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Special article

NAVIGATING THE LEGAL AND ETHICAL BOUNDARIES OF EMBRYO STATUS: A BALKAN PERSPECTIVE WITH A FOCUS ON BOSNIA AND HERZEGOVINA

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SUMMARY

The status of the human embryo remains one of the most debated issues at the intersection of science, ethics, and law. This paper explores the ethical, legal, and scientific perspectives on the embryo, with a particular focus on Bosnia and Herzegovina. A comparative analysis of legal frameworks across the Balkans highlights inconsistencies and gaps in regulation, particularly regarding embryo research and extended in vitro culture. Religious perspectives, predominantly shaped by monotheistic traditions, further complicate policy-making in this domain. By integrating scientific findings, ethical debates, and legal texts, this paper aims to provide a comprehensive overview of the current status of the embryo, emphasizing the need for legislative reforms in Bosnia and Herzegovina. The discussion underscores the importance of harmonizing national laws with European standards, such as the SOHO Directive and ESHRE guidelines, while considering the region's unique socio-cultural and religious landscape. The paper concludes with recommendations for policy changes, advocating for the extension of embryo culture up to the 14th day and the introduction of regulated research within IVF laboratories. These proposed changes aim to balance ethical concerns with scientific progress and align Bosnia and Herzegovina's legislation with contemporary European practices.

Keywords: *embryo status, bioethics, reproductive law, embryo research, Bosnia and Herzegovina.*

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INTRODUCTION

The birth of Louise Joy Brown in 1978 (Edwards and Steptoe, 1978) marked a turning point in reproductive medicine, heralding the success of in vitro fertilization (IVF). While IVF provided new hope for infertile couples, it also sparked ethical, legal, and religious debates regarding the moral and legal status of embryos, reproductive autonomy, and the broader implications of assisted reproductive technologies (ART) (Kamel, 2013; Roy et al., 2017). A central ethical dilemma is whether embryos should be regarded as persons with inherent rights or as biological entities subject to medical intervention and research.

Bioethics, emerging as a multidisciplinary field in the 20th century, has played a crucial role in shaping discussions on reproductive medicine. Ethical principles such as autonomy, justice, and informed consent challenge traditional paternalistic approaches, particularly in relation to embryo status (Jonsen, 2000; Jones, 1987). From a biological standpoint, human development is a continuous process without a universally agreed-upon starting point for life (Johnson, 2016). However, defining the embryo's moral or legal status extends beyond biology into cultural, religious, and philosophical domains.

In the Balkans, perspectives on the embryo's status vary, influencing legislation, ethical norms, and access to ART. Despite medical advancements, legal inconsistencies persist. This perspective article aims to synthesize scientific, religious, and legal viewpoints to critically assess the status of the human embryo in contemporary bioethical and legislative discourse. The analysis includes a comparative overview of regulations across Balkan countries, with a special focus on Bosnia and Herzegovina, particularly the Federation of Bosnia and Herzegovina. Recommendations for legal reform are proposed based on the argument that embryo status should be reconsidered in light of scientific progress and ethical reasoning, balancing embryo protection with patient-centred care in reproductive medicine.

METHODS

This study employs a qualitative analysis of scientific literature, religious texts, and legal documents. Scientific sources were selected through systematic searches in PubMed and Web of Science, focusing on publications from the last two decades discussing embryonic development, viability, and ethical considerations in assisted reproduction. Religious perspectives were drawn from theological texts and analyses of official monotheistic religions positions. Legal documents, including national laws, bylaws, and international legal instruments, were examined to compare regulatory frameworks in Bosnia and Herzegovina, Croatia, Slovenia, Montenegro, North Macedonia, and Serbia.

The first research segment explores scientific and medical perspectives on embryonic development. Peer-

reviewed studies from biomedical databases, embryology textbooks, and professional guidelines in reproductive medicine were reviewed to define key developmental stages, including fertilization, zygote, morula, and blastocyst formation.

Ethical and religious perspectives were analysed through theological and philosophical sources, including primary texts (the Bible, Qur'an, and Talmud) and interpretations from scholars within Catholicism, Orthodoxy, Islam, and Judaism. Official doctrinal statements, encyclicals, and scholarly theological discussions were examined alongside secondary bioethical analyses contextualizing religious views within contemporary ethical debates.

