



# Patentability of De-Extinction Animals: A Comparative Review of the International Legal Framework

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## **Author's contribution**

*The sole author designed, analyzed, interpreted and prepared the manuscript.*

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## **ABSTRACT**

The patentability of zoological discoveries is a fascinating and fluid intersection between intellectual property law and the biological sciences. As biotechnology progresses, so does our ability to discover and modify the genetic material of animals thereby amending animal patent jurisprudence. As CAS number-based search tools have been found to be relatively ineffective at returning records for species and gene sequences, especially when vast research results are included in these large chemical databases as described above. Case studies and legal precedents serve to exemplify the various ways in which different jurisdictions approach patentable zoological innovations. The paper also examines the ramifications of allowing living organisms to be patented and what this could mean for biodiversity, conservation projects, and indigenous rights. This paper is an attempt to peel away the layers of complexity that come with determining where to draw this delicate line between incentivizing innovation vs protecting moral or environmental issues by examining how patent eligibility in zoological discoveries stands today. These results highlight the importance of a

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balanced human-oriented approach that promotes scientific development simultaneously with moral commitment and compatible biodiversity protection. The paper adds to a wider conversation about the role of intellectual property rights by examining how broader issues in patenting play out with zoological discoveries.

*Keywords: Zoological discoveries; patentability; genetic material; ethical implications; biodiversity conservation.*

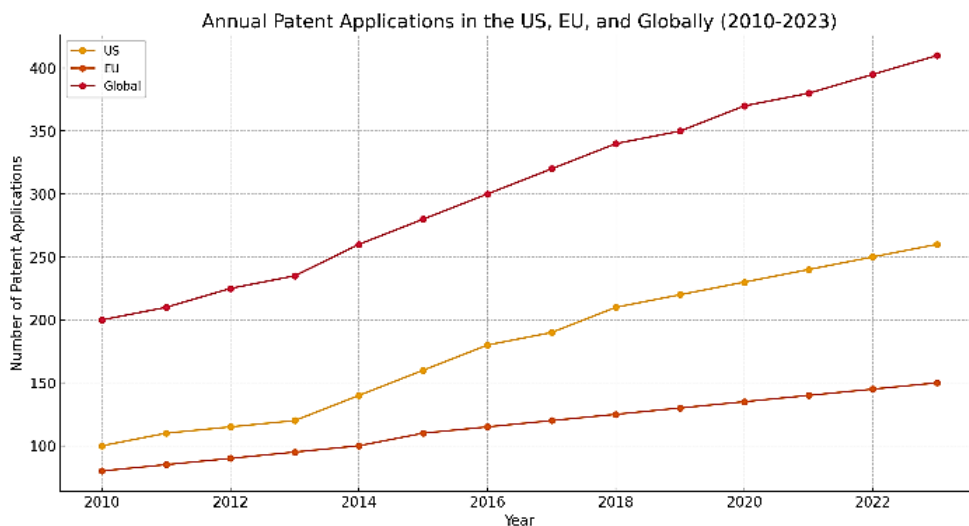
## 1. INTRODUCTION

De-extinction, the scientific endeavour of reviving extinct species using sophisticated biotechnology techniques, is at the forefront of modern science. Scientists want to restore long-extinct species using procedures such as cloning, genome editing, and selective breeding. Examples such as the potential rebirth of the woolly mammoth and the passenger pigeon demonstrate the technology's far-reaching consequences. However, when these scientific possibilities emerge, they raise complex legal and ethical issues, including the patentability of de-extinct creatures. With the passage of time, a huge number of applications have been filed to grant patent for the biotechnologically developed animals. The below chart represents the intensity and the growing importance of the same.

The number of patent applications for biotechnological inventions involving animals that are filed each year in the US, the EU, and other countries is displayed in this chart. The data shows patterns and growth rates across time, with notable peaks and drops that line up with important developments in science or the law.

Patentability in biotechnology is determined by three key criteria: innovation, non-obviousness, and usefulness. Patents promote innovation by giving inventors exclusive rights to their discoveries for a limited period. However, applying these criteria to de-extinct creatures sparks heated discussions. De-extinction does not generate wholly new creatures, but rather revives species that already lived, challenging the idea of novelty and presenting ethical quandaries about the monetization of life [1,2].

