THE GERMLINE GAMBIT: STRATEGIC STATE COMPETITION AND THE RACE FOR GENE SUPREMACY

By: Mike Sapp[*]

Abstract: *This Article introduces "strategic consequentialism" as a novel theoretical framework to explain how great power competition is fundamentally reshaping the governance of human germline editing. Unlike traditional bioethical approaches that prioritize universal principles of dignity, autonomy, and justice, strategic consequentialism reveals how nation-states systematically subordinate ethical considerations to a stark calculus: maximizing relative technological advantage in an anarchic international system. Drawing on patent landscape analysis, government assessments, and comparative legal frameworks, this Article demonstrates that the United States and China are locked in an accelerating race to control technologies that could permanently alter human evolution - a competition driven not by ethical permissibility but by the fear of strategic disadvantage.*

The empirical evidence is sobering. Patent data reveals that China surpassed the United States in CRISPR-related filings in 2020, while analysis of national innovation systems exposes a critical divergence: China's state-coordinated approach, operationalized through Military-Civil Fusion, contrasts sharply with America's fragmented, market-driven ecosystem, a fragmentation deepened by Amgen v. Sanofi's restrictions on broad biotechnology patents. Case studies of supply chain dependencies and next generation editing technologies illustrate how this structural mismatch creates exploitable vulnerabilities. Most troublingly, the international governance architecture maintains a deliberate vacuum, with neither the WHO, UNESCO, nor any binding treaty providing meaningful constraints on this competition.

This Article argues that without immediate strategic realignment - including establishment of a National Biotechnology Coordination Office, massive investment in domestic biomanufacturing capacity, and construction of an Allied Biotechnology Framework - the United States risks permanently ceding control over technologies that will define the future of human enhancement. The analysis employs scenario planning to map potential futures from "Coordinated Competition" to "Breakout Enhancement," providing policymakers with an early-warning framework for navigating this unprecedented challenge. The germline gambit represents more than another front in great power competition; it is a struggle for authorship of humanity's biological future, where the logic of strategic consequentialism threatens to override centuries of bioethical thought. The window for shaping this competition while preserving democratic values is rapidly closing.

[*] J.D. Candidate, California Western School of Law (2026). This Article examines the intersection of biotechnology, sovereign power, and international patent competition, and proposes a strategic framework for understanding the legal and geopolitical dimensions of human germline editing. All views and errors are the author's own.

I. INTRODUCTION: STATE INTERESTS AND THE RACE FOR GENETIC CONTROL

Imagine a not-so-distant future where a breakthrough cancer therapy is developed in Shanghai, but when tensions over Taiwan reach a breaking point, the Chinese Communist Party hoards the treatment, weaponizing American dependence on its supply chains. This harrowing scenario is not science fiction; it is the strategic future posited by the National Security Commission on Emerging Biotechnology (NSCEB)[1] to illustrate the stakes of the global biotechnology race.[2] In November 2018, this competition erupted from the hypothetical into reality when Chinese scientist He Jiankui announced the birth of the first gene-edited babies, twin girls whose DNA he had altered using CRISPR technology.[3] While the international scientific community erupted in condemnation, a more subtle message rippled through the corridors of power in Washington and Beijing: the age of human germline engineering had arrived, and with it, a new arena for the ultimate global power competition.[4]

The twenty-first-century geopolitical landscape is increasingly defined not by traditional military might alone, but by technological supremacy in transformative fields.[5] In this new battleground, no technology holds more revolutionary potential than human germline gene-editing,

---

[1] NAT'L SEC. COMM'N ON EMERGING BIOTECHNOLOGY, ENDURING DOMINANCE: A STRATEGY FOR U.S. LEADERSHIP IN THE BIO-REVOLUTION 6–7 (2025) [hereinafter NSCEB FINAL REPORT] (describing a scenario in which a breakthrough cancer therapy developed in China is hoarded during a geopolitical crisis, illustrating strategic vulnerabilities).

[2] NARIYOSHI SHINOMIYA & KIWAKO TANAKA, THE SECURITY IMPLICATIONS OF DEVELOPMENTS IN BIOTECHNOLOGY 6 (2025) [hereinafter SHINOMIYA & TANAKA REPORT] (predicting that states will compete to be first to develop new biotechnologies and to use them for strategic advantage).

[3] David Cyranoski & Heidi Ledford, *Genome-Edited Babies: What Does It Mean for Science?*, 563 NATURE 607, 607 (2018) (reporting on the announcement of the first CRISPR-edited babies).

[4] Henry T. Greely, *CRISPR'd Babies: Human Germline Genome Editing in the "He Jiankui Affair,"* 6 J.L. & BIOSCI. 111, 111 (2019) (reviewing ethical and legal issues raised by the He Jiankui experiment).

[5] CTR. FOR STRATEGIC & INT'L STUD., THE STRATEGIC IMPERATIVE OF BIOTECHNOLOGY: IMPLICATIONS FOR U.S. NATIONAL SECURITY 1 (2024) (explaining why national leadership in biotechnology is a security imperative).

the ability to make heritable changes to the human genome that will be passed to future generations.[6] The intense rivalry between the United States of America (U.S.) and The People's Republic of China (China) to dominate these technologies extends far beyond scientific prestige; it represents a foundational struggle for strategic advantage with permanent geopolitical implications.[7] As the National Security Commission on Emerging Biotechnology (NSCEB) concluded in its landmark 2025 report, the United States faces the sobering prospect of falling behind in this critical domain, a setback from which it "may never recover."[8]

This Article advances a provocative thesis: national security imperatives, economic dominance calculations, and strategic positioning, not abstract ethical principles, are the primary forces driving the germline editing competition. This thesis stands in contrast to much of the traditional bioethics literature, which analyzes gene editing primarily through established ethical lenses focusing on principles like dignity, autonomy, and justice without fully accounting for the overriding logic of state competition.[9] Contending that state practice reveals these traditional frameworks are being subordinated to a prototype of strategic consequentialism: a framework where the moral permissibility and desirability of a technological pursuit are evaluated based on its potential to enhance a state's relative power and secure its long-term strategic interests, a reality underscored by analysis concluding that powerful nations will inevitably "use their strategic advantage to exploit new biotechnologies… in pursuit of their own geopolitical goals."[10] Unlike

---

[6] NAT'L ACADS. OF SCI., ENG'G & MED., HUMAN GENOME EDITING: SCIENCE, ETHICS, AND GOVERNANCE 17-19 (2017) (providing a scientific overview of germline gene editing and its ethical implications).
[7] NSCEB FINAL REPORT, *supra* note 1, at 6 (stating that biotechnology allows humans to reprogram living cells and that the ability to program life constitutes a strategic capability).
[8] NSCEB FINAL REPORT, *supra* note 1, at 8 (describing pillars of U.S. biotechnology strategy).
[9] *See, e.g.*, Françoise Baylis, *Human Germline Genome Editing and Broad Societal Consensus*, 17 NAT. HUM. BEHAV. 234 (2023) (arguing that broad societal consensus is necessary before germline editing; provides context for bioethical frameworks); TOM L. BEAUCHAMP & JAMES F. CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS (8th ed. 2019) (articulating the foundational principles of autonomy, beneficence, non-maleficence, and justice that guide modern bioethics).
[10] SHINOMIYA & TANAKA REPORT, *supra* note 2, at 6 (confirming state competition for biotechnology).

classical consequentialism, which maximizes a general good like "well-being,"[11] this archetype defines the ultimate good as that which enhances national competitive advantage.[12] The state that masters heritable genome-editing tools will hold enduring influence over healthcare, military capabilities, and ultimately, the trajectory of human evolution itself.

This competition didn't emerge from the primordial soup of chance, it was carefully cultivated in the laboratories of state-run ambition. As the NSCEB report warns, "China is quickly ascending to biotechnology dominance, having made biotechnology a strategic priority for 20 years."[13] In stark contrast, the U.S. approach has been "piecemeal and uncoordinated," leaving the country with "no cohesive, intentional biotechnology strategy."[14] From this fracture emerges the raw nerve this analysis dares to touch, a critical vulnerability requiring surgical attention. The economic stakes of this competition are staggering, with the market for gene editing projected to surge to $44 billion by 2025.[15] Within this market, McKinsey & Company research suggests that bioengineering's applications could have an economic impact of up to $4 trillion per year from 2030 to 2040.[16] The urgency of this contest cannot be overstated. The NSCEB's stark warning that China's strategic focus on biotechnology has positioned it for potential dominance provides authoritative validation of this Article's central argument.[17] These findings provide the essential

---

[11] Walter Sinnott-Armstrong, *Consequentialism*, STANFORD ENCYCLOPEDIA OF PHILOSOPHY (June 3, 2003), https://plato.stanford.edu/entries/consequentialism (describing classical utilitarianism as maximizing happiness and well-being).

[12] JOHN J. MEARSHEIMER, THE TRAGEDY OF GREAT POWER POLITICS 29–31 (2001) (explaining offensive realism and the pursuit of relative power as drivers of state behavior; provides theoretical foundations for "strategic consequentialism").

[13] NSCEB FINAL REPORT, *supra* note 1, at 6 (reinforcing the concept that biotechnology allows the programming of life).

[14] NSCEB FINAL REPORT, *supra* note 1, at 26 (observing that the U.S. government lacks an intentional biotechnology strategy).

[15] ROLAND BERGER, TREND COMPENDIUM 2050 29 fig. 2 (2022) [hereinafter ROLAND BERGER TRENDS] (projecting the global gene-editing market to reach roughly $44 billion by 2025).

[16] MICHAEL CHUI ET AL., THE BIO REVOLUTION: INNOVATIONS TRANSFORMING ECONOMIES, SOCIETIES, AND OUR LIVES 3 (McKinsey Glob. Inst. 2020) (estimating that bioengineering could contribute up to $4 trillion annually by 2030-2040).

[17] NSCEB FINAL REPORT, *supra* note 1, at 28 (summarizing market opportunities and strategic imperatives).

legal, theoretical, and historical scaffolding for the Commission's urgent strategic warnings, aiming to build a durable academic framework for the vital policy debates it has awakened.

Patent data provides a powerful, quantitative lens for viewing this competition, revealing innovation trends more directly than academic citation metrics alone.[18] A comprehensive 2024 analysis by the technology intelligence firm Centredoc, commissioned by the Swiss Federal Institute of Intellectual Property, provides definitive data on this competition.[19] The report confirms a stunning reversal: between 2012 and 2022, Chinese entities accounted for 46.25% of all CRISPR-related patent priority filings, decisively surpassing the United States' 39.80%.[20] This shift was driven by a critical inflection point in 2020, when China's annual filings surged past those of the U.S., a lead it has since widened.[21] This raw data, however, masks a deeper strategic divergence. China's filings are overwhelmingly domestic, with only 8.7% of its priority patents being extended internationally, reflecting a deliberate focus on securing intellectual property within its own borders - a cornerstone of its strategy for technological self-reliance. The U.S., in contrast, pursues broader international patent extensions, leveraging its global reach.[22]

The legal architectures of both countries reflect these contrasting strategic approaches. The U.S. operates a market-driven model that has spawned breakthrough discoveries but, as the NSCEB notes, suffers from fragmented policymaking that creates strategic incoherence.[23] China

---

[18] Adrian Sven Geissler, Jan Gorodkin & Stefan Ernst Seemann, *Patent Data-Driven Analysis of Literature Associations with Changing Innovation Trends*, 9 FRONT. RES. METRICS & ANALYTICS 1432673 (2024) (explaining that patent data is a superior metric for identifying technological innovation).
[19] SCBT-CENTREDOC, CRISPR TECHNOLOGY: PATENT & LICENSE LANDSCAPES, No. 20231386, at 8 (Feb. 5, 2024) (prepared for the Swiss Federal Institute of Intellectual Property) [hereinafter CENTREDOC REPORT] (providing data on CRISPR patent filings).
[20] CENTREDOC REPORT, *supra* note 19, at 9 tbl. 2.3.2 (reporting that Chinese entities accounted for 46.25% of CRISPR priority patent families and U.S. entities 39.80% between 2012-2022).
[21] CENTREDOC REPORT, *supra* note 19, at 10 fig. 2.3.3 (illustrating the rapid growth of Chinese CRISPR filings).
[22] *Id.* at 11 fig. 2.3.4 (noting that only 8.7% of Chinese CRISPR priority filings have been extended internationally).
[23] NSCEB FINAL REPORT, *supra* note 1, at 26 (contrasting a fragmented U.S. approach with China's coordinated state-led initiatives).

employs a state-coordinated approach that integrates national planning with its Military-Civil Fusion (MCF) strategy. As a U.S. Department of State advisory report recently concluded, MCF is a national strategy through which the PRC systematically co-opts civilian research and commercial power to "strengthen and support the PLA."[24] It seeks to "eliminate barriers between the civilian and defense sectors" to ensure that advancements in fields like biotechnology are diverted to military applications, a process the PRC has identified as crucial to dominating the next "Revolution in Military Affairs (RMA)."[25] Despite widespread ethical concerns, no universally adopted treaty prevents actors from pursuing patents on germline-editing technologies, as the key state competitors in this race have strategically abstained from the primary international legal instrument that prohibits it.[26] This permissive environment allows the U.S.-China rivalry to unfold largely unconstrained by global norms, creating what this study terms a "governance vacuum" that both enables and accelerates the competition.[27]

This Article unfolds in ten tightly linked parts: Part II traces the historical trajectory from Asilomar's voluntary restraint through CRISPR's democratization to the He Jiankui shock; Part III offers a doctrinal comparison of U.S., Chinese, EU, and Brazilian patent regimes, highlighting how *Amgen v. Sanofi* deepens the U.S.'s "strategic fragmentation"; Part IV shows how realist security logic overcomes traditional bioethics, recasting the race as a prisoner's-dilemma; Part V

---

[24] U.S. DEP'T OF STATE, INT'L SEC. ADVISORY BD. [ISAB], REPORT ON BIOTECHNOLOGY IN THE PEOPLE'S REPUBLIC OF CHINA'S MILITARY-CIVIL FUSION STRATEGY 56 (2024) [hereinafter **ISAB Report**]; *see also* NSCEB FINAL REPORT, *supra* note 1, at 25 (discussing China's Military-Civil Fusion strategy).

