivated in botanic gardens and may be introduced into the parks in the future, but all of those plants will be genetically identical clones.[93] Thus, the lack of genetic diversity in species revived in the laboratory should not preclude ESA listing.[94]

The ESA also addresses instances of "similar species": a nonlisted species may be treated as endangered if it "so closely resembles in appearance" a listed species "that enforcement personnel would have substantial difficulty in attempting to differentiate between the listed and unlisted species."[95] This provision raises an interesting possibility: if a nonlisted living

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91. Peter Fimrite, *Manzanita Bush's Discovery Excites Scientists*, SAN FRANCISCO CHRONICLE (Dec. 26, 2009), http://www.sfgate.com/bayarea/article/Manzanita-bush-s-discovery-excites-scientists-3204961.php; *San Francisco's Namesake Shrub Protected—The Franciscan Manzanita Is an Endangered Species*, U.S. FISH & WILDLIFE SERV. (Sept. 5, 2012), http://www.fws.gov/sacramento/outreach/2012/09-05%20I/outreach_newsroom_2012-9-5.htm.

92. Determination of Endangered Status for Arctostaphylos franciscana (Franciscan Manzanita) Throughout its Range, 77 Fed. Reg. 54,434, 54,435-36 (Sept. 5, 2012) (to be codified at 50 C.F.R. pt. 17); *see generally* Designation of Critical Habitat for Franciscan Manzanita, 77 Fed. Reg. 54,517 (Sept. 5, 2012) (to be codified at 50 C.F.R. pt. 17).

93. 77 Fed. Reg. at 54,435. FWS also noted that a few living specimens survive in botanical gardens, descended from plants collected prior to 1947, when the last manzanita was seen in the wild. However, the cultivated plants have different morphological features and may have different genotypes. These plants are considered protected "until further genetic work can be conducted," *id.* at 54,437, but they may lose that protection if they prove to have diverged too greatly from the wild type. Therefore, their existence does not alter the fact that FWS listed a species consisting of a single known individual.

94. Of course, while a single asexually-reproducing plant can produce offspring, a single sexually-reproducing animal cannot. Thus, courts have held that single, isolated wolves do not constitute a listable "population." Wyo. Farm Bureau Fed'n v. Babbitt, 199 F.3d 1224, 1234 (10th Cir. 2000); United States v. McKittrick, 142 F.3d 1170, 1175 (9th Cir. 1999). FWS has defined a minimum population size as at least two breeding pairs of gray wolves that each successfully raise at least two young in each of two consecutive years. *See* discussion in Removing the Gray Wolf (Canis lupus) From the List of Endangered and Threatened Wildlife and Maintaining Protections for the Mexican Wolf (Canis lupus baileyi) by Listing it as Endangered, 78 Fed. Reg. 35,664, 35,675 (June 13, 2013) (to be codified at 50 C.F.R. pt. 17). While the gray wolf cases and proposed rule apply to one species only, they further support the suggestion that a very small number of resurrected individuals, representing a very limited range of genetic diversity, should not disqualify a population from ESA coverage.

95. 16 U.S.C. § 1533(e) (2012).

species were genetically engineered or artificially selected into a facsimile of an extinct species—thus so closely resembling the extinct species as to make differentiation difficult—it should then be treated as a listed species, *if* the extinct species were itself listed. However, this situation is unlikely to occur, as ordinarily the extinct species will not itself be listed; a listed endangered species should be delisted once it is determined to have become extinct.[96]

Of the three de-extinction methods surveyed above, individuals produced by SCNT would most clearly constitute a species under the ESA. Of course, it would be impossible to know whether the cloned individuals would have been able to interbreed with their extinct counterparts which are no longer available as potential mates. Nevertheless, they would be close facsimiles, almost entirely within the range of genetic variation of the extinct species that provided their nuclear DNA (though with a much smaller amount of mitochondrial DNA from the host egg species). Thus, there would be a strong case for endangered species status for the Pyrenean ibex or the gastric-brooding frog, were they to be resurrected successfully.

C. *Eligibility for Listing as a Distinct Population Segment*

Turning to the other two methods, it seems difficult to argue for ESA listing of species resurrected by genetic engineering or artificial selection as examples of either the extinct species or a "new" species. As discussed above, they are mere facsimiles of the extinct species. Arguably, they are new, in that the facsimiles never existed before. Nevertheless, beneath the surface resemblance, and the limited number of genotypic traits they have been engineered to share with passenger pigeons, the band-tailed pigeons would remain largely band-tails, with most of their genome within the range of variation of the band-tail. As such, they might be considered to constitute a distinct population segment (DPS) under the ESA—but not a DPS of the extinct species. Instead, the logical implication is that a flock of "resurrected passenger pigeons" could potentially qualify for ESA listing, if at all, not as passenger pigeons, but as a DPS of the band-tailed pigeon.

96. 50 C.F.R. § 424.11(d)(1) (2013). This provision states that "a sufficient period of time must be allowed before delisting to indicate clearly that the species is extinct" but that period is unlikely to be long enough to genetically engineer another species to resemble it. Thus, this intriguing application of the similar species rule is likely to remain merely theoretical.

The ESA treats as a species "any distinct population segment of any species of vertebrate fish or wildlife which interbreeds when mature."[97] FWS and NMFS rarely list species as DPS, in accordance with language in a Senate Report instructing that the designation be used sparingly.[98] In 1996, FWS and NMFS promulgated a policy for DPS listing.[99] The policy declared three elements to be important in listing a DPS for protection:

> 1. Discreteness of the population segment in relation to the remainder of the species to which it belongs; 2. The significance of the population segment to the species to which it belongs; and 3. The population segment's conservation status in relation to the Act's standards for listing (i.e., is the population segment, when treated as if it were a species, endangered or threatened?).[100]

Regarding the first element, a population may be "discrete" if it is "markedly separated from other populations of the same taxon as a consequence of physical, physiological, ecological, or behavioral factors."[101] Band-tailed pigeons engineered into facsimiles of passenger pigeons, or cattle back-bred into facsimiles of aurochs, necessarily would be "discrete" from other populations of band-tails or cattle in some or all of these ways.

Regarding the second, a population is "significant" based on considerations including, but not limited to, four factors, one of which is critical here: "evidence that the discrete population segment differs markedly from other populations of the species in its genetic characteristics."[102] By definition, both genetically

97. 16 U.S.C. § 1532(16) (2012).

98. *See generally* Policy Regarding the Recognition of Distinct Vertebrate Population Segments Under the Endangered Species Act, 61 Fed. Reg. 4722 (Feb. 7, 1996). NMFS has also adopted a controversial policy, applicable only to west coast salmon species, in which a population (or group of populations) is considered to be "distinct" for ESA purposes if it represents an evolutionarily significant unit (ESU) of the biological species. An ESU is defined as a population that is substantially reproductively isolated from other populations of the same species and represents an important component of the evolutionary legacy of the species. Policy on Applying the Definition of Species Under the Endangered Species Act to Pacific Salmon, 56 Fed. Reg. 58,612, 58,618 (Nov. 20, 1991); *see also* Long, *supra* note 84, at 433.

99. Distinct Vertebrate Population Segments, 61 Fed. Reg. at 4722-25.

100. *Id.* at 4725.

101. *Id.* A "taxon," or taxonomic unit, in this case refers to a species or subspecies. *Id.* at 4722.

102. *Id.* at 4725. The other three elements probably do not apply in the context of resurrected species: persistence of the population in an "unusual or unique" ecological

engineered and selectively bred facsimiles will differ markedly from the genetic characteristics of the rest of their species.

Regarding the third, the population's conservation status in relation to the ESA listing standards will depend on the circumstances in each case. However, the ESA listing standards likely would not be hard to satisfy, as discussed above, based on factors such as small numbers of individuals, susceptibility to habitat loss, disease and over-collection, low genetic diversity and inbreeding, which would justify listing the population as endangered if were a species.[103]

More generally, the ESA's broad purpose of preserving biological diversity would tend to support listing resurrected species' DPSs as endangered. As FWS and NMFS have acknowledged, the ESA's DPS and other provisions support the "interrelated goals of conserving genetic resources and maintaining natural systems and biodiversity over a representative portion of their historic occurrence."[104] Accordingly, notwithstanding the generally sparing use of DPS designations, the listing of resurrected species as DPSs may be viewed as consistent with both the terms and the purpose of the DPS policy, even though this specific application could not have been contemplated.[105]

In sum, the text and purpose of the ESA may be interpreted as qualifying resurrected species for listing, even though they are facsimiles rather than true revivals of extinct species. Although the facsimiles would not be identical to their extinct counterparts, they do not need to be in order to qualify as species or as DPSs (albeit of the living relative rather than the extinct species itself). The greater objection would be that they are artificial creations. Still, the statute on its face appears to cover *any* endangered species

setting; evidence that loss of the population would result in a significant gap in the range of the species or subspecies; and evidence that the population represents the only surviving natural occurrence of a taxon that may be more abundant elsewhere.