In the United States, the historic Supreme Court decision in *Diamond v. Chakrabarty* [3] established the patentability of genetically engineered organisms, including bacteria. This decision cleared the door for patents on genetically altered plants and animals. However, the patentability of de-extinct species has yet to be addressed in US courts. The United States Patent and Trademark Office (USPTO) has granted patents for biotechnological discoveries that include genetic alterations, but the unique nature of de-extinction creates new obstacles. Ethical issues, particularly the ramifications of patenting a species resurrected by scientific intervention, must be rigorously considered [4].



**Fig. 1. Annual Patent Applications in the USA, the EU, and globally from 2010-2023.**

*Source: USPTO and EPO Annual Reports*

In contrast, the European Union retains a more stringent approach to the patentability of biological creatures. Plant and animal types, as well as biological procedures used to produce them, are not patentable under the European Patent Convention (EPC). Nonetheless, patents might be awarded for biotechnological inventions that include technical procedures [5]. Whilst the European Patent Office (EPO) has awarded patents for genetically modified animals, the question of de-extinct species remains mainly unexplored. In Europe, ethical issues, notably regarding animal welfare and conservation of biodiversity, wield considerable influence over public and legal opinion [6].

International accords concerning genetic resources, such as the Nagoya Protocol and the Convention on Biological Diversity (CBD), highlight the significance of benefit-sharing and access. With a focus on the nations and people that supply these resources, these agreements seek to guarantee an equitable and just distribution of benefits resulting from the use of genetic resources. De-extinction brings up important issues regarding who owns and uses genetic material, which is frequently extracted from habitats of nature or museum specimens [7, 8].

The objective of this review is to present a thorough review of the patentability of de-extinction animals by assessing the ethical and ecological issues at play and looking at the legal frameworks in significant jurisdictions. This study aims to evaluate the merits and drawbacks of the existing legal frameworks and suggest possible solutions to balance scientific innovation with moral and environmental responsibility by contrasting the strategies of the US, the EU, and international agreements. The primary goal in doing this comparative analysis is to add to the current conversation on the function of intellectual property in the de-extinction era.

## 2. MATERIALS AND METHODS

The current study employs an interdisciplinary legal examination to examine the patentability of de-extinction the creatures in multiple jurisdictions, with an emphasis on the US, the EU, and global frameworks like the Nagoya Protocol and the Convention on Biological Diversity (CBD). The research methodology entails the following crucial steps:

### 2.1 Literature Review

Using scholarly databases, a thorough literature analysis was carried out to find pertinent academic papers, court cases, and policy documents. To find sources, terms like "de-extinction," "patentability," "biotechnology patents," "intellectual property," and "genetically modified organisms" were employed. Articles were chosen according to their effect on the field, citation count, and relevancy.

### 2.2 Legal Framework Analysis

A thorough examination was conducted of the legislative frameworks that control the patentability of biotechnological advances. This involved going over international treaties, court decisions, and regulatory guidelines from the USPTO, the EPO, and the US Patent and Trademark Office (USPTO). Important court decisions and judgements, such as *Diamond v. Chakrabarty* (1980), were reviewed in order to identify the norms and standards that are used for patent applications that contain organisms.

### 2.3 Comparative Analysis

To find parallels and discrepancies in their methods to patenting extinct species, the legal frameworks and customs of the US and the EU were examined. This required examining how each jurisdiction approaches the de-extinction process while taking into account the requirements of innovation, non-obviousness, and value. To present a comprehensive perspective, ethical issues and the ramifications for public policy were also taken into account.

### 2.4 International Agreements

To determine how international agreements, in particular the CBD and the Nagoya Protocol, affect access to and benefit-sharing of genetic resources used in de-extinction efforts, their significance has been assessed. Legal texts and implementation reports were examined in order to evaluate signatory countries' compliance and challenges.

### 2.5 Data Synthesis

In order to make judgements regarding the present status of patentability for the de-extinction of animals and to offer suggestions for

balancing legal frameworks with moral and environmental issues, findings from the literature study, legal analysis, and case studies were combined.

### **3. A COMPARATIVE ANALYSIS OF INTERNATIONAL LEGAL FRAMEWORK**

The notion of de-extinction entails restoring extinct animals by modern biotechnology procedures such as cloning and genetic engineering. This emerging field raises significant legal and ethical concerns, particularly with the patentability of de-extinct animals. The international legal system governing this topic is complex and varies greatly between states. This paper investigates the patentability of de-extinct creatures by examining international legislation and their ramifications.