[25] ISAB REPORT, *supra* note 24, at 6, 10 (detailing central government control over biotechnology).

[26] The most prominent binding legal instrument, the Oviedo Convention, explicitly prohibits germline modification in Article 13. However, its geopolitical reach is limited, as neither the United States nor China are signatories. *See* Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, Apr. 4, 1997, E.T.S. No. 164, art. 13; Council of Eur., CHART OF SIGNATURES AND RATIFICATIONS OF TREATY 164, https://www.coe.int/en/web/conventions/full-list?module=signatures-by-treaty&treatynum=164 [hereinafter OVIEDO CONVENTION]; *see also* WORLD HEALTH ORG., HUMAN GENOME EDITING: A FRAMEWORK FOR GOVERNANCE 10-12 (2021) [hereinafter WHO FRAMEWORK] (describing the WHO's role in gene-editing governance and acknowledging its lack of enforcement power).

[27] WHO FRAMEWORK, *supra* note 26, at 33 (noting that the WHO has no mandate to enforce its recommendations).

grounds theory in three case studies, the CRISPR patent wars, "therapeutic sovereignty" supply-chain risks, and China's leapfrog into base editing; Part VI models the economic stakes, contrasting U.S. venture capital with China's patient-capital strategy; Part VII exposes the international governance vacuum left by UNESCO, WHO, Oviedo, and TRIPS; Part VIII sketches four future scenarios from Coordinated Competition to Breakout Enhancement; Part IX proposes a U.S. response, NBCO creation, a Biomanufacturing Resilience Act, ARPA-H moonshots, an Allied Biotechnology Framework, and a National Defense Biotechnology Education Act, and Part X synthesizes the analysis, warning that decisive action is urgent to steer germline editing toward global benefit rather than zero-sum domination.

II. FROM VOLUNTARY RESTRAINT TO UNBOUND COMPETITION: A HISTORICAL EVOLUTION

The history of genetic governance reveals a consistent pattern: technological capabilities dramatically outpace the development of regulatory frameworks, creating windows of opportunity that strategic actors inevitably exploit.[28] For much of the twentieth century, the United States dominated this field, with domestic research institutions setting the global pace.[29] The progression from that era of leadership, marked by collegial self-regulation, to the current state of unbound, state-led strategic rivalry demonstrates a fundamental shift in how transformative technologies are managed, driven by an accelerating pace of innovation that compresses the time available for ethical deliberation.[30]

---

[28] Eileen M. Kane, *Human Genome Editing: An Evolving Regulatory Climate*, 101 **W**ASH. U. L. REV. 233, 234 (2023) (discussing regulatory developments and oversight challenges).
[29] NSCEB FINAL REPORT, *supra* note 1, at 26 (observing U.S. dominance in biotechnology during the twentieth century).
[30] Kane, *supra* note 28, at 235 (describing early gene-editing oversight).

A. The Asilomar Moment: When Scientists Governed Themselves

The modern era of genetic governance began with a magnanimous act of scientific self-regulation. In February 1975, 140 leading scientists, lawyers, and physicians gathered at the Asilomar Conference Center in Pacific Grove, California, to confront the risks of their own research into recombinant DNA (rDNA) technology.[31] Convened by Nobel laureate Paul Berg, the conference followed a self-imposed moratorium on certain experiments, a direct response to fears that splicing genes between different organisms could inadvertently create dangerous new pathogens.[32]

The resulting Asilomar consensus created a tiered system of physical and biological containment based on assessed risk levels, which became the foundation for the National Institutes of Health's (NIH) 1976 Guidelines for Research Involving Recombinant DNA Molecules.[33] This framework, establishing Institutional Biosafety Committees (IBCs) and a national Recombinant DNA Advisory Committee (RAC), proved remarkably durable, governing American biotechnology research for decades.[34]

Yet Asilomar's scope was deliberately limited, focusing almost exclusively on laboratory biosafety rather than broader bioethical questions.[35] Historians examining the correspondence of the organizers, such as Paul Berg and Joshua Lederberg, note intense internal debates about

---

[31] PRESIDENTIAL COMM'N FOR THE STUDY OF BIOETHICAL ISSUES, NEW DIRECTIONS: THE ETHICS OF SYNTHETIC BIOLOGY AND EMERGING TECHNOLOGIES 50-53 (2010).
[32] Paul Berg, *Asilomar 1975: Recombinant DNA Guidelines* (Nobel lecture, Dec. 8, 1980) (recounting the creation of voluntary guidelines for recombinant DNA research).
[33] Guidelines for Research Involving Recombinant DNA Molecules, 41 Fed. Reg. 27,902 (July 7, 1976) (codified in scattered sections of the C.F.R.) (formalizing Asilomar-based biosafety guidelines).
[34] SHELDON KRIMSKY, GENETIC ALCHEMY: THE SOCIAL HISTORY OF THE RECOMBINANT DNA CONTROVERSY 345-348 (1982) (analyzing public reaction to early gene-splicing experiments).
[35] PRESIDENTIAL COMM'N FOR THE STUDY OF BIOETHICAL ISSUES, *supra* note 31, at 52 (noting the importance of public deliberation).

whether to include the then-speculative topic of human genetic modification on the agenda.[36] Lederberg argued presciently that the genie of human genetic manipulation would not long remain bottled, but Berg successfully insisted on maintaining a narrow focus to achieve consensus.[37] The prospect of heritable human genetic modification, while acknowledged, was considered too distant for serious consideration. As one participant later recalled, "We were worried about bacteria escaping from labs, not about designing babies."[38] This narrow focus on immediate risks left conceptual and regulatory gaps that would later prove critical.

B. Early Gene Editing: Technical Barriers as De Facto Governance

The development of first-generation gene-editing tools in the 1990s and 2000s, zinc-finger nucleases (ZFNs) and transcription activator-like effector nucleases (TALENs), marked important technical progress.[39] Unlike the later CRISPR systems, these tools rely on custom-designed proteins to recognize a specific DNA sequence. Engineering a new ZFN or TALEN for each genetic target was a painstaking, artisan-like process requiring deep expertise in protein engineering and months of laboratory work.[40] The cost of developing a single functional ZFN pair could run into the tens of thousands of dollars,[41] making it commercially and practically infeasible for all but the most well-funded research labs.

---

[36] MATTHEW COBB, AS GODS: A MORAL HISTORY OF THE GENETIC AGE 158–61 (2022) (documenting debates leading to and following the Asilomar meeting).
[37] *Id.* at 160.
[38] Jon Cohen, *The End of the Beginning*, SCIENCE, May 22, 2015, at 826, 827 (quoting James Watson on scientists governing recombinant DNA research).
[39] NAT'L ACADS. OF SCI., ENG'G & MED., BIODEFENSE IN THE AGE OF SYNTHETIC BIOLOGY 4–8 (2018) (exploring emerging risks and regulatory considerations).
[40] Dana Carroll, *A CRISPR Approach to Gene Targeting*, 20 MOL. THERAPY 1658, 1659 (2012) (explaining the challenges of engineering ZFNs).
[41] Megan Scudellari, *Genome Editing: The TALENs Take Over?*, THE SCIENTIST (Dec. 1, 2011), https://www.the-scientist.com/uncategorized/genome-editing-the-talens-take-over-40224 (noting that designing a ZFN pair could cost $5,000–$10,000 and take months).

This complexity and expense served as an unintended form of governance. The high barrier to entry limited the technology's proliferation to a handful of academic labs and specialized corporations like Sangamo Therapeutics, creating what can be termed "governance by inaccessibility."[42] Regulators and ethicists came to implicitly rely on this dynamic, which allowed ethical discussions to proceed at a measured pace under the comfortable assumption that there was ample time to develop formal legal structures.[43] This reliance on technical barriers, rather than explicit regulation, would prove deeply problematic when those barriers suddenly collapsed.

C. The CRISPR Revolution: Simplicity Changes Everything

That assumption shattered in 2012 with the discovery that the CRISPR-Cas9 system could be easily reprogrammed to edit genomes.[44] The simplicity of CRISPR was revolutionary: by swapping out a small guide molecule, the same Cas9 protein could be directed to a new target. What once required months of intricate protein engineering and significant funding could now be accomplished in days for a few hundred dollars.[45] This technical breakthrough immediately triggered a competitive race for intellectual property rights among pioneering institutions including the Massachusetts Institute of Technology, the Broad Institute, the University of Vienna, and the University of California, Berkeley.[46]

---

[42] This framing is the author's.
[43] Kane, *supra* note 28, at 242–45 (discussing the evolving ethical debate and regulatory approaches to gene editing).
[44] Martin Jinek et al., *A Programmable Dual-RNA-Guided DNA Endonuclease in Adaptive Bacterial Immunity*, 337 SCIENCE 816 (2012) (demonstrating programmable CRISPR-Cas9 gene editing).
[45] Jennifer A. Doudna & Emmanuelle Charpentier, *The New Frontier of Genome Engineering with CRISPR-Cas9*, 346 SCIENCE 1258096, 1258096-5 (2014) (emphasizing CRISPR's simplicity and ease of use compared to protein-based tools).
[46] SHINOMIYA & TANAKA REPORT, *supra* note 2, at 7 (noting that CRISPR spread rapidly due to its low cost and accessibility).