103. *Id.*

104. *Id.* at 4723.

105. Although, as discussed above, facsimiles may represent a DPS of the species from which they were engineered or bred, it should also be noted that they would still satisfy the three policy elements if they were considered as a DPS of the extinct species they resemble. Considered as passenger pigeons, the facsimile populations would be both discrete and significant (there are no other populations of passenger pigeons) and would satisfy the ESA listing standards, for the reasons discussed above. Note that none of this discussion applies to species resurrected by SCNT which would be virtually, though not entirely, identical to the extinct species from which their nuclear DNA originated.

breeding in the wild, whether or not that species has been genetically modified, if only because it did not occur to the drafters that there might be a need to exclude GMOs. Fundamentally, the purpose of the ESA is to protect and restore species most at risk. Recreating and reintroducing close facsimiles of extinct species seems not so very different from rediscovering them, as happened with the Franciscan manzanita.

IV. NATIONAL ENVIRONMENTAL POLICY ACT

In addition to listing and authorization for establishing an experimental population under the ESA, a variety of federal, state, and local permits and approvals would be required for a de-extinction project, implicating the environmental impact review requirements of the National Environmental Policy Act (NEPA)[106] and equivalent state laws.

NEPA applies to "major" federal actions "significantly affecting the quality of the human environment."[107] These include actions that federal agencies undertake themselves (such as physical construction projects; making land management decisions; and adopting rules, programs, plans and policies) and also state, local or private projects for which federal agencies provide funding, lease federally owned property, issue permits or licenses, or otherwise provide approvals or authorizations.[108] Before a federal agency decides to undertake a project, provide funds, or issue an authorization, it must first consider the environmental impacts of its actions.[109]

As such, NEPA review would be required for a de-extinction project that is federally funded, undertaken at a federal laboratory or breeding facility, or is intended to release and attempt re-establishment of the species on federal land. As discussed in Part V, below, federal permit requirements apply to releases of certain categories of genetically modified organisms (GMOs). Even for

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106. 42 U.S.C. § 4321 (2012). The Council on Environmental Quality has promulgated regulations implementing NEPA at 40 C.F.R. § 1500. In addition, as provided in 40 C.F.R. §§ 1505.1, 1507.3, each federal agency has adopted its own NEPA implementation procedures which must be consulted in determining the appropriate environmental review process for projects undertaken or authorized by that agency.

107. 42 U.S.C. § 4332(c) (2012). A major federal action is one "with effects that may be major and which are potentially subject to Federal control and responsibility." 40 C.F.R. § 1508.18 (2013).

108. *Id.* § 1508.18.

109. *Id.* §§ 1502.4, 1502.5.

private de-extinction projects that are not federally funded or housed in a federal laboratory and would not release animals on federal land, federal permits or approvals may be required for specific project activities, such as captive propagation of listed species.[110] In addition, should the project proponents or others successfully petition to list the resurrected species as endangered under the ESA, a federal rulemaking would be required to designate an experimental population for release in the wild, and its subsequent management may be subject to ESA permitting requirements.[111] Each of these actions requires NEPA review.

NEPA does not dictate particular outcomes; rather, it requires agency decision-makers to be fully informed about environmental consequences before making decisions.[112] Such consequences are very broadly defined, however, and preparing the requisite Environmental Impact Statement (EIS) to evaluate the proposed action, alternatives, and mitigation measures in order to support fully informed decision is a substantial undertaking.[113]

The "lead agency" responsible for making the decision is also responsible for conducting NEPA review: for example, FWS for ESA permitting and experimental population rules and the U.S. Forest Service, Bureau of Land Management, or National Park Service, for authorizing use of lands managed by those agencies, etc.[114] The lead agency may begin by performing a limited review

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110. Until recently, FWS policy allowed take of certain captive nonnative species, including the scimitar-horned oryx, addax, and dama gazelle, without a permit. This policy was revoked in January 2012. *See* Endangered and Threatened Wildlife and Plants; Removal of Regulation that Excludes U.S. Captive-Bred Scimitar-Horned Oryx, Addax, and Dama Gazelle from Certain Prohibitions, 77 Fed. Reg. 431, 431 (Jan. 5, 2012); *see also* Endangered and Threatened Wildlife and Plants; 12-Month Findings on Petitions to Delist U.S. Captive Populations of the Scimitar-Horned Oryx, Dama Gazelle, and Addax, 78 Fed. Reg. 33,790, 33,797 (June 5, 2013) (declining to remove captive populations from endangered species list).

111. Note, however, that members of a species that are born in captivity before the species is listed as endangered will not become subject to ESA permitting requirements if that species is subsequently listed. *See Permits for Native Species Under the Endangered Species Act*, U.S. FISH & WILDLIFE SERV., (Mar. 2013), *available at* http://www.fws.gov/endangered/esa-library/pdf/permits.pdf.

112. Robertson v. Methow Valley Citizens Council, 490 U.S. 332, 350 (1989).

113. Impacts considered under NEPA include direct ecological effects (e.g., on natural resources and on the components, structures, and functioning of affected ecosystems), aesthetic, historic, cultural, economic, social, or health effects, and indirect effects including growth-inducing impacts, the consequences of changes in land uses, population density or growth rate, and related effects on air, water, ecosystems and other natural systems. 40 C.F.R. § 1508.8 (2013).

114. *Id.* § 1508.16.

in the form of an environmental assessment (EA).[115] If the EA demonstrates that the action will not cause significant environmental impacts, the agency may make a finding to that effect (a Finding of No Significant Impact (FONSI)) and terminate its review.[116] If, however, the EA indicates that significant impacts will occur, a full EIS must be prepared.[117] First, the lead agency publishes a notice of intent to do so in the Federal Register, soliciting comments from other federal, state and local agencies, Native American tribes, and the public on the scope of issues to be addressed in the EIS (referred to as "scoping").[118] The lead agency then prepares a Draft EIS and releases it for a public comment period of at least 45 days.[119] The agency must consider and respond to all substantive comments in the Final EIS, which may include revisions in response to comments or explanations as to why comments do not warrant revisions.[120] When complete, the Final EIS is issued a minimum of 30 days before the agency may make a final decision; the public may submit additional comments during this period.[121] Other federal agencies issuing their own permits, licenses, and approvals for the same project will rely on the EIS prepared by the lead agency, and any consultation and analyses required for such actions under other laws (such as the ESA) must be coordinated "[t]o the fullest extent possible" with the EIS process.[122]

Similar state laws, sometimes referred to as "little NEPAs," apply to decision-making by state and local governments.[123]

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115. *Id.* § 1508.9.

116. *Id.* § 1501.4. An agency may decide to skip the EA step and proceed directly to a full EIS. *Id.* § 1501.3(a).

117. 42 U.S.C. § 4332(c) (2012); 40 C.F.R. § 1502 (2013).

118. 40 C.F.R. § 1501.7 (2013).

119. *Id.* § 1506.10(c).

120. *Id.* § 1503.

121. *Id.* §§ 1505.2, 1506.10(b)(2).

122. *Id.* § 1502.25.

123. Seventeen states and the District of Columbia have adopted environmental impact review statutes similar to NEPA. *See* ARK. CODE ANN. § 8-1-101 (2013); CAL. PUB. RES. CODE §§ 21000–21177 (West 2013); CONN. GEN. STAT. §§ 22a-1 to 22a-1i (2013); D.C. CODE §§ 8-109.01 to 8-109.11 (2013); FLA. STAT. § 380.92 (2013); GA. CODE ANN. §§ 12-16-1 to 12-16-8 (2013); HAW. REV. STAT. §§ 343-1 to 343-8 (2013); IND. CODE §§ 13-12-4-1 to 13-12-4-10 (2013); MD. CODE ANN., NAT. RES. §§ 1-301 to 1-305 (West 2013); MASS. GEN. LAWS ch. 30, §§ 61 to 62H (2013); MINN. STAT. §§ 116D.01 to 116D.11 (2013); MONT. CODE ANN. §§ 75-1-101 to 75-1-324 (2013); N.Y. ENVTL. CONSERV. LAW §§ 8-0101 to 8-0117 (McKinney 2013); N.C. GEN. STAT. §§ 113A-1 to 113A-13 (2013); S.D. CODIFIED LAWS §§ 34A-9-1 to 34A-9-13 (2013); VA. CODE ANN. §§ 10.1-1188 to 10.1-1192 (2013); WASH. REV. CODE §§ 43.21C.010 to 43.21C.914 (2013); WIS. STAT. § 1.11 (2013).

Environmental review may be required under an applicable state statute, e.g., for a project funded by a state agency or undertaken at a state university facility. In addition, permits or approvals from state or local agencies may be required in order to maintain wild or nonnative animals in captivity and/or to release them.[124] For example, Connecticut, New York, and Wisconsin require permits for captive endangered, threatened and nonnative species,[125] while California, New York, and Wisconsin require permits in order to release them to the wild.[126] In states with such statutes applicable to such permitting decisions, state environmental impact review of de-extinction projects would be required before the requisite permits could be obtained.