The legal status of embryos was assessed through national laws, regulations, and judicial decisions related to ART in Balkan countries. Legal documents were sourced from government websites, ministry archives, and legal databases. Comparative legal analysis was conducted to highlight differences in embryo recognition, protection, and use in ART among countries.

Additionally, international guidelines were considered, including the European Society of Human Reproduction and Embryology (ESHRE) position on embryo ethics and the new Directive on Substances of Human Origin (SoHO). The study employs a comparative approach to identify key similarities and conflicts across scientific, ethical, religious, and legal perspectives, concluding with recommendations for Bosnia and Herzegovina.

SCIENTIFIC AND MEDICAL VIEW OF EARLY EMBRYONIC DEVELOPMENT

Early Development and the Embryogenic Phase

The earliest stages of human development lay the groundwork for cellular differentiation and organogenesis (Shahbazi, 2020). These stages determine not only embryonic development but also the supporting structures necessary for implantation and placental formation. Before the embryo fully develops, the product of fertilization is referred to as the conceptus, which includes both embryonic and extraembryonic components (Su, 2015; Jones, 2018; Johnson, 2016).

Fertilization occurs when a sperm cell fuses with an oocyte, forming a zygote – a single-cell entity carrying genetic material from both parents (Okabe, 2014). The zygote undergoes a series of mitotic divisions called cleavage, resulting in blastomeres that initiate the early stages of embryonic differentiation (Johnson, 2016). By day three or four post-fertilization, the zygote develops into a morula, a compact cluster of 16–32 cells. As division continues, it transforms into a blastocyst – a hollow structure with an inner cell mass (the future embryo) and an outer trophoblast layer, which will contribute to the placenta (Gauster et al., 2022; Coticchio et al., 2019; Ivec et al., 2011). During the first 14–16 days, the conceptus undergoes differentiation into embryonic and extraembryonic structures. The inner cell mass consists of pluripotent cells, which give rise to the embryo, while outer trophoblast cells support implantation and placenta formation (Shahbazi et al., 2024; Zheng et al., 2022; Johnson, 2016).

Why "Conceptus" is a More Appropriate Term than "Embryo"

The term conceptus more accurately describes the pre-embryonic stage because it includes both embryonic and extraembryonic structures. Referring to this early-stage entity as an embryo can be misleading, as the biological "oneness" of an individual is not yet established. Until approximately day 14 post-fertilization, the conceptus retains the potential for twinning, meaning individuality has not been definitively determined. This is the rationale behind the widely accepted 14-day rule in embryo research, marking the onset of the primitive streak, the first sign of organized development and a precursor to the nervous system. Before this, the conceptus remains a cluster of different cells with multiple developmental possibilities.

Scientific Advances and Ethical Considerations

Recent embryological and regenerative medicine advancements have intensified discussions about embryo viability and extended culture, particularly regarding stem cell research. This debate underscores the challenge of balancing scientific innovation with ethical constraints (Rugg-Gunn et al., 2023; Amadei et al., 2022). In Bosnia and Herzegovina, legal frameworks currently prohibit embryo culture beyond Day 6, despite scientific findings suggesting that certain embryos may develop successfully if cultured to Day 7 (Hammond et al., 2018; Hernandez-Nieto et al., 2019; Insogna et al., 2021).

Aligning legal definitions with contemporary scientific knowledge is essential to prevent unnecessary restrictions on reproductive medicine. Legal framework should balance ethical concerns with the potential for clinical advancements, ensuring that legislative barriers do not impede scientific progress and patient outcomes in ART.

RELIGIOUS AND ETHICAL PERSPECTIVE

The moral and legal status of the human embryo has been a central ethical and religious question for centuries. Different monotheistic religions offer diverse perspectives on when life begins, the moral status of embryos, and the ethical permissibility of ART. These religious perspectives have influenced ethical debates and legal frameworks across societies. This chapter examines these perspectives through sacred texts, theological interpretations, and ethical implications.

The Christian Perspective

Christianity's views on the embryo's moral status derive from biblical scripture, Church tradition, and theology. The three main branches, Catholicism, Eastern Orthodoxy, and Protestantism, present varying interpretations regarding the beginning of human life and the embryo's moral and legal standing.