This democratization had monumental strategic and commercial implications - the foundational scientific papers describing the technology immediately became some of the most consequential publications of the century.[47] The subsequent, intense competition for foundational patents, most notably the battle between the Broad Institute and the "CVC group" (comprising the University of California, the University of Vienna, and Dr. Emmanuelle Charpentier), marked the definitive end of the era of collegial restraint. Despite the CVC group filing its initial patent application first, the U.S. Patent Trial and Appeal Board (PTAB) ultimately sided with the Broad Institute, confirming its priority claim for the use of CRISPR in eukaryotic cells based on evidence of earlier reduction to practice.[48] This ruling set a critical precedent in the United States, emphasizing the importance of experimental validation in patent claims and heavily influencing subsequent global filing strategies.[49]

D. The He Jiankui Watershed: Crossing the Germline

If CRISPR's discovery marked a technical revolution, He Jiankui's 2018 announcement represented an ethical earthquake. He's development of twin girls with edited CCR5 genes demonstrated that heritable human germline editing was no longer theoretical.[50] While his experiment was widely condemned for its ethical recklessness, it must also be understood within a strategic context. The scientific community had built its governance on a permission-based architecture, layers of review boards, ethics committees, and international agreements. He revealed

---

[47] Jacob S. Sherkow, *The CRISPR Patent Interference Case: What You Need to Know*, 33 NAT. BIOTECHNOL. 256, 256-57 (2015) (reviewing the University of California v. Broad Institute interference proceeding).
[48] Geissler et al., *supra* note 18, at 3 (identifying Jinek et al. and Cong et al. as foundational works frequently cited in patent applications).
[49] *Regents of the Univ. of Cal. v. Broad Inst., Inc.*, Interference No. 106,048, 2017 WL 657413 (P.T.A.B. Feb. 15, 2017) (deciding priority in the CRISPR patent interference).
[50] Jacob S. Sherkow, *The CRISPR Patent Landscape: Past, Present, and Future*, 1 CRISPR J. 5, 5-6 (2018) (analyzing the past and future of the CRISPR patent landscape).

this system's fatal flaw: in a world where a single actor with CRISPR can rewrite humanity's code, the difference between permission and forgiveness is measured in generations of permanently altered human beings. Investigative reporting unearthed documents related to the experiment provides insight into his calculations, including consent forms that misleadingly framed the trial as a vaccine development program and highlighted a desire for international recognition.[51]

This act cannot be divorced from China's stated strategic ambitions. As the NSCEB observed, the Chinese Communist Party has long called for "population improvement" and has backed research into sensitive topics like the genetic basis of intelligence, actions that have raised profound ethical questions among international observers.[52] He's experiment, intended to confer HIV resistance,[53] aligns with this broader strategic interest in genetic enhancement. The global response was swift and revealing. While the scientific community condemned the act, the Chinese government imprisoned He and initiated a rapid, top-down transformation of its governance framework. The Shenzhen Nanshan District People's Court sentenced He to three years in prison for "illegal medical practice," finding he had deliberately circumvented ethical oversight and falsified review documents.[54] This judicial action was followed by landmark legislative reforms, including the 2020 enactment of the Civil Code and the 2021 passage of Criminal Law Amendment XI, which together mandated strict ethical compliance and explicitly criminalized non-compliant

---

[51] Marilyn Marchione, *Chinese Researcher Claims First Gene-Edited Babies*, ASSOC. PRESS (Nov. 26, 2018), https://apnews.com/article/4997bb7aa36c45449b488e19ac83e86d (reporting on He Jiankui's experiment and noting misleading consent forms).
[52] NSCEB FINAL REPORT, *supra* note 1, at 25.
[53] Marc Samson et al., *Resistance to HIV-1 Infection in Caucasian Individuals Bearing Mutant Alleles of the CCR-5 Chemokine Receptor Gene*, 382 NATURE 722 (1996) (showing that CCR5 mutations confer HIV resistance).
[54] *China Focus: Three Jailed in China's "Gene-Edited Babies" Trial*, XINHUA NEWS AGENCY (Dec. 30, 2019), http://www.xinhuanet.com/english/2019-12/30/c_138666754.htm (reporting the Shenzhen court verdict and sentences).

clinical applications.[55] Furthermore, following a high-level 2019 proposal, China established the National Science and Technology Ethics Committee (NSTEC) to ensure research aligns with state priorities.[56] The entire effort was consolidated in March 2022 with the issuance of the landmark Opinions on Strengthening the Governance of Science and Technology Ethics, which established comprehensive national principles for all scientific research.[57]

E. The Current Landscape: Strategic Competition Unleashed

Today's gene-editing landscape bears little resemblance to Asilomar's collegial self-governance and collaborative environment. Rather, it is characterized by explosive growth across multiple dimensions that reveal the intensity of strategic competition: massive state investment, particularly from China; blurred civil-military boundaries through policies like China's Military-Civil Fusion; and diverging national regulatory approaches that create opportunities for regulatory arbitrage.[58] This historical progression, from voluntary scientific restraint to intense, unbound strategic competition, has created the conditions for the current geopolitical contest.

The Military-Civil Fusion (MCF) doctrine exemplifies China's recalibration of national power toward long-term strategic dominance. Evolving from earlier Civil-Military Integration (CMI) programs of the late twentieth century, MCF was elevated by President Xi Jinping into a "grand strategy" to build the People's Liberation Army (PLA) into a world class military by

---

[55] CIVIL CODE OF THE PEOPLE'S REPUBLIC OF CHINA (promulgated by the Nat'l People's Congress May 28, 2020, effective Jan. 1, 2021); CRIMINAL LAW OF THE PEOPLE'S REPUBLIC OF CHINA (AMENDMENT XI) (promulgated by the Standing Comm. of the Nat'l People's Congress Dec. 26, 2020, effective Mar. 1, 2021).

[56] Proposal for the Establishment of a National Science and Technology Ethics Committee (Central Committee for Comprehensively Deepening Reform, July 24, 2019).

[57] Opinions on Strengthening the Governance of Science and Technology Ethics (General Office of the CPC Central Committee & State Council, Mar. 20, 2022) [hereinafter SCIENCE ETHICS OPINIONS] (articulating China's comprehensive ethics framework).

[58] U.S.-CHINA ECON. & SEC. REV. COMM'N, 2019 ANNUAL REPORT TO CONGRESS 173-76 (2019) (discussing Chinese science policy and state support).

2049.[59] As part of this effort, Beijing has explicitly identified biotechnology as a "nascent technological area" and strategic priority, with Chinese military strategists consistently framing it as a new domain of warfare.[60] This approach systematically "leverages joint ventures and commercial power to support military objectives," creating an ecosystem where civilian innovation is harnessed for national security ends.[61]

This dynamic creates profound challenges for the U.S., which depends on a globalized scientific workforce.[62] The risk of intellectual property theft and talent diversion must be balanced against the perils of a counterproductive, reactive posture.[63] The case of Qian Xuesen, a brilliant Chinese-born scientist who helped found Caltech's Jet Propulsion Laboratory, is a powerful historical lesson.[64] Accused of communist sympathies during the 1950s Red Scare, he was eventually deported to China, where he founded its aerospace institutes and became the father of its missile program, providing the PRC with decades of advanced organizational and technical knowledge.[65] This precedent underscores the immense strategic cost of mismanaging the complex relationship between national security and the open, international scientific enterprise.[66] The following parts will detail how each nation's legal, economic, and ethical frameworks are now being marshaled for the germline gambit.

---

[59] ISAB REPORT, *supra* note 24, at 6, 9 (examining supply-chain vulnerabilities and Military-Civil Fusion).
[60] *Id.* at 10-11 (assessing the strategic implications of Chinese biotechnology programs).
[61] *Id.* at 6.
[62] NAT'L SCI. BD., SCIENCE & ENGINEERING INDICATORS 2022: THE STEM LABOR FORCE OF TODAY (Nat'l Sci. Found. 2022).
[63] U.S. DEP'T OF JUSTICE, SUMMARY OF THE CHINA INITIATIVE (Jan. 2020) (providing background on DOJ enforcement efforts targeting Chinese economic espionage).
[64] Denis Fred Simon, *From JPL to China: The Case of Qian Xuesen*, in SCIENTIFIC DIASPORAS AND SCIENCE DIPLOMACY 59, 59-72 (Luis Sanz-Menéndez et al. eds., 2023) (analyzing the geopolitics of Qian Xuesen's repatriation).
[65] ISAB REPORT, *supra* note 24, at 15 (discussing the Qian Xuesen case).
[66] *Id.*

III. CONTRASTING PATENT FRAMEWORKS: PHILOSOPHICAL AND STRATEGIC DIVIDES

Patent systems do more than allocate property rights; they embody national philosophies about innovation, ethics, and state power.[67] As this section details, the stark differences between U.S. and Chinese approaches, and those of other nations like the EU and Brazil, reveal fundamentally divergent strategies for pursuing technological dominance. Where the U.S. system fosters market-driven discovery at the cost of strategic coherence, the Chinese system is explicitly engineered to achieve state-defined objectives.

A Note on Patent Data Methodology

The empirical patent analysis in this study relies primarily on the definitive data compiled in a 2024 technology intelligence report, *CRISPR Technology: Patent & License Landscapes*, prepared by the firm Centredoc for the Swiss Federal Institute of Intellectual Property.[68] This report was selected for its comprehensive methodology, its use of the professional FamPat patent family database, and its specific, verifiable quantification of innovation trends and filing strategies. Its data is supplemented where necessary by broader trend analysis from the World Intellectual Property Organization's (WIPO) public reports. This focus on patent data as a primary indicator of innovation is methodologically sound; recent empirical studies reveal that academic citation counts have a very low correlation (e.g. $r \approx 0.16$) with the frequency of patent citations, indicating that scholarly visibility often does not translate into technological relevance - however, statistical analysis of patent records is a highly vigorous method for "identifying scholarly work that enabled technological innovation."[69] This approach allows for a more accurate assessment of the strategic, rather than purely academic, trajectory of the biotechnology race.

[67] SHOBITA PARTHASARATHY, PATENT POLITICS: LIFE FORMS, MARKETS, AND THE PUBLIC INTEREST IN THE UNITED STATES AND EUROPE (2017).
[68] CENTREDOC REPORT, *supra* note 19.
[69] Geissler et al., *supra* note 18.

A. The U.S. Framework: Market-Driven Innovation and Strategic Fragmentation

The American patent system, deriving its authority from a constitutional mandate to promote "the Progress of Science and useful Arts," stands as a testament to the power of market-driven innovation.[70] Historically, this framework cultivated one of the world's most permissive environments for biotechnology patenting, characterized by broad subject-matter eligibility and a litigation-centric enforcement model that together fueled the rise of a dynamic, world-leading biotech industry.[71] The system's foundational legal principle was articulated in the landmark 1980 Supreme Court decision in *Diamond v. Chakrabarty*, which famously declared that "anything under the sun that is made by man" is potentially patentable subject matter under 35 U.S.C. § 101.[72] Even the Supreme Court's 2013 ruling in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, which curtailed the patenting of naturally occurring DNA sequences, deliberately preserved the patentability of complementary DNA (cDNA), thus reaffirming the central tenet that sufficient human intervention can render products of nature into patentable property.[73]

A defining feature of this structure is its deliberate ethical neutrality at the examination stage. Unlike its European counterpart, the U.S. Patent and Trademark Office (USPTO) possesses no explicit statutory power to reject patent applications for violating *ordre public* or morality.[74] The theoretical "moral utility" doctrine has been rendered effectively obsolete in modern jurisprudence.[75] Consequently, ethical guardrails are not embedded within the patent system itself

---

[70] U.S. CONST. art. I, §8, cl. 8.
[71] FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY, ch. 1, at 1-7 (Oct. 2003).
[72] *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (holding genetically modified organisms patentable).
[73] *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 594-95 (2013).
[74] Margo A. Bagley, *Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law*, 45 WM. & MARY L. REV. 469, 473 (2003) (noting that unlike European law, U.S. patent law contains no explicit morality exclusion).
[75] Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364, 1366–68 (Fed. Cir. 1999) (holding that patents are not invalid based on morality).

but are instead diffused across a "piecemeal and uncoordinated" system of downstream regulatory bodies and, crucially, private institutional governance.[76] For example, the Broad Institute's own licensing policies for its foundational CRISPR patents explicitly prohibit their use in human germline modification experiments, regardless of local laws.[77] This reliance on a patchwork of federal agencies and private actors to provide ethical oversight creates the "strategic fragmentation" that complicates the formation of a cohesive biotechnology strategy.

B. The Amgen Shockwave: Enablement, Fragmentation, and the Future of Biotech R&D

This dynamic of judicially-enforced fragmentation was dramatically amplified by the Supreme Court's unanimous 2023 decision in *Amgen Inc. v. Sanofi*.[78] The ruling sent a doctrinal shockwave through the biotechnology industry by robustly affirming a stringent interpretation of the enablement requirement of 35 U.S.C. § 112. The Court clarified that for a broad "functional genus claim," one that claims a potentially vast class of molecules by what they do rather than what they are, the patentee must enable the full scope of what is claimed without "undue experimentation."[79] Justice Gorsuch's opinion, which held that providing a mere "roadmap" for discovery is insufficient, makes it far more difficult to secure the broad, foundational patents that often underpin "platform" technologies.[80]

---

[76] NSCEB FINAL REPORT, *supra* note 1, at 42.
[77] STANFORD UNIV. CTR. FOR L. & THE BIOSCIENCES, LEGAL AND ETHICAL FRAMEWORKS FOR HUMAN GENOME EDITING 15 (2020) (noting that the Broad Institute prohibits use of its CRISPR licenses for human germline editing).
[78] Amgen Inc. v. Sanofi, 598 U.S. 594 (2023).
[79] *Id.* at 611 (holding that broad functional claims must be enabled across the full scope).
[80] *Id.*

The *Amgen* decision will have profound and lasting impacts on venture capital investment and R&D strategies, directly exacerbating the strategic fragmentation of the U.S. system.[81] The heightened enablement standard of *Amgen* directly increases the cost and risk of such leaps, forcing firms to undertake the expensive and time-consuming process of generating and characterizing a significant number of embodiments to secure durable patent protection.[82] This doctrinal shift is widely expected to result in a proliferation of even narrower patent filings, further densifying the existing patent thicket.[83] For a strategic competitor like China, which operates under a "techno-nationalist" industrial policy,[84] the *Amgen* decision is an unambiguous signal that the U.S. IP framework is cementing a model that structurally prefers piecemeal innovation over strategic consolidation.[85] It reinforces a system that complicates the ability of any single U.S. entity to aggregate the foundational IP needed for technological dominance, a vulnerability that a state-guided rival is uniquely positioned to leverage.