The little NEPAs vary considerably from one another and from NEPA in applicability, procedure, and substantive requirements. Given these differences, we have focused on NEPA itself in this Article. However, in conducting environmental review of any project in a state with a little NEPA statute, its specific provisions must be carefully considered. For example, in contrast to NEPA, which requires federal agencies to make fully informed decisions but does not require them to actually avoid or reduce impacts, the California Environmental Quality Act requires state and local agencies to adopt alternatives or mitigation measures that will actually avoid or reduce significant environmental impacts if it is feasible to do so.[127]

A. *NEPA Review of Endangered Species Reintroductions*

What impacts would be considered in the environmental review of a de-extinction project? As one possible model, we can look to EISs and EAs prepared for captive breeding and release

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124. Whether, for permitting purposes, facsimiles of extinct species that once were indigenous to the state should be considered "non-native" or a potential danger would be among the novel questions posed by de-extinction efforts.

125. N.Y. ENVTL. CONSERV. LAW § 11-0511 (McKinney 2013) (requiring a permit to possess endangered or threatened species and any other species the state finds would present a danger to health or welfare of people or indigenous wildlife); WIS. STAT. § 169.04 (2013) (requiring a permit to possess native wild species with specified exceptions, nonnative species and "harmful wild animals"); CONN. AGENCIES REGS. § 26-55-6(b)(5) (2013) (requiring a permit to possess endangered or threatened species).

126. N.Y. ENVTL. CONSERV. LAW § 11-507 (McKinney 2013) (requiring a permit to liberate wildlife within the state); WIS. STAT. § 169.06 (2013) (requiring a permit for the release of a wild animal); 14 CAL. CODE REGS. tit. 14, § 671.6 (2013) (requiring a permit to release animals which are not native, diseased or genetically detrimental to agriculture or native wildlife).

127. CAL. PUB. RES. CODE § 21081 (West 2013).

programs for living endangered species. These analyses have focused primarily on the impacts of removing individuals from the wild for breeding, and on the impacts of reintroducing their progeny on the environment and on the wild population. For example, EAs for breeding programs for the Florida panther and Mount Graham red squirrel evaluated the risk that reintroducing captive-bred individuals could spread disease in wild populations (though in both cases FWS found that impacts would be insignificant).[128] While the wild populations of extinct species no longer exist, reintroduction of their facsimiles could have such impacts on wild populations of the living species from which they were derived. Given that band-tailed pigeons genetically engineered to resemble passenger pigeons would largely retain the band-tail genome, it would not be surprising if wild band-tails were susceptible to diseases they might carry, or if cattle and zebras were afflicted by diseases borne by resurrected aurochs and quaggas. For example, in at least one case, there is evidence that animals from captive breeding programs may cause unintended harm to endangered populations in the wild: endangered brush-tail rock wallabies raised in captive breeding programs carry gut bacteria with antibiotic resistance genes, and released animals may transmit these genes into wild populations.[129]

Another model may be found in NEPA reviews for projects that relocate living endangered species from one area into another, attempting to restore them to areas from which they were extirpated. FWS has prepared EISs[130] or EAs[131] for a number of

128. *See* U.S. FISH & WILDLIFE SERV., DRAFT ENVIRONMENTAL ASSESSMENT: ESTABLISHMENT OF A CAPTIVE BREEDING PILOT PROGRAM FOR THE ENDANGERED MOUNT GRAHAM RED SQUIRREL (2010), *available at* www.fws.gov/southwest/es/arizona/Documents/SpeciesDocs/MGRS/Draft%20EA_Captive%20MGRS_09102010_final.pdf; U.S. FISH & WILDLIFE SERV., A PROPOSAL TO ESTABLISH A CAPTIVE BREEDING POPULATION OF FLORIDA PANTHERS: DRAFT SUPPLEMENTAL ENVIRONMENTAL ASSESSMENT (1991).

129. Michelle L. Power, et al., *Into the Wild: Dissemination of Antibiotic Resistance Determinants via a Species Recovery Program*, PLOS ONE (May 22, 2013), http://www.plosone.org/article/info:doi/10.1371/journal.pone.0063027; *see Captive-Bred Wallabies May Carry Antibiotic-Resistant Bacteria into Wild Populations*, SCI. DAILY (May 22, 2013), http://www.sciencedaily.com/releases/2013/05/130522180307.htm.

130. U.S. FISH & WILDLIFE SERV., REINTRODUCTION OF THE MEXICAN WOLF WITHIN ITS HISTORIC RANGE IN THE SOUTHWESTERN UNITED STATES: FINAL ENVIRONMENTAL IMPACT STATEMENT (1996) [hereinafter MEXICAN WOLF EIS], *available at* http://www.fws.gov/southwest/es/mexicanwolf/pdf/mw_eis.pdf; U.S. FISH & WILDLIFE SERV., REINTRODUCTION OF GRAY WOLVES TO YELLOWSTONE NATIONAL PARK & CENTRAL IDAHO: FINAL ENVIRONMENTAL IMPACT STATEMENT (1993) [hereinafter GRAY WOLF EIS], *available at* http://www.fws.gov/mountain-prairie/species/mammals/wolf/eis_1994.pdf;

such projects, including reintroductions of the gray wolf, Mexican wolf (a subspecies of the gray wolf), sea otter, Sonoran pronghorn, whooping crane, and California condor to parts of their former historic ranges. Some of these projects, in particular the reintroduction of gray wolves to Yellowstone National Park and central Idaho, have been major successes. Thus, release and reintroduction of species into their former habitat is not an unprecedented practice.

In each of these cases, the relocation projects were undertaken by FWS itself, often on federal land, thus triggering NEPA review.[132] In addition, in each case, the reintroduced animals were classified as a nonessential experimental population, limiting the protections of the ESA as discussed above.[133] In general, these NEPA reviews examined the impacts that reintroduction might

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U.S. FISH & WILDLIFE SERV., FINAL ENVIRONMENTAL IMPACT STATEMENT FOR TRANSLOCATION OF SOUTHERN SEA OTTERS (1987) [hereinafter SEA OTTER EIS].

131. U.S. FISH & WILDLIFE SERV., FINAL ENVIRONMENTAL ASSESSMENT FOR REESTABLISHMENT OF SONORAN PRONGHORN (2010) [hereinafter PRONGHORN EA], *available at* http://www.fws.gov/southwest/es/arizona/Documents/SpeciesDocs/SonoranPronghorn/Sonoran_Pronghorn_Final_EA%2010.06.2010c.pdf; U.S. FISH & WILDLIFE SERV., FINAL ENVIRONMENTAL ASSESSMENT: PROPOSED REINTRODUCTION OF A MIGRATORY FLOCK OF WHOOPING CRANES IN THE EASTERN UNITED STATES (2001) [hereinafter WHOOPING CRANE EA], *available at* http://library.fws.gov/EA/whoopingcrane_east01.pdf; U.S. FISH & WILDLIFE SERV., DRAFT ENVIRONMENTAL ASSESSMENT, RELEASE OF CALIFORNIA CONDORS AT THE VERMILION CLIFFS (1996) [hereinafter CONDOR DEA]; U.S. FISH & WILDLIFE SERV., FINAL ENVIRONMENTAL ASSESSMENT FOR REESTABLISHMENT OF THE NORTHERN APLOMADO FALCON IN NEW MEXICO & ARIZONA (JUNE 2006) [hereinafter FALCON EA].

132. For example, in 1995, FWS released gray wolves in Yellowstone National Park and Central Idaho, and in 1998, the agency released Mexican wolves into the Apache-Sitgreaves National Forest in Arizona and the Blue Range Wilderness Area in New Mexico.

133. *See, e.g.*, CONDOR DEA, *supra* note 131, at 54; WHOOPING CRANE EA, *supra* note 131, at 12; MEXICAN WOLF EIS, *supra* note 130, ch. II, at ii; GRAY WOLF EIS, *supra* note 130, ch. II, at 1. As with releases of hatchery fish, *see supra* note 83 and accompanying text, reintroductions of experimental populations to portions of the species' former range have been criticized as in some sense artificial, *see* Doremus, *supra* note 59, at 3. For example, in the EA for a project reintroducing the Northern Aplomado Falcon, some commenters objected to the "loss of recreational benefits resulting from replacement of high-valued wild falcons with released caged birds." FALCON EA, *supra* note 131, at 46. FWS responded:

> We expect that only a very small percentage of the public would view reintroduced falcons as "released caged birds." These would likely be bird watchers who would not want to add a reintroduced falcon to their birding lists. From the public comments we received, we believe that the great majority of the public would observe these falcons with interest and enthusiasm, and they would be expected to be indistinguishable from wild falcons in appearance and behavior except for a possible leg band.