Catholicism

The Catholic Church asserts that life begins at conception, granting full moral status to the embryo. This belief is grounded in Psalm 139:13: "For you created my inmost being; you knit me together in my mother's womb.". Donum Vitae (1987) affirms: "From the moment of its conception, life must be guarded with the greatest care while abortion and infanticide are unspeakable crimes.". Other references, such as Jeremiah 1:5 ("Before I formed you in the womb I knew you, before you were born, I set you apart.") and Psalm 139:16 ("Your eyes saw my unformed body; all the days ordained for me were written in your book before one of them came to be."), further reinforce this position. Dignitas Personae (2008) explicitly states that embryos have full moral status from conception, leading to opposition to IVF due to embryo destruction and the separation of conception from the marital act.

Eastern Orthodoxy

Orthodox Christianity generally upholds that human life begins at conception and emphasizes the sanctity of life. However, theological discussions allow for nuanced perspectives on ART. While the Greek Orthodox Church expresses ethical concerns about embryo manipulation, it does not entirely prohibit IVF, particularly when performed within marriage and without embryo destruction. Unlike Catholicism, Orthodoxy does not have a centralized doctrinal authority, and ethical positions often depend on pastoral guidance.

Protestantism

Protestant perspectives on embryonic status vary significantly due to the emphasis on personal interpretation of Scripture. Evangelical and conservative denominations often align with Catholic beliefs on life beginning at conception, while liberal branches may allow ART under specific conditions. Some Protestants reference Genesis 2:7 ("Then the Lord God formed a man from the dust of the ground and breathed into his nostrils the breath of life, and the man became a living being.") to argue that life begins with the first breath, leading to more permissive stances on embryo research and ART.

The Islamic Perspective

Islamic bioethics is shaped by the Qur'an, Hadith, and Fiqh (Islamic jurisprudence). Scholars widely agree that ensoulment (ruh) occurs at either 40- or 120-days post-conception, as referenced in Surah Al-Mu'minun (23:12-14): "And indeed, We created humankind from an extract of clay. Then placed each as a drop in a secure place, then We developed the drop into a clinging clot, then developed the clot into a lump, then developed the lump into bones, then clothed the bones with flesh, then We brought it into being as a new creation. So Blessed is Allah, the Best of Creators." A Hadith states: "Each of you is gathered in your mother's womb for forty days as a drop, then as a clot for the same period, then as a lump for the same period. Then the angel is sent to breathe the soul into him." (Sahih al-Bukhari, Hadith 3208; Sahih Muslim, Hadith 2643).

Islamic scholars conclude:

- Before ensoulment, the embryo lacks full human status and rights.
- IVF is permissible within marriage if third-party gametes are not involved.
- Embryo destruction before ensoulment is debated but is not equated with murder under Shariah law.

The Islamic Organization for Medical Sciences (IOMS) and Fiqh Councils in Egypt and Saudi Arabia permit ART while emphasizing the ethical responsibility to limit the number of embryos created to avoid unnecessary destruction.

The Jewish Perspective

Jewish perspectives on embryo status are based on the Torah, Talmud, and Rabbinic teachings. Judaism does not attribute full personhood to the embryo in its early stages. The Talmud states that the foetus is maya be-alma ("mere water") until 40 days post-conception (Yevamot 69b). The Mishnah (Ohalot 7:6) views a foetus as part of the mother rather than an independent entity.

Exodus 21:22-23 states: "If people are fighting and hit a pregnant woman and she gives birth prematurely but there is no serious injury, the offender must be fined... But if there is serious injury, you are to take life for life.". This suggests that a foetus does not hold the same legal status as a born human. The Talmud (Sanhedrin 91b) states that a foetus attains nefesh (personhood) only at birth.

Jewish law (Halakha) generally permits and even encourages assisted reproduction, particularly to fulfil the commandment of pru urvu ("Be fruitful and multiply" Genesis 1:28). However, ethical concerns about embryo destruction vary among Rabbinic authorities.

Comparative Ethical Considerations

Religious perspectives on embryo status led to diverse ethical positions:

- Catholicism grants absolute protection to embryos, whereas Islam and Judaism take a more gradual approach.
- Catholicism strictly limits ART, while Islam and Judaism permit it under conditions.
- Catholicism and Orthodox Christianity oppose embryo destruction, whereas some Islamic and Jewish scholars allow conditional embryo use in research.