C. China's Framework: State-Guided Innovation and Strategic Coordination

Where the U.S. system embodies market-driven fragmentation, China's approach represents state-guided coordination. For two decades, the Chinese Communist Party (CCP) has pursued an "aggressive, whole-of-nation effort" to achieve global biotechnology supremacy,

---

[81] Arti K. Rai, *The Aftermath of Amgen v. Sanofi: A Time of Reckoning for Biopharma*, 21 DUKE L. & TECH. REV. 145, 150 (2023) (criticizing the decision's impact on biotech patents).
[82] *Id.*
[83] Ryan P. Hiler & Andrew E. Levitt, *Amgen v. Sanofi: Seven Months In, Has Anything About Patent Enablement Changed?*, IP WATCHDOG (Jan. 9, 2024), https://ipwatchdog.com/2024/01/09/amgen-v-sanofi-seven-months-in-has-anything-about-patent-enablement-changed/id=171703/.
[84] DAN PRUD'HOMME & TAOLUE ZHANG, CHINA'S INTELLECTUAL PROPERTY REGIME FOR INNOVATION 18-20 (2019).
[85] NSCEB FINAL REPORT, *supra* note 1, at 51.

designating it a "strategic emerging industry" and using its legal system as a direct instrument of industrial policy.[86]

Article 5 of the Chinese Patent Law provides broad authority to reject patents contrary to social morality or detrimental to the public interest, a flexible tool for state guidance absent from U.S. law.[87] Following the He Jiankui incident, China initiated a rapid transformation of its legal and ethical governance architecture.[88] Criminal Law Amendment XI was enacted to explicitly ban germline genome editing for clinical purposes, and the 2020 Civil Code was updated to mandate compliance with strict ethical standards for any research involving human genes or embryos.[89] This legal framework is overseen by the National Science and Technology Ethics Committee (NSTEC), established in 2019 to ensure all genetic editing research aligns with state-defined ethical priorities.[90]

This patent system operates as one component of a coordinated domestic strategy within China's 14th Five-Year Plan which identifies genetic technologies as a frontier field critical to national development.[91] This designation is operationalized through a suite of policies the NSCEB terms "brute force economics," which includes massive state investments and streamlined regulatory pathways for domestic firms.[92] These are complemented by what U.S. government analysts describe as unfair and illegitimate practices, including state subsidies and discriminatory

---

[86] NSCEB FINAL REPORT, *supra* note 1, at 25; ISAB REPORT, *supra* note 24, at 7 (describing the coordinated Chinese strategy).
[87] PATENT LAW OF THE PEOPLE'S REPUBLIC OF CHINA (promulgated Mar. 12, 1984, amended 2020) art. 5 (prohibiting patents that violate social morality).
[88] SCIENCE ETHICS OPINIONS, *supra* note 57.
[89] *See supra* note 55.
[90] *See supra* note 56.
[91] OUTLINE OF THE PEOPLE'S REPUBLIC OF CHINA 14TH FIVE-YEAR PLAN FOR NATIONAL ECONOMIC AND SOCIAL DEVELOPMENT AND LONG-RANGE OBJECTIVES FOR 2035 (CSET trans., 2021), https://cset.georgetown.edu/publication/china-14th-five-year-plan/ (providing the official plan and economic priorities).
[92] NSCEB FINAL REPORT, *supra* note 1, at 51 (warning that China's coordinated strategy threatens U.S. leadership).

regulations designed to pressure foreign companies into joint ventures, which are then leveraged to force technology transfer.[93] This support is targeted to achieve specific outcomes, with Chinese entities focusing heavily on patenting applications in "diagnostics and therapeutics," including nucleic-acid detection and anti-aging therapies.[94] The CCP lavishes support on "national champions" like WuXi AppTec and BGI Genomics, which effectively serve to implement state technology policies and aggressively acquire foreign IP.[95]

D. Comparative Foils and Innovation Models

The U.S. and Chinese systems are not the only models. As summarized in Table 1, the European Union and Brazil offer important contrasts.

Table 1: Comparative National Innovation Models for Gene Editing

Feature	United States	China	European Union	Brazil
Ethics Filter	Minimal (Downstream; private & public)	High (State-defined; embedded in patent law)	High (Dignity-based; embedded in patent law)	High (Sector-specific moral/religious values)
Coordination	Low (Fragmented, market-driven)	High (State-directed, centrally coordinated)	Medium (Pan-EU directives, national implementation)	Medium (Federal law, sector-specific)
Commercialization	Fast (VC-funded, high-risk/reward)	Fast (State-funded, strategically targeted)	Slow (Precautionary principle, regulatory hurdles)	Slow (Restricted by embryo research laws)

[93] ISAB REPORT, *supra* note 24, at 12 (describing capacity-building in Chinese biotech).
[94] WORLD INTELL. PROP. ORG. (WIPO), PATENT TRENDS IN EMERGING BIOTECHNOLOGIES (2021); Qiong Zhou et al., *Genome Editing in China: Progress, Challenges, and Future Directions*, 32 CELL RES. 345, 348 (2022) (discussing Chinese genome editing progress).
[95] NSCEB FINAL REPORT, *supra* note 1, at 25, 28-29 (identifying market trajectories and policy recommendations).

The European Union's Directive on the Legal Protection of Biotechnological Inventions explicitly lists "processes for modifying the germ line genetic identity of human beings" as contrary to *ordre public* and therefore unpatentable.[96] This reflects a deeply embedded precautionary principle and is reinforced by the legally binding Oviedo Convention.[97] This different standard has tangible consequences; in Case T 844/18, the European Patent Office invalidated several of the Broad Institute's foundational CRISPR patents due to procedural discrepancies regarding inventorship, an outcome that contrasts sharply with the patents' validation in the U.S.[98]

Brazil offers its own variation; where their established Biosafety Law imposes significant restrictions on research involving human embryos, banning human cloning and most forms of genetic engineering on human embryos.[99] This law survived a landmark constitutional challenge, illustrating how specific societal and religious values can be directly translated into hard legal constraints on biotechnology research.[100]

E. Strategic Implications of Divergent Frameworks

These contrasting frameworks create diametrically different development dynamics. The U.S. system fosters rapid, entrepreneurial discovery but suffers from high transaction costs and

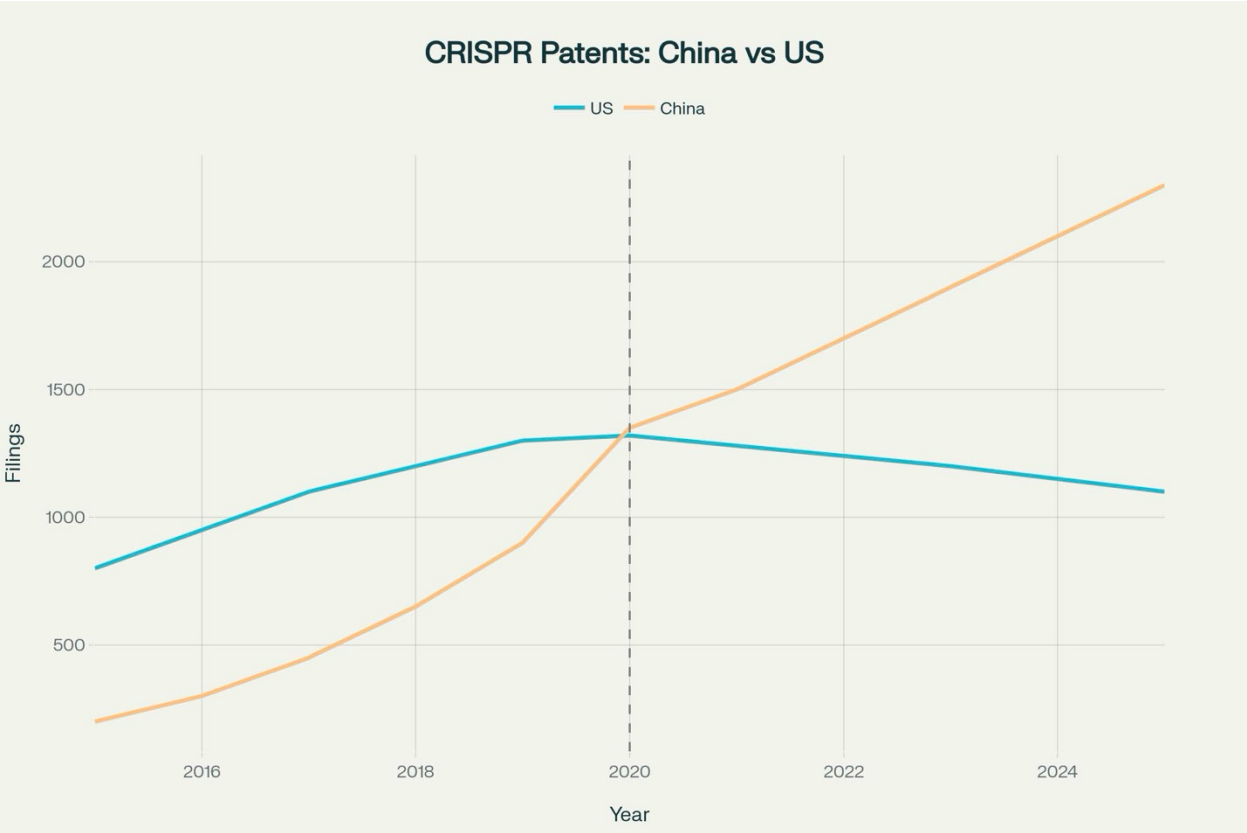
---

[96] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, art. 6(2)(b), 1998 O.J. (L 213) 13, 18 (excluding uses contrary to ordre public or morality).
[97] OVIEDO CONVENTION, *supra* note 26 (prohibiting germline modification).
[98] Case T 844/18, Opposition Proceedings Against Broad Institute Patents (E.P.O. Jan. 13, 2020) (invalidating several CRISPR patents on procedural grounds).
[99] Lei No. 11.105, de 24 de Março 2005, arts. 5-6 (Braz.) (permitting embryonic stem-cell research under restrictions).
[100] *Brazil: Stem Cell Research Approved*, GLOBE LEGAL MONITOR (July 2, 2008), https://www.loc.gov/item/global-legal-monitor/2008-07-02/brazil-stem-cell-research-approved/.

strategic incoherence, dramatically reinforced by *Amgen*. China's hybrid approach, backed by massive state investment and targeted industrial policy, has allowed it to surge in patent filings.[101]

As Figure 1 demonstrates, this surge culminated in a critical strategic inflection point in 2020, when China surpassed the United States in the number of annual CRISPR patent priority filings.[102]

Figure 1: Temporal Distribution of CRISPR Priority Patent Filings (2012-2022)