Id.

have on the population from which the relocated animals were taken, the risks to the relocated animals themselves, and the effects they may cause in their new habitat. However, their utility as models for de-extinction projects may be somewhat limited by their emphasis on impacts that the species in question may have on human activities, rather than the environment in general. This focus is consistent with the purpose of the ESA's experimental population provisions, which were intended both to provide a degree of regulatory flexibility for management of reintroduced populations and to reassure states and landowners regarding potential impacts to established uses of public and private lands such as hunting, fishing, livestock grazing, and agriculture.[134]

For example, the sea otter EIS considered both impacts on the donor population from removing individuals for relocation and risks to the otters in the new location from fishing, navy weapons testing, and oil spills. While those effects were found to be insignificant, the EIS also determined that relocated otters would cause major declines in abundance of their prey species and could affect commercial fishery populations.[135] The gray wolf EIS primarily examined impacts of wolf predation on livestock and wild prey populations and impacts on human land use and economic activities such as ranching and hunting.[136] The Mexican wolf EIS similarly focused on impacts of wolf predation on wild and domestic prey, ranching, and hunting.[137] The condor DEA evaluated impacts on livestock grazing and sport hunting, as well as predation by condors on other listed or special status species.[138] The EA for reintroduction of the Sonoran pronghorn (a grazing ungulate) identified restrictions on human land uses such as cattle grazing, farming, and recreation as the key impacts to be examined, though it also considered impacts on vegetation and other special status species.[139]

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134. *See supra* note 59 and accompanying text. It is also consistent with the terms of NEPA, which applies to actions "significantly affecting the quality of the *human* environment." 42 U.S.C. § 4332(c) (2012) (emphasis added).

135. SEA OTTER EIS, *supra* note 130, at 8-9.

136. GRAY WOLF EIS, *supra* note 130, ch. I, at 7-12. Reintroduction of predators such as wolves, raising fears of harm to livestock and humans, has been especially controversial. *See, e.g.*, Nicholas Podsiadly, *Howl of the Wolf or Bark of the Bureaucrat? The Endangered Species Act, the Future of North American Wolf Reintroduction Efforts and the Dilemma of Delisting*, 9 DRAKE J. AGRIC. L. 123, 124 (2004).

137. MEXICAN WOLF EIS, *supra* note 130, ch. I, at 7-10.

138. CONDOR DEA, *supra* note 131, at 5.

139. PRONGHORN EA, *supra* note 131, at 44-48.

B. *NEPA Review of GMO Introductions*

Another source of useful models for NEPA review of de-extinction projects may be found in reviews of the potential environmental impacts of introducing genetically modified organisms (GMOs) as crops or pesticides. Several courts have required NEPA review for agency decisions that authorize such introductions.[140] One prominent example, which led to a Supreme Court decision, is worth exploring in some detail.

Under the Plant Protection Act (PPA),[141] GMO versions of a variety of virus, bacteria, fungus, plant, and animal (mainly insect) species are presumed to be regulated as plant pests, unless the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) formally determines that they do not present a plant pest risk (referred to as a determination of "nonregulated status").[142] While introducing regulated GMOs into the environment requires a permit,[143] GMOs granted nonregulated status may be planted without restriction under the PPA. APHIS' determinations of nonregulated status are subject to NEPA review.

Monsanto v. Geertson Seed Farms[144] concerned the determination of non-regulated status for "Roundup Ready" alfalfa, a controversial GMO form of alfalfa resistant to the herbicide Roundup. Use of the GMO alfalfa enables farmers to apply higher concentrations of the herbicide for weed control purposes, without harming the alfalfa crop. After APHIS prepared an EA supporting its decision, plaintiffs sued, arguing that a full EIS was needed to evaluate the risks that the herbicide resistance gene would spread to "natural" alfalfa crops and that applying higher herbicide concentrations could result in selection for Roundup-resistant weeds. The trial court agreed, and APHIS proceeded to prepare an EIS, declining to appeal that holding.[145] After completing the EIS,

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140. *See, e.g.*, Ctr. for Food Safety v. Johanns, 451 F. Supp. 2d 1165 (D. Haw. 2006); Del. Audubon Soc'y v. U.S. Dep't of Interior, 612 F. Supp. 2d 442 (D. Del. 2009).

141. 7 U.S.C. §§ 7711-22 (2012).

142. 7 C.F.R. §§ 340.2, 340.6 (2013). A petition for non-regulated status of a GMO must, among other things, "[d]escribe known and potential differences from the unmodified recipient organism that would substantiate that the regulated article is unlikely to pose a greater plant pest risk than the unmodified organism from which it was derived . . . ." *Id.* § 340.6(c)(4).

143. *Id.* § 340.4; see *infra* Part V regarding regulation of GMOs. The definition of "introduce" includes release into the environment. 7 C.F.R. § 340.1 (2013).

144. 130 S. Ct. 2743 (2010).

145. *Id.* at 2751. Once APHIS conceded the need to prepare an EIS, the subsequent decisions by the Ninth Circuit and Supreme Court were limited to the proper scope of

APHIS again found that Roundup Ready alfalfa was not a plant pest and granted nonregulated status, and the EIS was upheld by the Ninth Circuit.[146]

In the final EIS, APHIS concluded that there was a low probability of adverse impacts from the introduction of Roundup Ready alfalfa. Based on the available scientific evidence, the probability of the resistance gene spreading to other alfalfa crops was low and Roundup-resistant weeds were unlikely to develop. The introduced genes would not spread by hybridization with other plant species, because no wild species closely related to alfalfa exist in the United States. The EIS also compared the biological traits of GMO and non-GMO alfalfa, and found no traits in the latter that might cause it to become invasive and displace other species. The GMO alfalfa was not toxic, allergenic, or nutritionally harmful to any wildlife (including endangered species) that might feed on it. Increased use of the Roundup herbicide in conjunction with Roundup Ready alfalfa would be expected to harm other plants (as it was intended to do). However, Roundup is considered less environmentally adverse than other herbicides used with alfalfa and its impacts would be mitigated by compliance with EPA restrictions on use of herbicides.[147]

APHIS reached similar conclusions in an EIS for Roundup Ready GMO sugar beets.[148] In addition, in February 2013, APHIS issued a notice of intent to prepare an EIS for GMO freeze-tolerant eucalyptus.[149] As explained in the notice, the genetically

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injunctive relief while NEPA review was pending. *Id.* at 2752.

146. Ctr. for Food Safety v. Vilsack, 718 F.3d 829 (9th Cir. 2012). Interestingly, the Ninth Circuit determined that the impacts of cross-pollination affecting natural alfalfa crops or increased pesticide use were not the types of effects that could support classifying Roundup Ready alfalfa as a plant pest under the PPA. *Id.* at 840-41.

147. U.S. DEP'T OF AGRICULTURE, ANIMAL & PLANT HEALTH INSPECTION SERV., FINAL ENVIRONMENTAL IMPACT STATEMENT FOR ROUNDUP READY ALFALFA (2010), http://www.aphis.usda.gov/biotechnology/alfalfa_eis.shtml. The analysis of environmental impacts is summarized in the EIS Executive Summary at iv-viii.

148. U.S. DEP'T OF AGRICULTURE, ANIMAL & PLANT HEALTH INSPECTION SERV., RECORD OF DECISION: GLYPHOSATE-TOLERANT EVENT H7-1 SUGAR BEET: PETITION FOR NONREGULATED STATUS (2012), http://www.aphis.usda.gov/brs/aphisdocs/03_32301p_feis_rod.pdff. The analysis of environmental impacts is summarized in the Record of Decision at 9-14.

149. *See generally* ArborGen Inc.; Availability of Petition, Notice of Intent to Prepare an Environmental Impact Statement for Determination of Nonregulated Status of Freeze Tolerant Eucalyptus Lines, and Notice of Virtual Public Meetings, 78 Fed. Reg. 13,308 (Feb. 27, 2013) [hereinafter ArborGen NOI]; *see also* CTR. FOR FOOD SAFETY, GENETICALLY ENGINEERED TREES: THE NEW FRONTIER OF BIOTECHNOLOGY 44 (2013) (discussing the current GMO eucalyptus proposal and prior NEPA litigation on field trial plantings).

engineered change will increase the range of the species, requiring analysis of potential environmental impacts and plant pest risks that may result from large-scale plantings, including impacts on local hydrology and fire ecology, altered susceptibility to disease or insects, direct and indirect effects on wildlife and habitats, as well as the potential of the GMO trees to become invasive.[150]

C. *NEPA Review of De-Extinction Projects*

NEPA documents prepared for reintroductions of living endangered species or releases of GMOs may prove somewhat useful as models, as discussed above. Considering the reintroduction of resurrected species, however, adds a far greater level of uncertainty to the analysis of environmental impacts.