Secular bioethicists also shape the debate. Peter Singer argues that personhood is tied to cognitive capacity rather than biological development, asserting that early-stage embryos lack sentience and therefore moral status (Singer, 1993). In contrast, Leon Kass emphasizes the intrinsic moral worth of human life from its earliest stages, cautioning against a purely utilitarian approach (Kass, 2002).

Conclusion

Religious and ethical perspectives on embryo status are deeply rooted in theological and philosophical traditions. While monotheistic religions recognize the embryo's significance, their interpretations of its moral and legal status differ, influencing national laws and ART policies. Understanding these perspectives is essential for ethical and legally sound reproductive medicine policies in diverse societies.

LEGAL FRAMEWORKS

International Legal Frameworks on Embryo Status

The moral and legal status of the human embryo has been debated extensively, leading to various international legal instruments and ethical guidelines designed to balance scientific progress with respect for human dignity. This section examines key frameworks addressing the protection of human embryos.

European Convention on Human Rights and Biomedicine - Oviedo Convention

The Oviedo Convention, adopted by the Council of Europe in 1997, is the first legally binding instrument to protect human rights in the biomedical field. It focuses on safeguarding human dignity and ensuring respect for human rights in biology and medicine. While the Convention does not define the moral or legal status of the embryo, it establishes a framework that has led to varying embryo-related laws across Europe, affecting reproductive treatments and embryo research policies.

European Court of Human Rights (ECHR) Rulings

The ECHR has ruled on cases involving embryo status, reproductive rights, and ART, reflecting the margin of appreciation that allows member states to regulate bioethical issues according to their national contexts. In Evans v. United Kingdom (2007), the Court ruled that destroying embryos created via IVF after one partner withdrew consent did not violate the applicant's right to family life under Article 8, highlighting the legal uncertainty of embryo status and its subjectivity to national discretion.

European Union Directives and Recommendations

The EU has developed regulations, such as the SoHO Regulation (Regulation (EU) 2024/1938), to ensure high standards for the safety and quality of substances of human origin, including reproductive cells and embryos. However, it does not define the embryo's moral or legal status, leaving this to national legislation.

Position of Professional Organizations

The European Society of Human Reproduction and Embryology (ESHRE) has contributed to the ethical discourse on the moral status of embryos. ESHRE's 2024 position paper argues that embryos have a limited moral status, shaped by local ethical, cultural, and legal factors. It advocates for extending the permissible research period to 28 days post-fertilization, citing scientific benefits and the need for ethical oversight.

Comparative Legal Analysis of Embryo Status in the Balkan Countries

This section compares the legal frameworks governing embryo creation, use, and research in six Balkan countries: Bosnia and Herzegovina (specifically the Federation of Bosnia and Herzegovina, FBiH), Croatia, North Macedonia, Montenegro, Serbia, and Slovenia. Key areas of comparison include embryo surplus, freezing policies, storage duration, and research regulations.

All countries allow the creation of surplus embryos in IVF, but only Croatia limits the number of oocytes that can be collected in an IVF cycle to 12. Surplus embryos can be frozen in all countries, but destruction of surplus embryos is forbidden in Croatia and allowed in the others analysed countries.

Duration of in-lab embryo cultivation varies from six days in Bosnia and Herzegovina and Croatia, 14 days in North Macedonia, Montenegro, Slovenia, while in Serbia it is stated that it is forbidden to allows human development outside the womb.

Storage duration varies from (mandatory) indefinite storage in Croatia to maximally allowed 15 years in Montenegro. Other countries have 10 years in max.

In Bosnia and Herzegovina and Slovenia, embryos must be disposed of after ten years, whereas Montenegro, North Macedonia, and Serbia permit scientific research on embryos with the couple's consent. Croatia, in contrast, mandates indefinite storage or donation to other couples. While research on donated embryos is legally permitted in Montenegro, North Macedonia, and Serbia, Slovenia allows research only if it does not affect the

outcome of the procedure. In Bosnia and Herzegovina and Croatia, embryo research remains strictly prohibited.