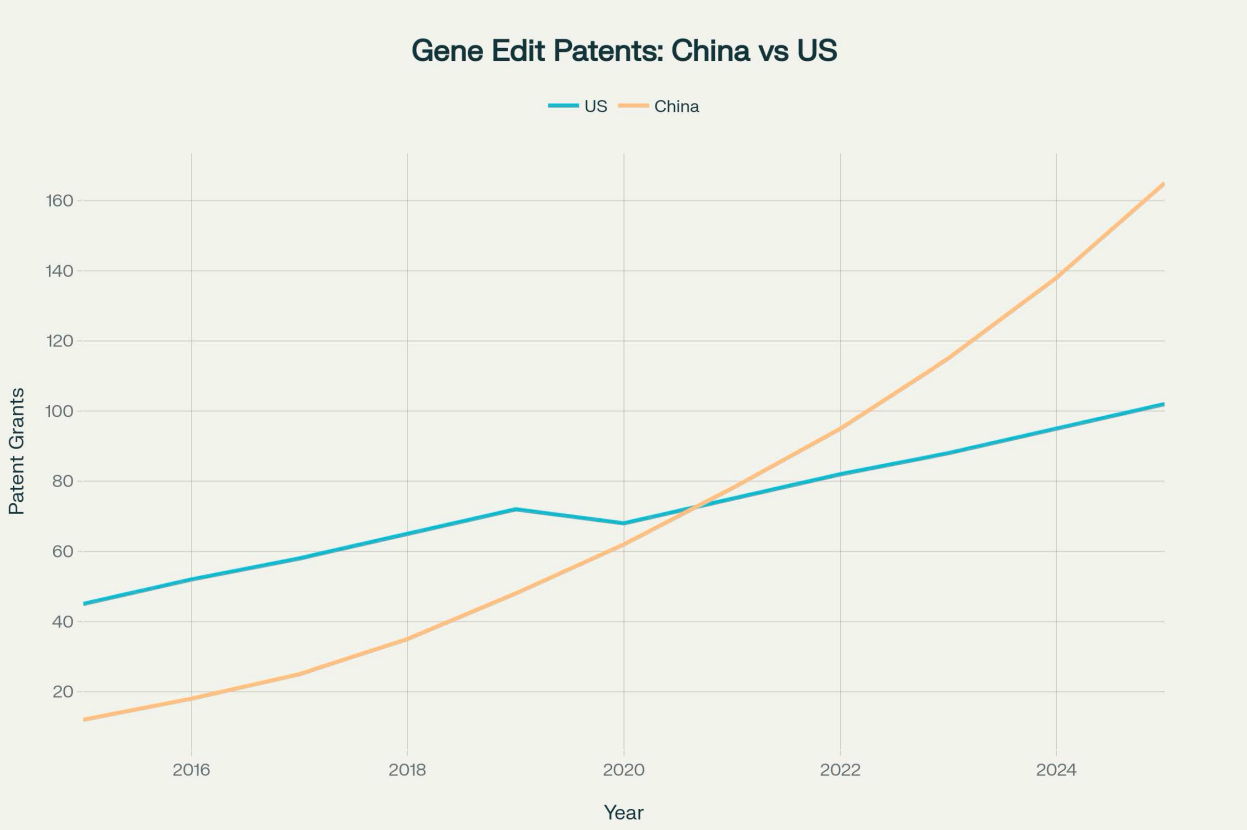


This trend, which culminated in China overtaking the United States in total annual patent filings by 2019, represents an "explosion" in Chinese innovation actively fostered by state policy.[103] The character of the leading patent holders in each state reveals the structural differences

[101] CENTREDOC REPORT, *supra* note 19.
[102] CENTREDOC REPORT, *supra* note 19, at 10.
[103] NSCEB FINAL REPORT, *supra* note 1, at 29 (noting that China's patent filings have exploded); WORLD INTELL. PROP. ORG., WORLD INTELLECTUAL PROPERTY INDICATORS 2020 11, 25 (2020) (reporting that China surpassed the United States in PCT patent filings in 2019).

in their innovation ecosystems. As shown in Figure 2, the most prolific patent assignees in China are state-directed institutions, whereas the leading U.S. filers are its world-class academic research universities.[104]

Figure 2: Top CRISPR Patent Grants: China vs U.S. (c. 2023)



These developments, however, mask crucial differences in patent quality and institutional control. The United States reportedly maintains a persistent 15-20 percentage point lead in the patent approval rate,[105] suggesting more stringent examination standards and a potential focus on higher-quality, foundational patents. This aligns with observed institutional patterns: U.S. foundational patents are held by world-leading academic institutions like the Broad Institute and

[104] CENTREDOC REPORT, *supra* note 19, at 12.
[105] CHINA NAT'L INTELL. PROP. ADMIN., 2021 ANNUAL REPORT (2022) (reporting China's invention patent authorization rate of 55% in 2021); Dennis Crouch, *USPTO Patent Grant Rate and Growing Backlog*, PATENTLY-O (Nov. 2024) (observing U.S. grant rates around 75-80%).

the University of California, whereas China's landscape is dominated by state-run entities like the Chinese Academy of Sciences.[106]

Furthermore, China's focus on domestic protection, with only 8.7% of patents extended internationally, underscores a techno-nationalist strategy aimed at consolidating a domestic IP base first.[107] Applying an analytical framework introduced by James March, the U.S. system excels at the "0 to 1" phase of inventing a new technology, while China's system is now ruthlessly optimized for the "1 to N" phase of scaling and directing that invention for national goals.[108] The ultimate objective of this strategy, as U.S. government analysts have concluded, is to create a future in which global industries "depend upon PRC-controlled pipelines for everything from pharmaceutical precursors to data needed for innovations in medicine, agriculture, and biosynthesis."[109]

IV. STRATEGIC CONSEQUENTIALISM IN PRACTICE: ETHICS UNDER STATE PRESSURE

The prospect of engineering heritable changes to the human genome raises some of the most profound ethical questions humanity has ever faced.[110] For decades, bioethicists have developed sophisticated frameworks to navigate these challenges, focusing on principles of justice, dignity, autonomy, and non-maleficence, dilemmas that now feature in mainstream strategic trend

---

[106] Leora Schiff, PATENTS AND HUMAN GENOME EDITING: LEGAL AND POLICY CONSIDERATIONS, Cong. Research Serv. Rep. No. R46792, at 8-9 (Mar. 5, 2021); Haochen Sun, *Patenting Human Genome Editing: A Comparative Analysis of the United States and China*, 10 J.L. & BIOSCI. 1, 10 (2023) (noting that China overtook the U.S. in granted gene-editing patents around 2021-2022).
[107] CENTREDOC REPORT, *supra* note 19, at 11.
[108] James G. March, *Exploration and Exploitation in Organizational Learning*, 2 ORG. SCI. 71 (1991) (foundational theory of balancing innovation and exploitation).
[109] ISAB REPORT, *supra* note 24, at 6 (warning about ethical risks and security implications).
[110] NAT'L ACADS. OF SCI., ENG'G & MED., *supra* note 6, at 1-3 (summarizing ethical frameworks for human genome editing).

analysis.[111] Yet as the U.S.-China rivalry intensifies, a competing and more powerful logic has emerged. This section argues that in the high-stakes arena of great power competition, traditional bioethical considerations are being systematically subordinated to a starker, yet undeclared paradigm: strategic consequentialism. This is a framework where the ultimate moral good is defined not by appeals to universal principles, but by that which enhances a state's relative power and secures its long-term competitive advantage. State practice, policy, and purchases reveal that the operative ethical question is not "Is this right?" but rather "What are the consequences of being left behind?"

A. Locating Strategic Consequentialism in International Relations Theory

The concept of strategic consequentialism builds upon, but is distinct from, established theories of international relations. It finds its closest intellectual relatives in political realism, the school of thought that posits states as the primary actors in an anarchic international system, where the foremost goal is survival and the maximization of relative power.[112] Specifically, it aligns with the "offensive realism" articulated by John J. Mearsheimer, which argues that the structure of the international system compels great powers to perpetually seek opportunities to gain power over their rivals, as hegemony is the only true guarantee of security.[113] From this perspective, a transformative technology like germline editing is not merely a tool for progress but an ultimate instrument of power. A realist analysis concludes that no rational state can afford to cede such a potentially decisive advantage to a competitor, an imperative echoed in the NSCEB's warning that countries that "win the innovation race tend to win actual wars, too."[114]

---

[111] BEAUCHAMP & CHILDRESS, *supra* note 9 (foundational treatise on deontological principles in biomedical ethics).
[112] KENNETH N. WALTZ, THEORY OF INTERNATIONAL POLITICS (1979) (articulating structural realism).
[113] MEARSHEIMER, *supra* note 12, at 29-31 (explaining the logic of great-power competition).
[114] NSCEB FINAL REPORT, *supra* note 1, at 7.

This realist logic explains why alternative theoretical frameworks have proven insufficient to constrain the emerging competition. Neoliberal institutionalism, for example, would predict that the profound shared risks of unregulated germline editing would drive states toward cooperation through international bodies like the World Health Organization.[115] While such institutions exist, their inability to forge binding commitments reveals the limits of institutionalism when core security interests are at stake.[116] Similarly, constructivism, which emphasizes the power of shared norms, would point to the global scientific consensus against premature germline editing as a powerful constraining force.[117] The near-universal condemnation of He Jiankui in 2018 seemed to validate this view. However, subsequent state behavior demonstrates the instability of such norms. This reveals a critical hierarchy: intersubjective norms are powerful, but they are often bent when they encounter the iron logic of the security dilemma. Strategic consequentialism thus provides a more specific lens, refining the general predictions of realism to explain state action in this unique domain.

B. The Nuclear Analogy: When Strategic Logic Colonized Ethics

To understand how strategic consequentialism operates, the history of the nuclear arms race offers a chilling but powerful model. The scientists of the Manhattan Project were initially driven by a security imperative, the fear that Nazi Germany would develop an atomic bomb first. Yet upon witnessing the Trinity test, many, like J. Robert Oppenheimer, were struck by a profound sense of moral horror.[118] This "Asilomar moment" for nuclear physics, however, was fleeting.

---

[115] ROBERT O. KEOHANE, AFTER HEGEMONY: COOPERATION AND DISCORD IN THE WORLD POLITICAL ECONOMY (1984) (discussing institutionalism).
[116] WHO FRAMEWORK, *supra* note 26.
[117] Alexander Wendt, *Anarchy Is What States Make of It: The Social Construction of Power Politics*, 46 INT'L ORG. 391 (1992) (outlining constructivist theory).
[118] KAI BIRD & MARTIN J. SHERWIN, AMERICAN PROMETHEUS: THE TRIUMPH AND TRAGEDY OF J. ROBERT OPPENHEIMER 557 (2005) (exploring ethical debates surrounding nuclear weapons).

Once the technology was deployed and the U.S.-Soviet rivalry began, the ethical debate was rapidly subsumed by strategic logic.

The discourse shifted from the moral implications of using nuclear weapons to the strategic calculus of deterring their use. Theorists like Thomas Schelling developed a new vocabulary of "credibility" and "escalation dominance" that became the lingua franca of national security.[119] The central ethical problem was reframed: the greatest evil was not the existence of nuclear weapons, but the strategic instability that might lead to their use. The solution was not disarmament, deemed naïve, but a stable balance of terror known as Mutually Assured Destruction (MAD).[120] This history provides a roadmap for the germline gambit. The fear of a genetic breakout by a competitor now mirrors the Cold War fear of a missile crisis. Consequently, the primary moral failure, as implicitly defined by national security documents, is not the violation of a bioethical principle but the failure to win the biotechnology race.[121]

C. The Inescapable Logic of the Game

This dynamic can be modeled formally using a classic prisoner's dilemma, which illustrates why two rational actors might not cooperate even when it appears to be in their mutual best interest.[122] This is the security dilemma in its most acute form: actions taken by one state to increase its security are perceived as threatening by another, compelling the second state to respond in kind, leaving both less secure. Consider the choices facing the U.S. and China regarding

---

[119] THOMAS C. SCHELLING, THE STRATEGY OF CONFLICT (1960) (introducing game-theoretic concepts central to deterrence).
[120] FRED KAPLAN, THE WIZARDS OF ARMAGEDDON (1983) (detailing the development of nuclear strategy).
[121] NSCEB FINAL REPORT, *supra* note 1, at 32 (warning that U.S. economic and military leadership will be weakened if it fails to act).
[122] Robert Jervis, *Cooperation Under the Security Dilemma*, 30 WORLD POL. 167, 169-70 (1978) (foundational analysis of the security dilemma).

heritable genetic enhancement. Each state has two options: "Restrain" (adhere to a global ethical moratorium) or "Pursue" (develop the technology). This creates four potential outcomes:

- **Mutual Restraint (Cooperate/Cooperate):** Both countries agree to abstain from developing enhancements. This avoids the immense risks and ethical costs of a genetic arms race. It is a collectively optimal outcome. (Payoff: +5, +5).
- **U.S. Pursues; China Restrains (Defect/Cooperate):** The U.S. achieves a decisive strategic advantage. This is the best possible outcome for the U.S. (Payoff: +10, -10).
- **China Pursues; U.S. Restrains (Cooperate/Defect):** China achieves the decisive advantage. For the U.S., this is the "sucker's payoff", a catastrophic strategic failure. This could manifest as a military disadvantage against adversaries who could "engineer 'super soldiers' with genetically enhanced physical capabilities,"[123] or through the realization of more sinister scenarios contemplated by PLA strategists, such as the development of "specific ethnic genetic attacks."[124]
- **Mutual Pursuit (Defect/Defect):** Both nations engage in a costly and dangerous genetic arms race. Neither gains a decisive edge, and both incur massive expense. Yet, this outcome is still preferable to unilateral restraint while the rival advances. (Payoff: -5, -5).