Wolves, sea otters, condors, and whooping cranes still exist and a great deal of information about them is available. Indeed, these species are intensively studied precisely because they are endangered. The effects of reintroducing them to areas where they have long been absent cannot be predicted with complete certainty. They may bring, or be exposed to, unexpected diseases, or may turn to novel prey unavailable elsewhere, with unexpected impacts on other species that depend on that prey. Even though they are being restored in a part of their historic range, if they have long been absent, it will no longer be the same ecosystem they are returning to, and other species may have occupied their ecological niche. Nevertheless, despite the uncertainties, living endangered species are very well known and the environmental consequences of reintroducing them are predictable to a considerable extent.

GMO releases represent a greater degree of uncertainty. GMO crops such as Roundup Ready alfalfa and sugar beets, or freeze-tolerant eucalyptus, do not exist in nature and have never before existed. They are intended to be grown under relatively controlled conditions as agricultural crops, rather than intentionally released to establish unsupervised, self-sustaining breeding populations in the wild. But substantial concerns have been raised regarding the novel risks that GMOs may pose. In particular, NEPA documents for GMO crops have focused on the risks of their escape from agricultural confines with potential impacts on the species from which they were genetically modified as well as other species and

150. ArborGen NOI, 78 Fed. Reg. at 13,311.

habitats.[151]

Resurrected species, in most cases, would represent a still greater unknown. Aurochs have been extinct for many centuries. Even for quaggas and passenger pigeons, which became extinct in the nineteenth and early twentieth centuries, respectively, the best information available is not even close to what is known about wolves and condors using modern scientific methods. More important, facsimiles fashioned by combining extinct and living species through genetic methods, or even by selective breeding, are not truly recreations of species that were reasonably well known to nineteenth-century science, but something that never before existed.[152] The absence of information about newly resurrected species could be partly addressed by observations in the course of the captive breeding program, while building up sufficient numbers in captivity before beginning to release individuals.[153] However, behavior in captivity is an inherently imperfect predictor of behavior in the wild. Thus, the artificiality and novelty of de-extinction legitimately may enhance the concern with unlikely but potentially catastrophic outcomes.

For these reasons, NEPA review of captive breeding programs for resurrected species necessarily will raise a wider set of issues than that of captive breeding programs for living endangered species, and NEPA review for reintroductions of resurrected species will raise broader issues than that of reintroductions of living endangered species. We lack sufficient knowledge for accurate prediction of a resurrected species' behavior if restored to its former range, including its interactions with the other species. These effects may be categorized broadly as the direct effects on other species, direct and indirect effects on the ecosystem, and direct and indirect effects on humans. For example, uncontrollable proliferation is the concern frequently mentioned for resurrected passenger pigeons.[154] More generally, resurrected

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151. *See supra* Part IV.B.

152. The exceptions would be thoroughly studied endangered species that recently became extinct, like the Pyrenean ibex and gastric-brooding frog.

153. For example, 104 captive condors and 6 wild condors (captive-bred survivors of a previous release attempt) existed in 1995 when FWS developed its condor release plan. CONDOR DEA, *supra* note 131, at 1-2. One-hundred and twenty whooping cranes existed in captive breeding centers and 264 in the wild in 2001 when FWS undertook a crane release project. Endangered and Threatened Wildlife and Plants; Establishment of a Nonessential Experimental Population of Whooping Cranes in the Eastern United States, 66 Fed. Reg. 33,903, 33,905 (June 26, 2001).

154. Stone, *supra* note 29, at 19. Even if a resurrected passenger pigeon were

species may outcompete or displace the species that replaced them, or cause habitat destruction or disrupt food chains in ecosystems established since their time. They may act as vectors for the spread of diseases and parasites. The regions they inhabit may be more vulnerable to disruption now, as a result of human development, climate change, and the disappearance of habitat and other species, while their historic range may no longer contain habitat that is suitable for them. Just as unintended cross-pollination may occur between GMO and unmodified crops, unintended cross-breeding may occur between genetically modified facsimiles and the species from which they were derived, potentially further spreading their altered traits. Finally, as discussed in the EISs and EAs for endangered species reintroductions referenced above, resurrected species reintroductions could have consequences for the human environment, including impacts on livestock and commercial fisheries, on agriculture and recreational uses, and even on the safety of humans (especially should anyone attempt the resurrection of potential human predators such as dire wolves).[155]

Nevertheless, we are not entirely without resources for evaluating these and other potential consequences of releasing facsimiles of extinct species into the contemporary world. To some extent, environmental impact review is always an exercise in prediction of uncertain risks and outcomes. More important, facsimiles would be physically and genetically closest to the living species from which they were modified.[156] Band-tailed pigeons are

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intended for captive or domestic propagation only, rather than reintroduction, the risk of accidental releases must be evaluated. *See supra* note 69 and accompanying text.

155. It should be noted that FWS has adopted a categorical exclusion from NEPA which, in theory, could apply to reintroductions of resurrected species if they were considered as "native." *See* National Environmental Policy Act Revised Implementing Procedures, 62 Fed. Reg. 2375, 2381 (Jan. 16, 1997) (making a categorical exclusion for "the reintroduction or supplementation (e.g., stocking) of native, formerly native, or established species into suitable habitat within their historic or established range, where no or negligible environmental disturbances are anticipated"). Even though extinct species were once native to their former range, resurrected species that are facsimiles rather than exact recreations arguably would not qualify as "native" for this purpose. Moreover, while projects subject to a categorical exclusion ordinarily do not require an EIS or EA, there are exceptions to the exclusions, e.g., if environmental disturbances are anticipated or there is "significant controversy over the environmental effects of the proposal." *Id.* at 2382. Significant controversy is not unlikely in the case of a de-extinction project, for the reasons discussed in the paragraph above.

156. Again, the exception would be species resurrected by SCNT which would most closely resemble the extinct donor of the nuclear DNA. However, as discussed above, if the method works at all, its use will likely be limited to recently extinct species that are

well known to modern science, as are cattle and plains zebras. As discussed in the survey of methods in Part II, there is little reason to expect that band-tailed pigeons engineered to resemble passenger pigeons would also reproduce the characteristics of the passenger pigeon other than its appearance. If anything, they should more closely resemble band-tailed pigeons in their biology and behavior.

Based on information available on the band-tail, reasonable, science-based analysis of the facsimile passenger pigeon's likely biology and behavior should be possible. It is true that novel genes would be inserted into the facsimiles, and it is possible that those genes could result in resurrected passenger pigeons as prolific as their extinct model, with devastating impacts on North American agriculture and other wildlife. But it is not likely. Although many genes have multiple functions, it would be a highly unlikely coincidence if genes spliced into the band-tailed pigeon genome to make it resemble a passenger pigeon would also code for mass flocking behavior. It would be still more unlikely for the resulting birds, produced in the laboratory and released in small experimental populations, to succeed in establishing themselves as the ultimate invasive species.

The NEPA regulations provide methods for dealing with uncertainties due to incomplete or unavailable information.[157] If complete information cannot be obtained, because the costs of obtaining it are unreasonable or (more relevant here) the means to obtain it are unknown, the EIS must state that information is incomplete or unavailable, explain the ways in which it would be relevant to evaluating reasonably foreseeable significant impacts, and provide both a "summary of existing credible scientific evidence" and "the agency's evaluation of such impacts based upon theoretical approaches or research methods generally accepted in the scientific community."[158] NEPA also allows for analysis of "catastrophic consequences" with low probability of occurrence, provided that the analysis "is supported by credible scientific evidence, is not based on pure conjecture, and is within the rule of reason."[159] Within these guidelines, based on

thoroughly studied, so that the consequences of their resurrection and reintroduction will be more predictable.

157. 40 C.F.R. § 1502.22 (2013).

158. *Id.*

159. *Id.* This regulation replaced a prior requirement for "worst-case" analysis that was revoked by the Council on Environmental Quality in 1986, on the ground that it was

information available both from the living egg donor species and from the captive-bred population of the resurrected species before attempting to release and reestablish it in the wild, it should be possible to prepare a reasonably supportable EIS that evaluates the likely and unlikely impacts of de-extinction projects and enables the informed decision-making required by NEPA.

V. GMO REGULATION

In the United States, several legal regimes exist for the regulation of GMOs. As discussed above, facsimiles of extinct species produced by SCNT or genetic engineering will be GMOs and as such will be subject to any applicable GMO regulation.[160] At the federal level, GMO regulations follow the principles laid out in the Coordinated Framework for the Regulation of Biotechnology, issued in 1986 by the Executive Office of the President's Office of Science and Technology Policy.[161] The Framework details statements of policy from a number of federal agencies including the Food and Drug Administration, Environmental Protection Agency, Department of Agriculture, Occupational Safety and Health Administration, and National Institutes of Health. These statements focus mostly on genetically engineered foods, medicines (including vaccines and hormones), and pesticides.