Legal Status of the Embryo in Bosnia and Herzegovina (Federation of Bosnia and Herzegovina – FBiH)

This section provides an overview of the legal framework governing embryo status in FBiH, focusing on implications for ART, embryo freezing, and research.

The law in FBiH defines the embryo as a fertilized egg capable of development from the moment the nuclei merge. It treats all stages of embryo development uniformly, without distinguishing between early and later phases.

IVF is available to both married and non-married couples. There are no age restrictions for IVF, but public funding has age caps for state-supported treatments. A formal diagnosis of infertility is required.

Freezing surplus embryos is allowed, with proper storage and traceability. The default storage period is five years, extendable for another five years upon request. Once the storage period expires, embryos are automatically destroyed. Donation for reproduction or research is prohibited, with disposal being the only legally permitted option.

The law prohibits all forms of embryo research, including:

- Development of embryos outside the womb beyond six days

- Creation of embryos for research

- Any scientific or experimental procedures on embryos

Violations are punishable by 3 to 10 years in prison.

FBiH's restrictive stance, including the prohibition on embryo research and donation, hinders scientific advancement. In contrast, Slovenia allows embryo cultivation up to 14 days and permits controlled research. These legal restrictions prevent the development of new ART techniques and limit FBiH's ability to align with European scientific standards. Legal reforms are necessary to foster scientific progress and bring Bosnia and Herzegovina closer to international practices.

COMPARATIVE AND ANALYTICAL APPROACH

This chapter synthesizes scientific, ethical, religious, and legal perspectives on embryo status, highlighting key conflicts and areas for legal reform. It discusses the biological and philosophical distinction between the conceptus and the embryo, examines religious perspectives on embryo development, and analyses legal contradictions in Bosnia and Herzegovina, particularly the six-day limit on embryo culture and the prohibition of embryo research. The chapter concludes with a call for legal reform in light of scientific advancements.

Biological and Philosophical Perspective: The Conceptus vs. the Embryo

The debate over when life begins is central to discussions on embryo status. Biologically, life is a continuous cycle that has remained unbroken since the first living cell billions of years ago and continues through the gametes inherited from both parents. Death, not fertilization, marks the interruption of life (Brown, 2018). However, a meaningful distinction is the point of biological unity, when the embryo begins to develop as a single organism. Prior to Day 14, the conceptus is undifferentiated and can potentially split into twins or fuse with another conceptus. This period is marked by the lack of biological unity (Alvarez-Diaz, 2007).

Day 14 is recognized as the key developmental milestone because the primitive streak forms, signalling the onset of a unified organism. Scientific consensus allows embryo culture up to Day 14, with some experts advocating for an extension to 28 days to gain more insights into early development (ESHRE, 2024). This evolving understanding challenges current legal restrictions based on outdated notions of embryo status.

Scientific vs. Religious Perspectives on Embryo Status

Religious perspectives on embryo status vary significantly. Christianity, especially Catholicism and Orthodoxy, holds that the embryo is fully human from conception., which contrasts with scientific milestones, when biological unity is established. Islam recognizes gradual development, with ensoulment occurring later (at 40 or 120 days), aligning more closely with scientific perspectives. Judaism also follows a gradual approach, with the embryo regarded as "mere water" until after 40 days.

These religious views highlight the ethical dilemma of whether national policies should prioritize scientific evidence or religious doctrine when it comes to embryo research and regulation. The divergence between scientific and religious interpretations poses significant challenges for legal frameworks.

Legal Contradictions in Bosnia and Herzegovina

Bosnia and Herzegovina impose a six-day limit on embryo culture, which is at odds with modern reproductive medicine. Clinical studies suggest that

extending embryo culture to Day 7 can enhance IVF outcomes, yet the legal framework remains restrictive. This discrepancy raises concerns about Bosnia's adherence to contemporary medical standards.

Ethical Paradox: The Destruction of Surplus Embryos

A major ethical contradiction exists in Bosnia and Herzegovina's policy on surplus embryos. Embryos not used by the couple must be destroyed, even if they are viable. Moreover, research on embryos is prohibited, even though such research could advance IVF treatments and benefit future patients. This raises an ethical question: If embryos must be destroyed, why not use them for scientific research that could improve medical practices?

The Case for Legal Reform

Given the scientific evidence supporting the benefits of extending embryo culture and allowing controlled research, Bosnia and Herzegovina's restrictive policies appear outdated. Measured legal reforms could lead to significant medical advancements.