From a purely rational-actor perspective, each state must consider its opponent's likely move. If China restrains, the dominant U.S. strategy is to pursue (+10 is superior to +5). If China pursues, the dominant U.S. strategy is also to pursue (-5 is superior to -10). The same logic applies to China. The result is a Nash equilibrium[125] where both nations are driven inescapably toward

[123] NSCEB FINAL REPORT, *supra* note 1, at 16 (citing PLA writings on genetic enhancements).
[124] ISAB REPORT, *supra* note 24, at 11 (citing PLA proposals for genetic warfare).
[125] John F. Nash Jr., *Equilibrium Points in N-Person Games*, 36 PROC. NAT'L ACAD. SCI. 48, 49 (1950) (defining equilibrium points).

mutual pursuit, a costly and dangerous outcome that is nonetheless rationally unavoidable because it is the only way to foreclose the catastrophic possibility of the "sucker's payoff."[126]

This dynamic illustrates what might be called the *Jurassic Park* paradox of modern biotechnology. As Dr. Ian Malcolm warned in that prophetic work of fiction, scientists can become "so preoccupied with whether or not they could, they didn't stop to think if they should."[127] Yet in the context of great power competition, the logic inverts: states become so preoccupied with whether their rivals could that they conclude they must. The ethical question transforms from 'should we?' to 'can we afford not to?'

D. The Subordination of Traditional Bioethics

This logic explains why traditional ethical frameworks, while intellectually developed, have had limited practical influence on state policy in this domain. A sophisticated analysis reveals not that China is an ethical vacuum, but rather that its ethical framework is itself a tool of state strategy, reinforcing the realist calculus for the United States.

China's regulatory approach reflects a state-directed governance model that subordinates ethical frameworks to strategic national interests, implementing a precautionary principle only when it serves broader policy objectives.[128] After the He Jiankui incident threatened to derail its strategic ambitions, the CCP moved swiftly to implement "significant reforms," establishing the National Science and Technology Ethics Committee (NSTEC) and updating the Civil and Criminal

---

[126] R. DUNCAN LUCE & HOWARD RAIFFA, GAMES AND DECISIONS: INTRODUCTION AND CRITICAL SURVEY 94-102 (1957) (presenting the prisoner's dilemma).
[127] JURASSIC PARK (Universal Pictures 1993).
[128] ISAB REPORT, *supra* note 24, at 7; NSCEB FINAL REPORT, *supra* note 1, at 25 (describing China's whole-of-nation effort to achieve biotechnology supremacy).

codes to impose strict oversight.[129] While these actions present the appearance of a convergence toward global ethical norms, they are more accurately interpreted as a tactical reassertion of state control. Rather than a fundamental shift in values, this regulatory transformation serves to manage international reputation and more effectively channel innovation toward state-approved applications, a maneuver fully consistent with a general strategy that subordinates all elements of power, including its ethical posture, to the goal of achieving "comprehensive national power."[130]

This pragmatism is further reflected in public opinion; surveys in China reveal greater public support for therapeutic applications, such as curing genetic disorders, than for controversial enhancements, allowing the state to pursue a more socially acceptable and strategically defensible path.[131] Yet beneath this public-facing regulatory architecture, the underlying strategic impulse remains. The U.S. State Department's 2024 compliance assessment noted with concern that the PRC "continued to engage in biological activities with potential BW [biological warfare] applications... Which raise concerns regarding its compliance with... The BWC."[132] This assessment aligns with analyses by PLA-affiliated scholars who have openly discussed "biology as a domain of military struggle" and asserted that biotechnology shows "strong signs characteristic of an offensive capability."[133]

For a U.S. strategist observing this behavior, the conclusion is clear: China is not an actor bound by a universal, deontological conception of human dignity but a highly pragmatic competitor that calibrates its ethical posture to serve its domestic interests. This reinforces the logic

---

[129] SCIENCE ETHICS OPINIONS, *supra* note 57; CRIMINAL LAW OF THE PEOPLE'S REPUBLIC OF CHINA (AMENDMENT XI), *supra* note 55; Proposal for the Establishment of a National Science and Technology Ethics Committee, *supra* note 56; *see also* Zhou et al., *supra* note 94, at 350 (linking the He Jiankui incident to reforms).
[130] ISAB REPORT, *supra* note 24, at 7 (reaffirming the objective of comprehensive national power).
[131] Xiaoyan Chen & Li Wei, *Public Attitudes Toward Germline Editing in China: Survey Results and Policy Implications*, 15 ASIAN BIOETHICS REV. 131, 140 (2023) (showing nuanced Chinese public views on germline editing).
[132] ISAB REPORT, *supra* note 24, at 24 (assessing Chinese investment trajectories).
[133] *Id.* at 11 (discussing vulnerabilities in supply chains).

of the prisoner's dilemma. The belief that a rival will pragmatically defect from any non-binding norm in the pursuit of strategic advantage compels a rational state to do the same to avoid the "sucker's payoff." In this context, the careful ethical deliberations of bodies like the Nuffield Council on Bioethics in the UK are a luxury that a great power competitor believes it cannot afford.[134] As bioethicist R. Alta Charo has observed, ethical considerations often shape the path or pace of technological development but rarely determine the ultimate destination when powerful capabilities intersect with existential state interests.[135] The germline gambit is a clear and compelling case of this dynamic in action.

V. THE GAMBIT IN ACTION: CASE STUDIES IN FRAGMENTATION AND SOVEREIGNTY

Abstract legal and philosophical frameworks become concrete through the specific patent disputes, supply chain vulnerabilities, and industrial policies that define the race for genetic supremacy. The following case studies illuminate how the divergent approaches of the United States and China, one fostering market-driven fragmentation, the other state-guided coordination, produce tangible and strategically significant consequences.

A. The CRISPR Patent Wars: A Parable of American Fragmentation

The decade-long battle over foundational CRISPR-Cas9 patents epitomizes both the enthusiasm and the profound structural inefficiency of the American innovation system. What began as a revolutionary scientific discovery devolved into a multi-front legal war that created

[134] NUFFIELD COUNCIL ON BIOETHICS, GENOME EDITING AND HUMAN REPRODUCTION: SOCIAL AND ETHICAL ISSUES (2018).
[135] R. Alta Charo, *The Legal and Regulatory Context for Human Gene Editing*, 32 ISSUES SCI. & TECH. 39, 43-44 (2016) (outlining regulatory frameworks).

deep uncertainty for investors and fragmented the intellectual property landscape.[136] This was not an abstract institutional conflict but a battle orchestrated by a recognized global class of elite intellectual property strategists, a profession whose leading members are catalogued for their ability to manage and monetize such high-stakes portfolios.[137]

The central dispute, between the Broad Institute and the CVC group (comprising the University of California, Berkeley, the University of Vienna, and Dr. Emmanuelle Charpentier), was fought over who first invented the use of the CRISPR-Cas9 system in eukaryotic cells. After years of costly proceedings, the U.S. Patent Trial and Appeal Board (PTAB) in Interference No. 106,048 ultimately upheld the Broad Institute's patents, creating a fractured landscape where different entities held foundational IP covering different aspects of the technology.[138] This legal outcome created immediate commercial chaos and a classic "patent thicket."[139] The result is a system where U.S. firms must engage in complex and costly licensing strategies to achieve commercial success. For example, the agricultural giant Corteva Agriscience leveraged an extensive and astute licensing portfolio, including sublicensing agreements with competitors, to surpass Bayer-Monsanto and establish dominance in the soybean market by 2023.[140] This adversarial, litigation-centric model for resolving ownership of a foundational technology is a

---

[136] Jorge L. Contreras & Jacob S. Sherkow, *CRISPR, Patents and the Public Interest*, 35 NAT. BIOTECHNOL. 719, 720 (2017).
[137] IAM STRATEGY 300: THE WORLD'S LEADING IP STRATEGISTS (2023) [hereinafter IAM STRATEGY 300] (listing Michael Arciero of ERS Genomics and describing CRISPR portfolio management).
[138] Regents of the Univ. of Cal. v. Broad Inst., Inc., *supra* note 49, 2017 WL 657413; Sherkow, *supra* note 47, at 256-57.
[139] Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 698 (1998).
[140] CENTREDOC REPORT, *supra* note 19, at 38 (noting that Corteva surpassed Bayer-Monsanto in the soybean market via patents and licensing strategies).

textbook example of the "piecemeal and uncoordinated approach" to biotechnology that the NSCEB has identified as a core American vulnerability.[141]

B. Therapeutic Sovereignty: The Geopolitics of Production

A second critical arena reveals the strategic consequences of fragmentation: the race for "therapeutic sovereignty," a nation's capacity not just to invent novel medicines, but to reliably manufacture and deliver them to its own population.[142] The United States leads the world in the discovery of cutting-edge gene therapies, exemplified by the FDA's historic 2023 approval of Casgevy and Lyfgenia for sickle cell disease.[143] Yet this very success masks a critical strategic vulnerability: an overwhelming dependence on foreign, and particularly Chinese, contract manufacturing organizations (CDMOs). The NSCEB report quantifies this dependency with alarming precision, finding that "79 percent of U.S. biopharmaceutical companies depend on... China-based companies" for at least some component of their manufacturing.[144]

This dependency is not limited to advanced therapies but extends to the fundamental building blocks of modern medicine. As a State Department advisory report details, disruptions early in the COVID-19 pandemic revealed that global supply chains for critical Active Pharmaceutical Ingredients (APIs) were critically dependent on a small number of Chinese manufacturing facilities.[145] This vulnerability threatens the production of everything from

---

[141] NSCEB FINAL REPORT, *supra* note 1, at 42 (describing the U.S. approach to biotechnology as uncoordinated and piecemeal).
[142] NSCEB FINAL REPORT, *supra* note 1, at 36, 77 (warning of national security risks from dependence on foreign biomanufacturing and calling for domestic supply chain resilience).
[143] U.S. FOOD & DRUG ADMIN., *FDA Approves First Gene Therapies to Treat Patients with Sickle Cell Disease* (Dec. 8, 2023), https://www.fda.gov/news-events/press-announcements/fda-approves-first-gene-therapies-treat-patients-sickle-cell-disease (announcing approval of gene therapies for sickle cell disease).
[144] NSCEB FINAL REPORT, *supra* note 1, at 8 (identifying supply chain and manufacturing vulnerabilities).
[145] ISAB REPORT, *supra* note 24, at 20-21 (discussing estimated market value of Chinese biotech firms, reporting a 100-fold increase to over $300 billion between 2016 and 2021).

antibiotics to advanced cancer therapies and has been openly identified as a point of strategic leverage; a Chinese economist warned in 2019 that the PRC could exert control over pharmaceutical exports as a tool in its great power competition with the United States.[146] This strategy is operationalized through state-backed "national champions," none more significant than WuXi AppTec, a firm the NSCEB has labeled the "Huawei equivalent for biotechnology."[147] Through state support and a string of acquisitions of American IP, WuXi AppTec has grown to dominate global biomanufacturing supply chains, creating profound national security risks, including channels for intellectual property theft and, in a crisis, supply chain blackmail.[148]

While the CRISPR Wars illustrate fragmentation in discovery, the high-profile litigation in *Juno Therapeutics, Inc. v. Kite Pharma, Inc.* demonstrates the legal and financial stakes in therapeutic development itself. The case involved Chimeric Antigen Receptor T-cell (CAR-T) therapy, a revolutionary immunotherapy where a patient's own T-cells are genetically engineered to recognize and attack cancer cells.[149] On appeal, the Federal Circuit invalidated Juno's broad patent, finding that it failed to meet the stringent written description requirement of 35 U.S.C. § 112.[150] The court's reasoning, a direct precursor to the Supreme Court's logic in *Amgen*, powerfully illustrates the Federal Circuit's demanding standards for genus claims in biotechnology. It incentivizes a patenting strategy focused on narrow, structurally defined claims rather than broad, functional platforms, thereby reinforcing the very legal architecture of fragmentation.