The Framework recognizes that "existing laws available for the regulation of products developed by traditional genetic manipulation techniques . . . address regulatory needs adequately."[162] As such, there is no overarching federal law regulating GMOs, but a variety of specific regulations. Any relevance to de-extinction would depend on the applicability of those specific regulations. For example, if a GMO resurrected species were to be used for food, then the relevant GMO regulations regarding food would apply.[163]

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inconsistent with the general "rule of reason" followed in preparing impact analyses in EISs. The Supreme Court upheld the revocation of the worst-case analysis rule in *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 354 (1989).

160. The discussion in this section would not apply to species produced by artificial selection.

161. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (June 26, 1986).

162. *Id.* at 23,302.

163. Use of resurrected species as human food is not an impossible scenario; for example, passenger pigeons were edible. Alexis Madrigal, *Pigeons: The Next Step in Local Eating (No, Really)*, WIRED.COM (July 18, 2008), *available at* http://www.wired.com/wiredscience/2008/07/does-pigeon-mea/ (citing EDWARD HOWE

One journalist recently described this Framework, its complexities, and its potential problems:

> The web of regulations used to govern genetically engineered species draws on more than 10 laws, all written for other purposes. Some were crafted to address issues such as tainted drugs, wheat spiked with sawdust and pollution by industrial chemicals. The results can be odd. Atlantic salmon that grow quickly thanks to a growth hormone gene from another salmon species are deemed "new animal drugs" because the Food and Drug Administration decided to regulate genetically engineered animals under the Food, Drug and Cosmetic Act of 1938. A cotton plant that makes insect-killing proteins with the help of a gene from a soil bacterium is a pesticide in the eyes of the Environmental Protection Agency, which regulates the crop under the Federal Insecticide, Fungicide and Rodenticide Act of 1972.
>
> In what some critics deem the biggest contortion, many genetically modified crops are classified as "potential plant pests" so that the U.S. Department of Agriculture may preside over them through the Federal Plant Pest Act of 1957—even though the key traits added to the plants have nothing to do with pests. Some crops are regulated by more than one agency: A corn plant engineered to kill insects, for example, is reviewed by the EPA and USDA and also gets a voluntary assessment from the FDA.[164]

Permits and notifications are required to introduce into the environment GMOs regulated as potential plant pests and for the use of GMOs as pesticides.[165] Issuance of permits and regulated

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FORBUSH, *Passenger Pigeon: Ectopistses Migratorius (Linnaeus)*, *in* GAME BIRDS, WILD-FOWL AND SHORE BIRDS 433 (1917)). In the late nineteenth century, the American bison (or "buffalo") verged on extinction, see Dean Lueck, *The Extermination and Conservation of the American Bison,* 31 J. LEGAL STUD. S609, S610 (2002), but today its meat is available for human consumption, *see, e.g.*, *Cooking with Bison*, THEBISONCOUNCIL.COM, http://thebisoncouncil.com/cooking-with-bison#bison-basics (last visited Dec. 3, 2013).

164. Rosie Mestel, *Genetic Modification Strains Old Food and Drug Laws*, L.A. TIMES (Mar. 23, 2013), http://articles.latimes.com/2013/mar/23/science/la-sci-gmo-regulations-20130324. A survey of federal regulation of GMOs as food, pesticides, or drugs is provided in PEW INITIATIVE ON FOOD & BIOTECHNOLOGY, GUIDE TO U.S. REGULATION OF GENETICALLY MODIFIED FOOD & AGRICULTURAL BIOTECHNOLOGY PRODUCTS (2001), *available at* http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Food_and_ Biotechnology/hhs_biotech_0901.pdf.

165. 7 C.F.R. § 340.4 (2013) (permits for introduction into the environment of GMOs regulated as potential plant pests); 40 C.F.R. § 172 (2013) Subparts A and B (federal and state experimental use permits for pesticides, including GMOs) and Subpart C (special notification requirements for GMO microbial pesticides).

status determinations are subject to NEPA review.[166] As discussed above, NEPA evaluations of regulatory decisions under these programs can raise a variety of direct and indirect environmental impacts such altered susceptibility to disease or pests and effects on wildlife and habitats.[167]

At the federal level, then, resurrected species that are GMOs may be subject to permit requirements as plant pests or pesticides, if they fall within the scope of regulations governing agricultural uses. Absent such uses, however, there is no general federal law or regulation that would automatically apply by virtue of the species' recreation using genetic technology. By contrast, at the state and local levels, resurrected species may be subject to a range of laws and regulations that apply generally to "GMOs" without specifying particular uses (such as food, pesticides, etc.). Some of these regulations may apply to the process of recreating facsimiles of extinct species in the laboratory as well as to their release. In fact, under some local anti-GMO ordinances, laboratory experiments on de-extinction would seem to be flatly prohibited. We examine here a few examples of ordinances taken from California cities to illustrate the kinds of regulations that GMOs—and thus species resurrected by GMO technologies—may face generally.

Three California county ordinances expressly ban GMOs from the county; there appears to be no discretion to permit the creation or use of GMOs.[168] Two of the counties make GMOs a *per se* public nuisance and provide for their removal or destruction by the county.

In Marin County's ordinance, the findings and purposes section explicitly references the introduction of GMOs into the marketplace and potential risks to consumers.[169] Nevertheless, the text of the ordinance is sweepingly broad, banning *all* GMOs except those that will be used only in enclosed, licensed medical facilities.[170] GMOs are defined as "an organism, or the offspring of an organism, the DNA of which has been altered or amended

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166. *E.g.*, 7 C.F.R. § 372 (2013) (providing details about NEPA review for permitting or acknowledgment of notifications for GMO releases).

167. *See* ArborGen NOI, *supra* note 149 and text accompanying note 150.

168. MARIN CNTY., CAL., CODE OF ORDINANCES §§ 6.92.010–6.92.050 (2013); MENDOCINO CNTY., CAL., CODE OF ORDINANCES §§ 10A.15.010–10A.15.040 (2013); TRINITY CNTY., CAL., CODE OF ORDINANCES §§ 8.25.010–8.25.140 (2013).

169. MARIN CNTY. § 6.92.010.

170. *Id.* §§ 6.92.020, 6.92.030.

through genetic engineering."[171] Organism is further defined as "any living thing, exclusive of human beings and human fetuses."[172] Thus, genetically engineered facsimiles of extinct species would fall under this definition of organism. It appears that in Marin County, then, the creation as well as the release and reestablishment of resurrected species is prohibited.

Mendocino County has an ordinance similarly aimed at food products, contained in the agriculture title of the county code. The language, however, is again sweepingly broad, banning the propagation, cultivation, raising, or growing of GMOs. GMOs are defined as "specific organisms whose native intrinsic DNA has been intentionally altered or amended with non-species specific DNA" but not including "organisms created by traditional breeding or hybridization, or to microorganisms created by moving genes or gene segments between unrelated bacteria."[173] Scientists are thus prohibited altogether from even conducting laboratory experiments on de-extinction using GMO technologies in Mendocino County.

Trinity County's ordinance places enforcement responsibility with the agricultural commissioner.[174] But again, the ordinance sweepingly defines GMOs as "any organism or the offspring of an organism the DNA of which has been altered or amended through genetic engineering," where organism "means any living thing, exclusive of human beings and human fetuses."[175] The prohibition is itself sweeping: "It is unlawful for any person to propagate, cultivate, raise, or grow genetically engineered organisms in Trinity County, and any act in violation of this provision is declared to constitute a public nuisance."[176] Creating or releasing resurrected species would therefore constitute a nuisance *per se* in Trinity County.

Proponents of de-extinction projects by SCNT or genetic engineering should be mindful of the possibility of such local restrictions, as well as federal regulations that would apply to

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171. *Id.* § 6.92.040.

172. *Id.*

173. MENDOCINO CNTY. § 10A.15.020. Under this definition, which excludes traditional breeding and hybridization, resurrected species produced by artificial selection would be expressly exempted from the GMO category. While not explicit, the same generally would be true under other definitions of GMOs.

174. TRINITY CNTY., CAL., CODE OF ORDINANCES § 8.25.070 (2013).

175. *Id.* § 8.25.040.

176. *Id.* § 8.25.030.

resurrected species produced for agricultural uses. Nevertheless, throughout most of the United States, there is no general prohibition or regulation of GMOs as such.

VI. PATENT LAW

We turn finally to the last of the questions raised at the beginning of this Article: would resurrected species be patentable? This is no minor issue. Even where the ultimate goal is release and reestablishment of the species (or facsimiles) in the wild, projects could generate considerable value. 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. Moreover, there could be a market for resurrected species as pets, not unlike the market for exotic animals, though as noted above, no de-extinction project proponent has yet announced an attempt to exploit this potential opportunity.