The Table 1 compares the primary patentability criteria for biotechnological innovations in the United States with the European Union. It emphasises the variations in legal methods, particularly in terms of ethical issues and specific exclusions under the EPC.

#### **3.1 USA**

The US Patent and Trademark Office (USPTO) is responsible for determining the patentability of live species, including genetically engineered animals, under the Patent Act. The landmark decision *Diamond v. Chakrabarty* (1980) recognised that living organisms, including genetically modified bacteria, can be patented if they meet the originality, non-obviousness, and utility requirements. Following this precedent, the USPTO has granted patents for different genetically altered animals, such as the "oncomouse," which was created for cancer research [9].

#### **3.2 European Union**

The European Union (EU) has a more limited approach to the patentability of biological creatures. According to the European Patent Convention (EPC), patents can be awarded for biotechnological inventions involving animals if they are original, entail an innovative step, and are industrially relevant. However, Article 53(a) of the EPC exempts from patentability discoveries whose economic use would be detrimental to "ordre public" or morality [10].

The European Patent Office (EPO) has used this clause in a variety of cases, including the "Harvard Oncomouse" case, in which ethical considerations played an important role in the decision-making process. Given the potential ethical and environmental considerations involved with de-extinction, it is expected that the EPO would scrutinise patent applications for de-extinct animals closely, taking the broader consequences for society and the environment [11].

#### **3.3 Japan**

Japan's method to patenting living beings is fairly consistent with international standards. The Japanese Patent Office (JPO) permits the patenting of genetically engineered animals under certain conditions. However, the Guidelines for Patent Examination state that inventions using animals must not violate public order or morality [12].

In the context of de-extinction, the JPO will most likely assess the patentability of such species on an individual basis, taking into account scientific value as well as potential ethical and environmental consequences. While Japan has not yet encountered particular cases involving de-extinct creatures, its existing legal framework provides a foundation for resolving such challenges if they arise [13].

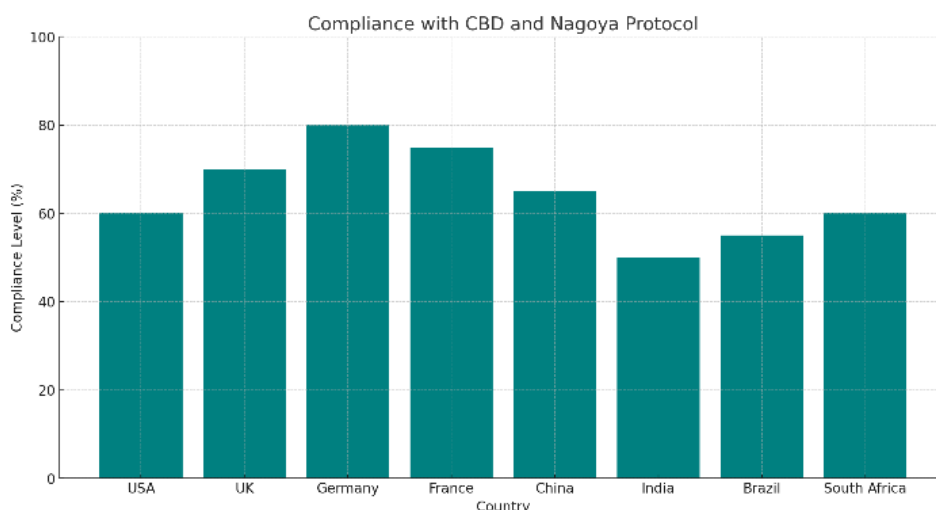
#### **3.4 China**

China has made remarkable advances in biotechnology and intellectual property legislation in recent years. The China National Intellectual Property Administration (CNIPA) issues patents for biotechnological inventions, including genetically modified animals, that meet the normal criteria of novelty, inventiveness, and industrial usefulness [14].

China's patent law includes restrictions that prevent inventions that are damaging to the public interest or morality from being patented. In the context of de-extinction, ethical and environmental considerations would play a significant role in the evaluation process. The CNIPA is anticipated to require sufficient explanation for the patentability of de-extinct creatures, taking into account the possible benefits and hazards connected with such advances [15].