---

[146] *Id.* at 21 (providing examples of supply chain disruptions and vulnerabilities).
[147] NSCEB FINAL REPORT, *supra* note 1, at 8, 29 (detailing China's whole-of-nation efforts to dominate biotechnology).
[148] *Id.* at 77 (providing projections for biotechnology market and required investment).
[149] Carl H. June & Michel Sadelain, *Chimeric Antigen Receptor Therapy*, 373 N. ENG. J. MED. 1040 (2015) (describing CAR-T therapy).
[150] *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330, 1333, 1341 (Fed. Cir. 2021) (vacating a $1.2 billion verdict due to lack of enablement).

C. Base Editing Competition: The Next Frontier and China's Leapfrog Strategy

While CRISPR-Cas9 dominated the first wave of the gene-editing revolution, a quieter but fierce competition was developing over next-generation technologies: base editing and prime editing. These tools, developed largely by researchers at the Broad Institute, offer the potential for more precise therapeutic interventions with fewer off-target effects.[151]

This case study reveals how China is proactively applying lessons from the CRISPR patent wars to shape the next technological frontier. Instead of competing on the now-crowded ground of foundational CRISPR discovery, Chinese entities have mounted a concerted effort to lead in these emerging areas. Patent landscape analyses show that the Chinese Academy of Sciences has become a central player in filing patents for "advancements in base editing, prime editing, and CAST systems."[152] This state-backed academic research is complemented by a commercial sector focused on applied technologies; Chinese industrial patent filings frequently address specific applications like "fertility gene manipulation" and "anti-aging therapies," aligning with state-defined public health priorities.[153]

This effort is backed by the deliberate state industrial policy and "brute force economics" described by the NSCEB.[154] Shanghai has been established as a global hub for gene therapy development through coordinated municipal and national action, including a planned "patient capital" fund of $8.7 billion that prioritizes long-term strategic capability over short-term commercial returns.[155] The results of this coordinated push are now detailed in a 2024 review of

---

[151] Hye Kyung Kim et al., *CRISPR in the Clinic: Current Advances and Future Considerations*, 23 NAT. REV. GENETICS 291, 298–299 (2022) (discussing clinical trial results and mosaicism risks).
[152] CENTREDOC REPORT, *supra* note 19, at 44 (outlining licensing strategies for CRISPR technologies).
[153] Zhou et al., *supra* note 94, at 349 (noting Chinese firms' focus on applied technologies).
[154] NSCEB FINAL REPORT, *supra* note 1, at 51 (arguing that strategic investment is essential for U.S. leadership).
[155] SHANGHAI MUN. GOV'T, SHANGHAI BIOPHARMACEUTICAL INDUSTRY DEVELOPMENT "14TH FIVE-YEAR" PLAN (2021); SHANGHAI MUN. BUREAU OF JUSTICE, SHANGHAI ACTION PLAN FOR PROMOTING

the clinical landscape published in *Nature Biotechnology* revealed that, as of its writing, China had initiated seven clinical trials for *in vivo* gene-editing therapies compared to just two in the United States.[156] This demonstrates a sophisticated "leapfrog" strategy: by focusing intense, coordinated resources on the next-generation technology and its means of production, China is positioning itself to bypass the fragmented U.S. discovery ecosystem and achieve dominance in the actual delivery of advanced genetic medicines.[157]

D. The BGI Group: State-Sponsored Data and Market Domination

The history of the BGI Group, formerly the Beijing Genomics Institute, serves as a textbook example of China's state-guided economic strategy in action. As detailed by the State Department's International Security Advisory Board, BGI's rise was fueled by direct state intervention. The state-owned China Development Bank financed its initial purchase of over one hundred advanced DNA sequencers, and it received substantial government funding upon going public.[158] This support enabled BGI to acquire a key U.S. competitor, Complete Genomics, in 2013, and to later undercut global rivals by offering prenatal genetic tests at extremely low prices.[159] This strategy served a dual purpose: it crippled foreign competition while allowing the PRC to amass a vast repository of genomic data from millions of individuals across roughly 100 countries, managed by the state-run China National GeneBank.[160] This case demonstrates how

---

GENE-THERAPY-RELATED SCIENTIFIC AND TECHNOLOGICAL INNOVATION AND INDUSTRIAL DEVELOPMENT (2023-2025) (Dec. 25, 2023), https://english.shanghai.gov.cn (detailing Shanghai's local plans).

[156] Ling Xin, *China Is Fast-Tracking Its Next-Generation Gene-Therapy Drugs to Market*, 41 NAT. BIOTECHNOL. 1445, 1446 (2023) (reporting on Chinese regulatory reforms speeding gene therapy approvals).

[157] YUEN YUEN ANG, CHINA'S GILDED AGE: THE PARADOX OF ECONOMIC BOOM AND VAST CORRUPTION 98-101 (2020) (discussing corruption and economic development).

[158] ISAB REPORT, *supra* note 24, at 13 (estimating Chinese biotechnology valuations).

[159] *Id.*

[160] François Candelon et al., *Synthetic Biology Is About to Disrupt Your Industry*, BOST. CONSULTING GRP. (Feb. 10, 2022), https://www.bcg.com/publications/2022/synthetic-biology-is-about-to-disrupt-your-industry (discussing supply chains and synthetic biology).

China leverages state capital not merely to compete economically, but to acquire the fundamental biological data - the "new oil" - that fuels the next generation of AI-driven discovery and innovation.

VI. THE ECONOMIC DIMENSIONS OF GERMLINE COMPETITION

The strategic competition in germline editing extends beyond patents and laboratories to encompass the fundamental economic forces that will shape the twenty-first century. These technologies are not merely scientific curiosities; they are the bedrock of a burgeoning bioeconomy that could have a direct economic impact of $2 trillion to $4 trillion per year globally over the next decade.[161] This section analyzes the market dynamics, investment patterns, and long-term economic scenarios that reveal the true stakes of the germline gambit, demonstrating how divergent economic philosophies directly fuel the race for genetic supremacy.

A. Market Size and Growth Trajectories

The economic potential of gene-editing technologies dwarfs most other emerging sectors, valued at approximately $9.26 billion in 2024, and is projected to exceed $55.43 billion by 2034, growing at a compound annual growth rate (CAGR) of 19.60%.[162] While somatic therapies currently dominate this market, the prospect of heritable interventions stimulates much of the

[161] Chui et al., *supra* note 16, at 9 (projecting significant economic contributions of bio-engineering).
[162] GLOBAL MARKET INSIGHTS, GENE EDITING MARKET SIZE, SHARE & TRENDS ANALYSIS REPORT (Report No. GMI3487, 2024) (projecting the gene-editing market to reach USD 55.4 billion by 2032 with a CAGR of 19.6%).

current strategic investment. A recent analysis projects the market for gene editing alone will surge to $44 billion by 2025.[163]

A geographic analysis of this market reveals a deeply concerning trend for the United States. While the U.S. currently captures the majority of gene therapy revenue, China's share is expanding at a blistering pace. This is evidenced by an "unprecedented surge in patent applications" since 2014, driven by targeted government policy.[164] From 2016 to 2021, the estimated market value of Chinese biotech firms grew a hundredfold to over $300 billion, with their combined market capitalization now second only to that of U.S. companies.[165] This financial growth is mirrored in clinical development: from 2017 to 2021, clinical trial activity in China more than doubled, and in 2023, the share of global clinical trials launched by Chinese-headquartered firms skyrocketed to 28% from just 3% a decade prior.[166] These figures illustrate a clear trajectory: China is rapidly closing the gap, positioning itself to challenge U.S. leadership in the commercial bio-revolution.

B. Investment Patterns: Patient Capital vs. The Valley of Death

The divergent trajectories of the U.S. and Chinese biotech sectors are a direct result of their fundamentally different economic philosophies. The United States relies predominantly on a world-leading private venture capital ecosystem that excels at funding discovery but creates structural vulnerabilities in long-term strategic development.[167] This model is notoriously

---

[163] ROLAND BERGER TRENDS, *supra* note 15, at 29, fig. 2 (reiterating the $44 billion 2025 projection).
[164] WIPO, *supra* note 103 (offering data on global patent filings and China's position).
[165] ISAB REPORT, *supra* note 24, at 5-6 (citing a hundredfold increase in Chinese biotech market value to over $300 billion between 2016 and 2021).
[166] ISAB REPORT, *supra* note 24, at 17-18; NSCEB FINAL REPORT, *supra* note 1, at 29 (discussing the need for patient capital and supply chain resilience).
[167] William B. Bonvillian, *The New Model of Innovation*, 28 ISSUES SCI. & TECH. 53, 56 (2012) (arguing for a shift from technology push to mission-driven innovation).

susceptible to what is known as the "valley of death," the critical funding gap between early-stage discovery and late-stage commercial scale-up. The biotechnology valley of death has its own cruel geography: researchers can see the distant shore of commercial success, can even describe in detail the life-saving therapies that await there, but lack the resources to complete the crossing. It's as if we've invented telescopes powerful enough to see the cure for cancer on the other side but can't afford the bridge to reach it. Meanwhile, China airlifts its chosen champions across the divide. As the NSCEB explains, "venture capitalists are willing to fund biotechnology development and private equity is willing to fund expansion once there is a proven product, but between those two stages capital is harder to come by."[168] The U.S. therefore grapples with maintaining its edge amidst "volatile venture capital investments," where market sentiment can "discourage companies from making bold technological leaps."[169]

China's model is explicitly designed to solve this problem; through a strategy of "brute force economics," the CCP provides its "leading companies with cheap capital through government subsidies and substantial investment in research and development," lavishing support on "hand-picked winners" to ensure they can cross the valley of death and seize global market share.[170] This state-directed ecosystem enables the kind of patient capital deployment nearly impossible in market-driven systems, allowing the state to support strategically vital research and infrastructure development over decade-long timelines. As a recent State Department advisory report details, practices such as state-backed governance guidance funds and other subsidies support later-stage R&D, allowing favored domestic companies to "enter global markets

[168] NSCEB FINAL REPORT, *supra* note 1, at 50 (emphasizing the need for domestic biomanufacturing capacity).
[169] KAUFFMAN FOUND., U.S. INNOVATION INDEX: PATENT TRENDS AND REGIONAL CLUSTERING (2022) (assessing the impact of venture capital volatility on patent trends).
[170] NSCEB FINAL REPORT, *supra* note 1, at 11, 28, 51; WIPO, *supra* note 103 (highlighting China's strategic investment in biotech patents).

unencumbered by debt, and cushioned against innovation risk."[171] This national strategy gives Chinese firms a formidable competitive advantage, allowing them to bring products to market "at prices that have no floor," systematically undercutting U.S. competitors.[172]

C. Economic Modeling of Competitive Outcomes

While precise forecasting is difficult, economic modeling based on these divergent dynamics illuminates potential long-term outcomes. The explicit goal of China's state-led economic strategy, as identified by the NSCEB, is to "dominate the global biotechnology industry so that other countries, including the United States, are dependent on the channels it controls."[173] Under current trajectories, China is positioned to achieve economic parity in key biotechnology sectors and potentially overtake the U.S. within the next decade.[174] However, this rapid ascent is not without potential vulnerabilities; some analyses raise questions about the "long-term sustainability of its IP ecosystem," noting an emphasis on patent quantity that may not always translate to quality.[175]

Nonetheless, the logic of strategic consequentialism is reinforced by the potentially transformative economic impact of successful germline enhancement. While highly speculative, analyses exploring the macroeconomic impact of even modest, heritable cognitive enhancements suggest they could yield sustained GDP growth and massive compounding advantages in national productivity and innovation capacity.[176] These staggering, albeit theoretical, economic prizes help

---

[171] ISAB REPORT, *supra* note 24, at 19 (analysing supply chains).
[172] NSCEB FINAL REPORT, *supra* note 1, at 51 (identifying supply chain vulnerabilities).
[173] NSCEB FINAL REPORT, *supra* note 1, at 6.
[174] *Id.*
[175] WIPO, *supra* note 103 (discussing challenges in China's IP ecosystem, including quality vs. quantity of patents).
[176] Carl Shulman & Nick Bostrom, *Embryo Selection for Cognitive Enhancement: Curiosity or Game-Changer?*, GLOBAL POLICY (2013), https://www.globalpolicyjournal.com/articles/science-and-technology/embryo-selection-cognitive-enhancement-curiosity-or-game-changer (examining potential uses of embryo selection for cognitive traits).

explain why the stakes are perceived as too large for any nation to willingly accept a competitive disadvantage. It is the pursuit of such ultimate economic and strategic rewards that fuels the state-directed race for genetic control, transforming biotechnology from a scientific enterprise into a central battlefield of twenty-first-century geopolitics.