The leading American case on patenting living organisms is *Diamond v. Chakrabarty*.[177] In that case, Chakrabarty, a microbiologist, genetically engineered bacteria to break down components of crude oil. While the patent office allowed claims to a process for creating the bacteria, it denied claims for the bacterium itself on grounds that microorganisms are "products of nature" and that living things are not patentable.[178]

The Supreme Court disagreed. The Court began by citing 35 U.S.C. § 101, the statutory authority for granting patents: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."[179] Citing precedent, the Court then defined "manufacture" as "the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery" and further defined "composition of matter" to include "all compositions of two or more substances and . . . all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or

177. 447 U.S. 303 (1980).
178. *Id.* at 305-06.
179. *Id.* at 307 (citing 35 U.S.C. § 101 (2012)).

solids."[180] Finally, the Court noted that "Congress plainly contemplated that the patent laws would be given wide scope" and that the committee reports accompanying the statute indicated that Congress intended to include within this scope "anything under the sun that is made by man."[181] Not included within the statute's scope, however, were the "laws of nature, physical phenomena, and abstract ideas."[182] Thus, a natural phenomenon that is merely discovered, such as a new plant found in a rainforest (or, for that matter, the Franciscan manzanita rediscovered in San Francisco), is not patentable. By contrast, Chakrabarty had not merely discovered a natural phenomenon; he had created a bacterium that was a "nonnaturally occurring manufacture or composition of matter—a product of human ingenuity 'having a distinctive name, character, [and] use,'" which therefore could be patented.[183]

The Court in Chakrabarty distinguished another leading case, *Funk Brothers Seed Co. v. Kalo Inoculant Co.*[184] There, the patentee had merely discovered the existence in nature of a group of bacteria that could inoculate seeds of certain plants, enabling them to fix nitrogen from the air. The bacteria infect specific plant species and generally inhibit one another, so they cannot be combined. However, the patentee discovered a set of bacteria that were not mutually inhibitory and could be used with a wider range of plants. The Court concluded that his discovery was a product of nature, reasoning that:

> No species [of the bacteria] acquires a different use. The

180. *Id.* at 308.

181. *Id.* at 308-09 (citing S. Rep. No. 1979, at 5 (1952); H.R. Rep. No. 1923, at 6 (1952)).

182. *Id.* at 309.

183. *Id.* at 309-10. Regarding the last criterion—a distinctive "use"—Chakrabarty's bacteria had a specific, commercial *use*: the breakdown of oil components which could be used to clean up oil spills. De-extinct facsimiles intended for release and re-establishment in the wild would not be *useful* in quite the same way; rather, they would represent a human attempt to return nature to a more original condition. In that sense, resurrected species might seem more like the rediscovery of a natural phenomenon, or recreation of what was previously a natural phenomenon, which would not be patentable. On the other hand, arguably, there is a "use" to restoring part, or a facsimile of part, of the world's lost biodiversity. Moreover, resurrecting extinct animals for more conventional pecuniary gain, for exhibition or as pets, remains a possibility. These uses need not be exclusive. For example, charismatic species such as mammoths could be exhibited in a Pleistocene Park for the dual purposes of restoring biodiversity and selling tickets.

184. 333 U.S. 127 (1948).

> combination of species produces no new bacteria, no change in the six species of bacteria, and no enlargement of the range of their utility. Each species has the same effect it always had. The bacteria perform in their natural way. Their use in combination does not improve in any way their natural functioning. They serve the ends nature originally provided and act quite independently of any effort of the patentee.[185]

In contrast, Chakrabarty had "produced a new bacterium with markedly different characteristics from any found in nature," and his discovery "is not nature's handiwork, but his own."[186]

Although *Chakrabarty* itself applied to microorganisms, in 1987 the Board of Patent Appeals reversed an examiner's holding that oysters genetically engineered to be polyploid (rather than diploid), so that they could be harvested and edible year-round, were not patent eligible.[187] The Board reversed on the grounds that the *Chakrabarty* Court had upheld the patenting of living organisms created by man.[188] Following this case, the Patent and Trademark Office (PTO) issued a notice that henceforth the office would examine "claims to multicellular living organisms, including animals."[189] The PTO stated, "To the extent that the claimed subject matter is directed to a non-human 'nonnaturally occurring manufacture or composition of matter—a product of human ingenuity' (*Diamond v. Chakrabarty*), such claims will not be rejected under 35 U.S.C. 101 as being directed to nonstatutory subject matter."[190]

Applying *Chakrabarty*'s reasoning to facsimiles of resurrected species, it seems clear that, in at least some cases, the facsimiles are *not* products of nature but are manmade in the strictest sense, thus falling within Congress's intent to include "anything under the sun that is made by man" in the scope of patent law. A resurrected species—that is, the species itself, not just the process of creating it—is the "result of human ingenuity and research" rather than a natural phenomenon.[191] Moreover, even species resurrected by the

185. *Chakrabarty*, 447 U.S. at 310 (citing *Funk*, 333 U.S. at 131).

186. *Id.*

187. *Ex Parte* Allen, 2 U.S.P.Q.2d 1425 (B.P.A.I. Apr. 3, 1987).

188. *Id.*

189. Animal Legal Def. Fund v. Quigg, 932 F.2d 920, 923 (Fed. Cir. 1991) (quoting U.S. Patent & Trademark Office Patent Notice 134, Apr. 7, 1987, *available at* http://www.uspto.gov/ web/patents/ patog/week52/OG/TOCCN/item-134.htm).

190. *Id.*

191. *See id.* at 313.

SCNT method would not be exact copies or recreations of the extinct species donating the nuclear genome, since the mitochondrial genome would be that of the living species donating the egg.[192] A court might conclude that this distinction would not suffice for SCNT-resurrected species to satisfy the standard of "markedly different characteristics from any found in nature" as expressed in *Chakrabarty*. Facsimiles produced by genetic engineering, however, would be still more "markedly different" products of human ingenuity, whose nuclear genome would be neither that of the extinct species nor the living egg donor species, but a human-created combination of the two, never before found in nature.[193] Moreover, they would be distinctive compared to any existing product of nature, because the products of nature which they superficially resemble are extinct. By contrast, facsimiles of extinct species produced by artificial selection are no different in principle from any other domestic breed, e.g., of cattle or dogs. While genetic techniques and gene markers utilized in animal breeding can be patented,[194] it does not appear that modification by conventional selective breeding—utilizing genetic variation that exists in nature—is generally considered sufficiently "non-naturally occurring" to be patentable.[195]

Alternatively, opponents of patenting resurrected species (or competing sellers of Carolina parakeets) might focus on the intent to recreate a naturally-occurring phenomenon, the original extinct species, as closely as possible. The whole point of the exercise is to produce a semblance of nature that is not too visibly distinctive in character. In rebuttal, proponents of patenting resurrected species would reply, their resemblance to the extinct species is literally skin-deep (while at the same time those proponents would be emphasizing the surface similarities in announcing that they had succeeded in "bringing back" an extinct species). Thus, a court would have to decide whether the surface similarity or underlying genetic distinctiveness is more fundamental to determining whether the resurrected species is naturally occurring or the

192. *Supra* notes 19 and 20 and accompanying text.

193. *Supra* note 29 and accompanying text.

194. *See, e.g.*, M.F. Rothschild et al., *Patenting in Animal Breeding and Genetics*, WORLD ASSOCIATION OF ANIMAL PRODUCTION BOOK OF THE YEAR 2003, 272-74 (2003).

195. In one sense, selective breeding is no more "natural," and no less the result of human ingenuity, than genetic engineering. However, it is certainly more familiar, having been practiced for thousands of years. Only the goal (e.g., selectively breeding cattle to resemble extinct aurochs rather than to produce more milk) is novel, not the method.

product of human ingenuity.

The *Chakrabarty* decision was revisited in a recent and high-profile case on the patent eligibility of isolated DNA sequences.[196] In the decision below, the Federal Circuit discussed how "markedly" different a product must be from that found in nature to be patentable.[197] The court held that the isolated DNA sequences (consisting of a specific sequence of nucleotides, removed from the chromosome in which that sequence is naturally found) are *not* found in nature and are patentable. That the sequences ultimately derived from nature was not determinative, because all compositions of matter are derived from nature. The Supreme Court disagreed, however, holding that "the claims understandably focus on the genetic information encoded" in the isolated sequences, and that simply severing them from other sequences to which they normally are attached does not make them inventions.[198] Thus, the Court found that the isolated sequences were not different from those in nature.

Conversely, the Court determined, a sequence consisting only of the functional coding portions of an isolated gene, with the non-coding "intron" sequences removed, was a patentable invention because intron-less sequences are not naturally occurring. Thus even the modest modification of removing the introns—without in any way altering the coding portions of the gene—was sufficient to establish patent eligibility.[199] Inserting genetically functional, appearance-altering sequences from an extinct species into a living one would be a more extensive manipulation than merely deleting the introns, thus qualifying as an invention under this standard.

By contrast, under Canadian patent law, resurrected species would not be patentable. Section Two of Canada's Patent Act defines an invention in terms almost identical to those of U.S. law: an invention "means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter."[200] However, the Canadian Supreme Court

196. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2116 (2013).

197. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 689 F.3d 1303, 1327-28 (Fed. Cir. 2012).

198. *Myriad Genetics*, 133 S. Ct. at 2118.

199. *Id.* at 2119.

200. Patent Act, R.S.C. 1985, c. P-4, § 2 (Can.).

held that the "Harvard oncomouse"—genetically engineered to carry cancer genes for the purpose of medical studies—could not be patented because it was a higher life form.[201] While acknowledging that the patenting of lower life forms such as bacteria is accepted in Canada, the court concluded that *higher* life forms are not mere "compositions of matter," because they are "generally regarded as possessing qualities and characteristics that transcend the particular genetic material of which [they are] composed."[202] In distinguishing between higher and lower life forms, the court focused on the fact that human beings cannot be patented (the same is true in U.S. law)[203]. The Canadian decision is, however, of limited utility to a U.S. court, not only because it is outside the jurisdiction but because the oncomouse itself, notwithstanding its "higher" status, was patented in the United States in 1988 and has been patented in dozens of other countries.[204]

Before concluding this section, it should be noted, even *if* a subject matter is patentable, that does not mean a patent will be granted. An invention or creation must also be new and nonobvious to be patented. Because issues already discussed arise under this topic as well, we touch on them only briefly. First, the requirement for nonobviousness is laid out in 35 U.S.C. §103:

> "A patent for a claimed invention may not be obtained . . . if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains."

Given the effort necessary to create facsimiles of extinct species in the laboratory, not to mention the novelty of the attempt in the first place, it seems reasonably obvious that they are nonobvious.

Second, the requirement for novelty is laid out in 35 U.S.C. §102: "A person shall be entitled to a patent unless the claimed invention was patented, described in a printed publication, or in

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201. Harvard Coll. v. Canada (Comm'r of Patents), [2002] 4 S.C.R. 45 (Can.).

202. *Id.* para. 177.

203. *See* U.S. Patent & Trademark Office Patent Notice 134, Apr. 7, 1987 ("A claim directed to or including within its scope a human being will not be considered to be patentable subject matter under 35 U.S.C. 101."), *available at* http://www.uspto.gov/web/patents/patog/week52/OG/TOCCN/item-134.htm#cli134.

204. *Harvard College*, [2002] 4 S.C.R. 45 para. 2 (McLachlin, C.J., dissenting).

public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention." In other words, one cannot patent something that existed as part of the "prior art." This is the obverse of the distinctiveness issue: if resurrected species were exact replicas of extinct originals, those originals might be considered as a form of "prior art." However, to the extent that its genetic distinctiveness from the extinct original qualifies the resurrected species as a non-naturally occurring human invention, it seems reasonable to consider it as novel as well.

Other authors have addressed the novelty issue, on the assumption that resurrected species would be identical to the (formerly) naturally occurring extinct originals.[205] An extinct species would have been "available to the public" before extinction, and therefore a genetically identical clone of that species would not be novel. Nevertheless, two authors have argued, the doctrine of "lost arts" could apply to restore the necessary element of novelty.[206] Since the extinct species has been completely lost, the creation of new copies using genetic technology would constitute an independent invention, in that knowledge of the "prior art" would not "permit one with ordinary skill in the art to reproduce the living animal, by way of breeding for instance, without reliance on the ingenuity embodied in the second invention."[207] Another author argues that the lost arts doctrine would not apply, because the extinct species' DNA was never lost and its identical copy is not "independent from nature, the first inventor."[208] As discussed above, however, resurrected species would be facsimiles, rather than exact copies, of the extinct originals. It is their underlying distinctiveness that constitutes the "novelty" of the facsimile, in which case the "lost arts" issue would not arise.

Finally, there seems to be little policy reason to deny a patent to those who have devoted considerable resources to research and development of cutting-edge genetic technology for the recreation

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205. *See* Ryan Hagglund, *Patentability of Cloned Extinct Animals*, 15 GEO. MASON L. REV. 319, 404 (2008); Darren M. Jiron, *Patentability of Extinct Organisms Regenerated Through Cloning*, 6 VA. J.L. & TECH. ¶ 33 (2001), http://www.vjolt.net/vol6/issue2/v6i2-a09-Jiron.html; Mark. L. Rohrbaugh, *The Patenting of Extinct Organisms: Revival of Lost Arts*, 25 AIPLA Q.J. 371, 383-88 (1997).

206. Hagglund, *supra* note 205, at 419-21; Rohrbaugh, *supra* note 205, at 404-07.

207. Hagglund, *supra* note 205, at 420.

208. Jiron, *supra* note 205, ¶ 57.

of extinct species, whether intended to produce (facsimiles of) lost biodiversity or domestic pets. Rather, it seems reasonable that de-extinction project proponents, in most cases, should be rewarded for their human ingenuity and investment in bringing back extinct species which otherwise would no longer exist on earth, and which are not unpatentably exact replicas of what is or was found in nature. That said, there may be at least one policy reason to deny *exclusive* patents to private proponents of de-extinction projects: if doing so would be inconsistent with reestablishing the species in the wild. An exclusive patent would deny the federal government the opportunity to create more of the species in order to propagate, reintroduce, and manage them. Inasmuch as this approach would be consistent with the public benefit purpose of de-extinction and the environmental laws discussed above, it would seem reasonable for any patents issued to private parties for resurrected species to permit the federal government, and perhaps other public agencies and nongovernmental organizations, to undertake such activities without requiring a license from the patentee.[209]

VII. CONCLUSION

De-extinction, in some form, has become a distinct possibility that may raise a host of legal issues in the not-so-distant future. Articles in the popular press have explained the science and considered the moral and ethical issues relevant to resurrecting and reintroducing extinct species, and some law review articles have discussed patent law with respect to cloning of such species.[210]

This Article has examined a more thorough range of legal issues through a detailed analysis of the three different types of de-extinction methods being pursued, and the legal ramifications that follow from the differences among the methods. These methods are SCNT (somatic cell nuclear transfer), genetic engineering, and artificial selection. Facsimiles produced by any of these methods may warrant ESA protection, but under different components of the law—the basic listing procedures for SCNT facsimiles, and the

209. To the extent that federal funding is utilized for a de-extinction project, the government may be able to use its "march-in rights" under 35 U.S.C. § 201 (2012).

210. As discussed in Part VI, the articles on patent law ultimately are rather unhelpful, as the authors assume that resurrected species would be identical copies of the extinct models, when in fact the plausible methods of de-extinction would result in facsimiles.

DPS listing procedures for those produced by genetic engineering or artificial selection. Projects to release such facsimiles into the wild, in an attempt to reestablish the species, would trigger environmental impact review under NEPA and applicable state laws. Facsimiles produced by SCNT and genetic engineering would be sufficiently genetically modified to count as GMOs under some specific federal laws as well as under some local regulations prohibiting GMOs. In addition, facsimiles produced by genetic engineering should be sufficiently genetically distinct to be patent eligible. Though it could be claimed that facsimiles produced by SCNT may be too close to the original species to constitute patentable subject matter, even those would be distinct, to a degree, from anything in nature and arguably should be patent eligible as products of human ingenuity.

The legal regimes may occasionally overlap or conflict. A resurrected species might be patentable, but may also be listed as endangered under appropriate circumstances. Patent law may have to accommodate the environmental laws, perhaps by granting the federal government or other institutions rights to propagate the species for reintroduction notwithstanding exclusive rights for commercial use on the part of the creators. The issues raised by de-extinction will have to be addressed by the courts in cases of first impression, unless Congress decides to adopt new or adapt and extend existing legislation.

Finally, we must acknowledge the central role of the relevant regulatory agencies. If resurrecting extinct species does become a reality, FWS and NMFS, in particular, will find themselves contending with these issues the first time someone files a listing petition or seeks to establish an experimental population. In this Article, we have analyzed the language and intent of existing statutes, regulations, and policies, and examined analogies and precedents such as reintroductions of locally extirpated endangered species and releases of GMOs. Some of these examples have been intensely controversial and raised serious concerns, for example, that the reintroduction of wolves could harm livestock and humans,[211] or that the introduction of GMO crops could contaminate the genotypes of other crops.[212] Assuming resurrected species do not remain confined to laboratories or zoos, the prospect of their release into the wild is

211. *See* Doremus, *supra* note 59, at 28, 37; Podsiadly, *supra* note 136, at 140-41.
212. *See* Monsanto Co. v. Geertson Seed Farms, 130 S. Ct. 2743, 2755 (2010).

likely to provoke still greater public debate regarding potential ecological risks and land use conflicts. Ultimately these decisions will be made by the regulators, subject to amendments of the governing statutes and to review by the courts. We recognize that, after struggling with past controversies, agencies may be inclined to more conservative interpretations than some of those we suggest in this Article, or to look for legislative direction. Our analysis demonstrates that existing law provides most or all of the necessary tools that may be utilized or adapted if and when agencies and legislatures are confronted with the once-inconceivable prospect of de-extinction.