DISCUSSION

This chapter summarizes key findings, outlines legal recommendations, and proposes changes to Bosnia and Herzegovina's laws regarding embryo culture and scientific research. It emphasizes the need for a balanced approach that promotes scientific progress while maintaining ethical standards and social acceptability.

Legal Recommendations for Bosnia and Herzegovina

Bosnia and Herzegovina's current legal framework restricts embryo culture to Day 6 and imposes a complete ban on scientific research involving embryos. These limitations hinder medical progress and reduce the potential for improved IVF outcomes. Scientific evidence indicates that:

• Extending embryo culture to Day 7 can enhance IVF success rates in selected clinical cases.

• Permitting strictly regulated research on surplus embryos can lead to improved assisted reproductive technology (ART) protocols.

Several European countries, including Slovenia, the United Kingdom, and Belgium, allow embryo research under strict ethical oversight. Based on this, the following legal amendments are proposed:

Amendment to Article 47, Paragraph 1

Current text:

"(1) In the process of medically assisted reproduction, it is prohibited to allow in vitro development of embryos older than six days." Translation: "(1) U postupku biomedicinski potpomognute oplodnje zabranjeno je: a) omogućiti vantjelesni razvoj embriona starijih od šest dana.").

Proposed amendment:

"(1) In the process of medically assisted reproduction, it is prohibited to allow in vitro development of embryos beyond day seven, or after hatching from the zona pellucida." Translation: "(1) U postupku biomedicinski potpomognute oplodnje zabranjeno je: a) omogućiti vantjelesni razvoj embriona starijih od sedam dana, odnosno nakon oslobađanja iz zone pelucide.".

Justification:

Extending embryo culture to Day 7 is supported by clinical evidence as beneficial in selected cases, improving pregnancy rates. Harmonizing the legal framework with European standards, where culture is permitted up to 14 days, should be a long-term goal. Extending to Day 7 represents an initial and realistic step.

Amendment to Article 47, Paragraph 3

Current text:

"(3) Scientific or research work on embryos is prohibited." Translation: "(3) Zabranjen je naučni ili istraživački rad na embrionu."

Proposed amendment:

"(3) Scientific or research work is prohibited if it may have negative implications for the treatment outcome or embryo itself." Translation: "(3) Zabranjen je naučni ili istraživački rad koji može imati negativne implikacije na ishod liječenja ili na sami zametak."

Justification:

The absolute ban on embryo research is overly restrictive and prevents IVF advancements. The reform would allow ethical research without endangering treatment outcomes or embryo itself.

Amendment to Article 65

Current text:

"… or conducts scientific or research work on embryos shall be punished by imprisonment from three to ten years." Translation: "... ili obavlja naučni, odnosno istraživački rad na embrionu, bit će kažnjen kaznom zatvora od tri do 10 godina."

Proposed amendment:

"... or conducts scientific or research work without prior consent of the Commission and Ethics Committee shall be punished by imprisonment for a term of three to 10 years." Translation: "... ili obavlja naučni, odnosno istraživački rad bez prethodne saglasnosti Komisije I Etičkog komiteta bit će kažnjen kaznom zatvora od tri do 10 godina."

Justification:

This change removes the absolute criminalization of embryo research while still penalizing unethical practices.

Balancing Science, Ethics, and Law

To balance scientific progress with ethical oversight, Bosnia and Herzegovina should establish national or institutional ethics committees to review research proposals. Countries like Slovenia, the UK, and Belgium have successfully implemented ethical oversight mechanisms to ensure that research advances without moral or legal compromise.

CONCLUSION

Key findings include:

- Religious traditions define life's beginning based on spiritual beliefs.
- Scientific advancements necessitate legal adaptation.
- Bosnia and Herzegovina's restrictive framework is out of step with modern practices.

Proposed reforms:

- Extend embryo culture to Day 7 (preferably aligning with the 14-day European standard).
- Allow controlled embryo research that does not compromise treatment outcomes or embryo itself.
- Harmonize legal terminology and establish Ethical committees.

Implementing these reforms will align Bosnia and Herzegovina with recent medical and ethical standards, ensuring reproductive rights and scientific progress.

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