**Table 1. Comparative analysis of international legal framework**

Criteria	United States	European Union
Novelty	Strict application, case law <i>Diamond v. Chakrabarty</i> , [10]	Strict, EPC excludes plant/animal varieties <i>Van Overwalle</i> , [5]
Non-obviousness	Evaluated case-by-case	Evaluated case-by-case
Utility	Practical utility required	Industrial application required
Ethical Considerations	Limited impact on patentability decisions	Significant impact, animal welfare considered <i>Gevers et al.</i> , [6]



**Fig. 2. A Bar Chart representing compliance with CBD and Nagaya Protocol by various countries**

Source: *Coolsaet et al., 2013; Rosendal, 2006*

This bar chart depicts the levels of compliance with the Convention on Biological Diversity (CBD) and the Nagoya Protocol in various countries. The graphic shows variances in adherence to international agreements governing the use of genetic resources, which is critical for de-extinction efforts.

### 3.5 International Agreements

Several international agreements influence the patentability of biotechnological inventions, including de-extinct animals. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) sets minimum standards for patent protection among World Trade Organization (WTO) member countries. TRIPS requires members to provide patent protection for inventions in all fields of technology, subject to certain exceptions, such as protecting public order and morality [16].

Furthermore, the Convention on Biological Diversity (CBD) emphasises biological diversity protection, the long-term use of its components,

and the equitable distribution of benefits derived from the exploitation of genetic resources. The possible impact of de-extinct animals on biodiversity and ecosystems corresponds with the CBD objectives, which may influence patentability considerations under national laws aligned with international standards [17].

The Nagoya Protocol is a supplementary agreement to the Convention on Biological Diversity (CBD) that was adopted in 2010 and became effective in 2014. Its goal is to ensure a fair and equitable distribution of benefits resulting from the use of genetic resources. This protocol has important implications for the patentability of de-extinction animals, especially in terms of access and benefit-sharing (ABS) mechanisms.

The Nagoya Protocol establishes a framework for accessing genetic resources and sharing the advantages of their utilisation, with the goal of encouraging biodiversity conservation and sustainability. The protocol demands that monetary and non-monetary advantages be shared with genetic resource producers, which

are primarily nations of origin or indigenous groups. This agreement promotes transparency and legal clarity in the use of genetic resources [18].

De-extinction projects frequently make use of genetic resources from extinct species, which may be maintained in natural history collections or biobanks. Access to these genetic materials is subject to the Nagoya Protocol, which requires prior informed consent (PIC) and mutually agreed terms (MAT) with the provider country or community. This ensures that any benefits resulting from the utilization of such genetic resources are fairly distributed [19].

Compliance with the Nagoya Protocol is critical for researchers and companies working on de-extinction efforts. Failure to comply with the ABS standards may result in legal issues and hamper the ability to patent de-extinct creatures. This compliance assures that the genetic resources employed are lawfully obtained, which is a requirement for obtaining patents in many nations [20].

The benefits of commercializing de-extinct animals, such as patents, must be shared with genetic resource producers. This involves distributing revenue from patents, research findings, and other derived benefits. The Nagoya Protocol impacts the parameters under which patents for de-extinct animals can be acquired and enforced [21].

The Nagoya Protocol emphasizes ethical considerations in the exploitation of genetic resources, which is consistent with the larger ethical debates surrounding de-extinction. By ensuring benefit sharing, the protocol resolves some ethical concerns concerning the use of genetic materials from biodiversity-rich, but frequently economically disadvantaged, countries [22].

The Nagoya Protocol has the potential to impact the scope and direction of de-extinction research. Researchers must manage ABS restrictions, which can impact the feasibility and cost of de-extinction efforts. This can result in a more collaborative and egalitarian research environment, thereby stimulating innovation in the subject.

## **4. LEGAL AND ETHICAL ISSUES**

The patentability of de-extinct creatures brought back by modern biotechnology procedures such

as cloning and genetic engineering raises significant legal and ethical concerns. This analysis looks at the differences in foreign legal frameworks, as well as the ethical considerations that come with them.

### **4.1 Legal Issues**

#### **4.1.1 Novelty and non-obviousness**

**Novelty and Non-Obviousness:** The major legal challenge is whether de-extinct animals meet the patentability requirements, which are novelty and non-obvious. In the United States, the landmark Supreme Court decision in *Diamond v. Chakrabarty* [3] authorized the patenting of genetically engineered organisms. However, the novelty of de-extinct creatures is debatable because these species once existed [23]. The USPTO requires that an invention be "new" and not previously known or used.

#### **4.1.2 Ordre public and morality**

In the European Union, the European Patent Convention (EPC) includes Article 53(a), which prohibits patenting ideas whose commercial use would be detrimental to "ordre public" or morals. This provision has been used in situations involving biotechnological inventions, including the "Harvard Oncomouse" [24]. The European Patent Office (EPO) must strike a balance between scientific innovation and ethical considerations, which may limit patents on de-extinct creatures.

#### **4.1.3 Benefit-sharing and access to genetic resources**

The Nagoya Protocol on Access and Benefit-Sharing is an important component of the Convention on Biological Diversity (CBD). It necessitates that the advantages of genetic resources be distributed evenly among the supplier countries. De-extinction projects frequently incorporate genetic material from preserved specimens, and compliance with the Nagoya Protocol is critical to minimize biopiracy and ensure an equal distribution of benefits [25].

#### **4.1.4 Jurisdictional differences**

Japan and China also have distinct legal landscapes. Japan's patent law is consistent with international standards, although its Guidelines for Patent Examination place an emphasis on public order and morality. In China, the China

National Intellectual Property Administration (CNIPA) allows patents for biotechnological discoveries, including genetically modified animals, but patent applications are evaluated using ethical principles [26]. Both countries need a rigorous ethical and legal review of de-extinct animal patents.

## 4.2 Ethical Issues

### 4.2.1 Animal welfare

The process of de-extinction poses serious ethical considerations about animal welfare. The reintroduction of extinct species via cloning or genetic engineering can result in suffering if the animals have health issues or are unable to adapt to present settings. Ethical principles and animal welfare legislation must address these concerns [27].

### 4.2.2 Ecological impact

Introducing extinct creatures into present environments risks causing ecological upheaval. These species may become invasive, displacing existing species or altering established ecological balances. To minimize unforeseen effects, ethical considerations must incorporate the precautionary principle and potential environmental impacts [28].

### 4.2.3 Moral justification

The moral rationale for de-extinction is debatable. While some suggest that recovering extinct species will restore lost biodiversity and atone for human-caused extinctions, others believe that resources should be directed towards protecting existing species and environments. The ethical question includes the ethics of deploying modern biotechnological technologies for such aims [29].

The patentability of extinct creatures requires navigating complex legal and ethical landscapes that differ across jurisdictions. In the United States, novelty and non-obviousness are paramount, but the European Union concentrates on public order and morals. The Nagoya Protocol's emphasis on benefit sharing is vital worldwide. Concerns about animal care, environmental effect, and moral justification are all important from an ethical standpoint. As de-extinction technology progresses, clear, consistent, and ethical policies will be required to address these complex issues.

## 5. CASE STUDIES OF PATENTED BIOTECHNOLOGICAL ANIMALS

The patenting of biotechnological animals has resulted in tremendous innovation and controversy. Key case studies demonstrate the breadth and significance of these patents.

### 5.1 Oncomouse

One of the first and most well-known instances is the Harvard Oncomouse, which was genetically modified to be cancer-prone for scientific studies. The USPTO issued a patent in 1988, but the European Patent Office (EPO) encountered ethical issues before finally granting a patent with limits in 1992 [9].

### 5.2 AquaBounty Salmon

The AquaBounty genetically modified fish, which is meant to grow faster than wild salmon, was granted a patent in the United States in 2001. This patent covers both the process of manufacturing the fish and the fish itself, sparking debates about food safety and environmental effect [30].

### 5.3 Enviro Pig

The EnviroPig, created at the University of Guelph, is designed to digest plant phosphorus more efficiently, hence minimizing environmental pollution from pig farming. EnviroPig, which was patented in the United States and Canada, had commercialization hurdles because of public and regulatory concerns [31].

### 5.4 GloFish

The GloFish, a fluorescent zebrafish originally intended for environmental monitoring, was patented in the United States in 2003. While largely promoted as a pet, its patent has sparked concerns about the ethics of changing animals for commercial purposes [32].

### 5.5 Knockout Mice

Knockout mice, which have certain genes "knocked out" to research gene function, have received numerous patents. These patents have encouraged progress in genetic research and medicine development, but have also prompted concerns about access to research equipment [33].

## 5.6 SynDaver Labs' Synthetic Animals

SynDaver Labs' trademarked synthetic animals for surgical training and research are not genetically changed, but they represent a merging of biotechnology and synthetic biology. These patents address ethical problems and provide alternatives to live animal testing [34].

These case studies highlight the diverse applications and challenges of biotechnological animal patents, emphasising the importance of careful ethical and legal considerations.

## 6. FINDINGS

The investigation into the patentability of extinct creatures reveals considerable differences in legal frameworks and ethical issues between jurisdictions.

The U.S. legal system, influenced by the precedent made in *Diamond v. Chakrabarty* (1980), permits the patenting of genetically modified organisms if they meet the criteria of innovation, non-obviousness, and utility [35]. However, the novelty of de-extinct animals is questionable because these species once existed, thus compromising patent eligibility [36].

Article 53(a) of the European Patent Convention (EPC) prohibits patenting ideas whose economic exploitation would be contrary to "ordre public" or morals [37]. This rule offers a severe hurdle to the patenting of de-extinct creatures, as ethical reasons concerning biodiversity, animal welfare, and environmental impacts are of paramount importance.

The Nagoya Protocol's global implementation emphasizes access and benefit-sharing (ABS) systems, which ensure that genetic resources used in de-extinction are obtained legally and benefits are shared with supplier countries [38]. Compliance with the Nagoya Protocol is critical for lawful patenting and avoiding charges of biopiracy, emphasizing the necessity of ethical sourcing and equitable benefit distribution.

Japan's patent law, which is consistent with international standards, emphasizes public order and morality, mandating careful examination of the implications of de-extinction [34]. China's rapid biotechnology breakthroughs are aided by legislative frameworks that promote innovation while following to ethical principles, ensuring that

patent applications involving extinct species are rigorously assessed [39].

The review emphasizes the importance of a consistent international approach to the patentability of de-extinct species. Legal and ethical norms differ among nations, which can pose obstacles for academics and organizations participating in de-extinction efforts. A unifying framework could assist balance innovation and ethical concerns, enabling responsible use of biotechnological developments [40].

The findings show that, while de-extinction technology has great potential, patentability is laden with legal and ethical complications that must be carefully navigated to ensure equitable and sustainable outcomes [41,42].

## 7. CONCLUSION

To summarize, the patentability of de-extinction animals is a complex and diverse problem within the international legal framework. This comparative analysis indicates considerable differences in how various jurisdictions handle the junction of biotechnology, intellectual property rights, and ethical concerns. While countries such as the United States are more lenient about the patentability of genetically modified organisms, even extinct species, the European Union takes a cautious approach, prioritizing ethical issues and biodiversity conservation. These divergences underscore the need for a unified international legal framework that balances innovative incentives with ethical and environmental concerns.

The future research scope in this topic is extensive and diverse. The ethical concerns of patenting extinct creatures are one area of additional inquiry, with an emphasis on animal welfare, ecological repercussions, and moral considerations. Furthermore, studying the socioeconomic effects of such patents, particularly in poor nations with abundant biodiversity, might shed light on equity and access issues. Another crucial area of research is the possibility for patent infringement, where monopolies on extinct species could lead to biopiracy and the exploitation of genetic resources.

Furthermore, it is necessary to investigate the role of public engagement and indigenous knowledge in defining de-extinction and biotechnology patent regulations. Comparative



studies comparing jurisdictions with varying levels of technical innovation and biodiversity can provide insights into best practices and policy recommendations.

To summarize, while the patentability of de-extinction animals presents significant potential for scientific advancement and biodiversity protection, it also poses serious ethical, ecological, and socioeconomic concerns. Future research should focus on creating a comprehensive, ethically sound, and globally harmonized legal framework that promotes innovation while protecting the interests of all stakeholders, including the environment, society, and future generations. This balanced approach will ensure that the benefits of de-extinction technologies are realized while upholding our ethical and environmental responsibilities.

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#### COMPETING INTERESTS

Author has declared that no competing interests exist.

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