VII. THE INTERNATIONAL GOVERNANCE VACUUM: A DELIBERATE ARCHITECTURE OF UNRESTRAINT

The intense U.S.-China competition in germline editing does not occur in a normative void; rather, it thrives within a carefully constructed international governance vacuum.[177] This is not a failure of global bureaucracy but a deliberate feature of the international system, a condition actively maintained by powerful states that refuse to accept binding constraints on a technology deemed essential to national security and economic providence.[178] The current structure provides an "illusion of governance," where a web of high-minded declarations and non-binding recommendations creates the public appearance of ethical oversight while preserving near-total freedom of action for strategic competitors.[179] This architecture of aspirational but unenforceable rules is the crucial permissive element that enables the germline gambit to proceed without meaningful international brakes.

A. The Architecture of Empty Promises

Efforts to govern germline editing at the international level are marked by ambitious rhetoric but minimal enforceability. The World Health Organization (WHO) has produced a

---

[177] Françoise Baylis, *Human Genome Editing: Our Future Belongs to All of Us*, 35 ISSUES SCI. & TECH. 42 (2019) (arguing that current governance approaches lack adequate consensus).
[178] Mearsheimer, *supra* note 12.
[179] David P. Fidler, *The COVID-19 Pandemic and the Future of Global Health Governance*, 98 INT'L AFFS. 1425, 1430 (2022) (criticising the international community's response to COVID-19).

comprehensive governance framework, explicitly calling for tiered oversight and public engagement.[180] Yet, the WHO's own documents concede a critical limitation: it "has no mandate to enforce the adoption or implementation of its recommendations."[181] Similarly, UNESCO's 1997 Universal Declaration on the Human Genome and Human Rights articulates the foundational principle that the human genome is the "heritage of humanity," but as a declaration, it carries no legal force.[182] Even efforts by bodies like the Organisation for Economic Co-operation and Development (OECD) to promote "responsible innovation" and harmonize standards function as guidelines, not binding law.[183]

Where binding legal instruments exist, their impact is nullified by the strategic non-participation of the key actors. The Council of Europe's Convention on Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Oviedo Convention) is the only legally binding multilateral treaty to explicitly prohibit heritable germline modification.[184] Its geopolitical irrelevance, however, is sealed by its list of signatories: neither the United States nor China has signed or ratified the convention.[185] This strategic abstention transforms a powerful regional standard into a global footnote.

---

[180] WHO FRAMEWORK, *supra* note 26.
[181] *Id.* at 33.
[182] Universal Declaration on the Human Genome and Human Rights, UNESCO Res. 29 C/Res. 16, arts. 1, 24 (Nov. 11, 1997); Roberto Andorno, *The Universal Declaration on the Human Genome and Human Rights: The First Legal and Ethical Framework at the Global Level*, 3 J. INT'L BIOTECH. L. 11, 14 (2006) (explaining the declaration's legal significance).
[183] ORG. FOR ECON. CO-OPERATION & DEV. [OECD], OECD GUIDELINES ON RESPONSIBLE INNOVATION IN BIOTECHNOLOGY (Science, Technology and Industry Policy Papers No. 122, 2021).
[184] OVIEDO CONVENTION, *supra* note 26, art. 13.
[185] Council of Eur., CHART OF SIGNATURES AND RATIFICATIONS OF TREATY 164, https://www.coe.int/en/web/conventions/full-list?module=signatures-by-treaty&treatynum=164 (showing limited ratification of the Oviedo Convention).

B. Why Binding Governance Fails: The Collingridge Dilemma

The failure to establish a meaningful international regime is not accidental, but reflects structural obstacles rooted in the anarchic nature of the international system. The impasse is a textbook example of the *Collingridge Dilemma*, a concept from technology governance that highlights a fundamental paradox: in the early stages of a technology's development, its future societal impacts are not well enough understood to justify regulation; however, by the time its consequences become clear, the technology is so socially and economically embedded that control becomes prohibitively difficult and expensive.[186] The international community is thus caught between the fog of uncertainty and the iron cage of path dependency, a condition that national security actors are uniquely positioned to exploit. The dual-use nature of gene-editing technology exacerbates this dilemma, creating an insurmountable "verification problem" reminiscent of Cold War arms control challenges.[187] In such an environment of deep mistrust and imperfect information, the prisoner's dilemma logic detailed in Part IV becomes inescapable. This is not merely a theoretical concern; it is informed by observed state behavior. The NSCEB report notes that "China has also repeatedly failed to honor international commitments," fostering an environment where the perceived risk of being the "sucker" who adheres to a ban while a rival cheat renders mutual, verifiable restraint rationally untenable for strategic planners.[188]

---

[186] ROLAND BERGER TRENDS, *supra* note 15, at 61 (discussing ethical and societal concerns associated with gene editing).
[187] GREGORY D. KOBLENTZ, LIVING WEAPONS: BIOLOGICAL WARFARE AND INTERNATIONAL SECURITY 45-48 (2009) (examining the risk of biological weapons).
[188] NSCEB FINAL REPORT, *supra* note 1, at 25 (reiterating Chinese strategic ambitions).

C. Consequences: Racing Without Brakes

This governance vacuum directly enables the paradigm of strategic consequentialism and accelerates an ethical race to the bottom. It creates perverse incentives for what some analysts term "ethics dumping," wherein researchers are tempted to exploit lenient jurisdictions to conduct controversial experiments.[189] This regulatory fragmentation is now being actively weaponized. In lieu of a universal regime, the United States and its rivals are hardening the lines of competition by using regulatory and trade tools to assert technological sovereignty.

The NSCEB report explicitly recommends a strategy of using "national security tools to protect our innovation and industrial base," including considering "country-wide export controls blocking the sale of specific, highly sophisticated U.S. biotechnology items to China."[190] This is mirrored by China's own expansion of its Export Control Law and the European Union's scrutiny of gene-editing tools under its dual-use regulation.[191] This demonstrates that states are weaponizing regulation not to build a global regime, but to construct competing techno-economic blocs. The U.S. strategy, as outlined by the Commission, is to "mobilize the collective strengths of our allies and partners" to create a high-standards coalition that can out-compete, rather than universally govern, its rivals.[192]

---

[189] EUROPEAN GRP. ON ETHICS IN SCI. & NEW TECHS. [EGE] TO THE EUROPEAN COMM'N, OPINION NO. 17: ETHICAL ASPECTS OF CLINICAL RESEARCH IN DEVELOPING COUNTRIES 17-18 (Feb. 4, 2003) (discussing double standards and ethics dumping).
[190] NSCEB FINAL REPORT, *supra* note 1, at 10 (Principle 3) and 93 (Recommendation 3.3.b).
[191] Ministry of Commerce of the P.R.C., Announcement No. 38 (Aug. 30, 2020) (updating China's Catalogue of Prohibited and Restricted Export Technologies); Commission Delegated Regulation 2023/2616 of 15 September 2023 Amending Regulation 2021/821 of the European Parliament and of the Council as Regards the List of Dual-Use Items, 2023 O.J. (L 2023/2616) (updating the EU's dual-use export control list).
[192] NSCEB FINAL REPORT, *supra* note 1, at 13 (Pillar 6 title).

D. Toward a Provisional Governance Model

Given the unlikelihood of a near-term binding treaty, an interim model focused on risk reduction and confidence-building is necessary. This aligns with the NSCEB's acknowledgment that even in a competitive environment, the U.S. should "work with the international community, including China where prudent, to develop best practices and standards for biosafety and biosecurity."[193] Such a model could include a WHO-hosted Confidence-Building Registry, modeled on the Biological Weapons Convention's (BWC) Confidence-Building Measures (CBMs), where states voluntarily disclose preclinical germline research under a standardized format to increase transparency.[194] Additionally, a high-level, politically endorsed Global Moratorium on Clinical Use for Enhancement could create a clear red line, distinguishing between prohibited enhancement and potentially permissible therapeutic research, thereby creating a minimum ethical baseline until stronger institutions can emerge.[195] An example of such normative development can be found in the Tianjin Biosecurity Guidelines, which were developed by an international group of scientists and later endorsed by the InterAcademy Partnership as a code of conduct for responsible science.[196]

VIII. FUTURE SCENARIOS: STRUCTURED ANALYSIS OF POTENTIAL OUTCOMES

To move from analysis to strategic foresight, this section employs structured scenario analysis to map four plausible futures for the U.S.-China germline editing rivalry over the next

---

[193] *Id.* at 10 (Principle 4).
[194] Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, Apr. 10, 1972, 26 U.S.T. 583, 1015 U.N.T.S. 163.
[195] INT'L COMM'N ON THE CLINICAL USE OF HUMAN GERMLINE GENOME EDITING, HERITABLE HUMAN GENOME EDITING 11 (2020) (outlining recommended governance structures).
[196] ISAB REPORT, *supra* note 24, at 44 (discussing manufacturing and supply chain bottlenecks).

fifteen years. These are not predictions but rigorously constructed analytical tools designed to stress-test assumptions and illuminate the range of potential outcomes, thereby clarifying the stakes of today's policy choices.[197]

A. Analytical Framework: A 2 x 2 Scenario Matrix

	Low Cooperation / High Competition	**High Cooperation / Low Competition**
Accelerated Tech	Scenario 3: Breakout Enhancement	Scenario 1: Coordinated Competition
Gradual Tech	Scenario 2: Technological Divergence	Scenario 4: Normative Snap-Back

B. Scenario 1: Coordinated Competition (Medium Probability)

In this future, the U.S. and China, while remaining fierce competitors, establish a framework of "strategic stability" for biotechnology to mitigate catastrophic risks. The catalyst is a widely publicized global biosafety crisis in the late 2020s, perhaps a supply chain collapse for a critical medicine, echoing the API vulnerabilities exposed during the COVID-19 pandemic.[198] Recognizing a shared interest in preventing a global backlash, they engage in limited cooperation, consistent with the NSCEB's call to "work with the international community, including China where prudent, to develop best practices and standards."[199] Key indicators of this future would include bilateral U.S.-China dialogues under WHO patronage, the publication of reciprocal ethics frameworks, and partial data-sharing on adverse events. The primary legal implication would be a

[197] PETER SCHWARTZ, THE ART OF THE LONG VIEW: PLANNING FOR THE FUTURE IN AN UNCERTAIN WORLD 3–4 (1991) (foundational work on scenario planning).
[198] ISAB REPORT, *supra* note 24, at 20-21 (noting supply chain disruptions during the COVID-19 pandemic).
[199] NSCEB FINAL REPORT, *supra* note 1, at 10 (Principle 4).

soft harmonization of export control lists and agreement on basic data governance norms to de-conflict and prevent accidental escalation. The central policy lever would be to establish a permanent U.S.-China Biotechnology Stability Council modeled on the Cold War-era Nuclear Risk Reduction Centers.[200]

C. Scenario 2: Technological Divergence (Higher Probability)

This is the most probable future, representing a direct extension of current trends where the world bifurcates into two distinct, largely incompatible biotechnological spheres of influence, a "biotech splinternet."[201] The United States and its allies form a high-standards "Democratic Bio-Alliance," built on the NSCEB's recommendation to "mobilize the collective strengths of our allies and partners."[202] This effort aligns with a broader U.S. strategy to "build partner capacities to participate in the global bioeconomy," creating diversified and resilient supply chains insulated from PRC control.[203] This bloc, however, faces internal friction, as divergent legal standards (e.g., European invalidation of certain U.S. CRISPR patents) complicate efforts to harmonize regulations.[204] Meanwhile, China accelerates its strategy of domestic IP consolidation, with its patent internationalization rate remaining below 10%.[205] Indicators of this trend would be the launch of a joint U.S.-EU Allied Biotech Certification Scheme, CFIUS blocking a series of Chinese acquisitions in the U.S. biotech sector, and China formalizing its own bio-economic bloc through the Shanghai Cooperation Organisation. Extraterritorial application of standards would

---

[200] Agreement Between the United States of America and the Union of Soviet Socialist Republics on the Establishment of Nuclear Risk Reduction Centers, Sept. 15, 1987, T.I.A.S. No. 12,357.
[201] ADAM SEGAL, THE HACKED WORLD ORDER 8-10 (2016) (drawing parallels between cyber and biotech competition).
[202] NSCEB FINAL REPORT, *supra* note 1, at 13 (Pillar 6).
[203] ISAB REPORT, *supra* note 24, at 31, 44 (providing policy recommendations for export controls and multilateral cooperation).
[204] Case T 844/18, *supra* note 98 (illustrating complexities of harmonizing IP regimes between the U.S. and Europe).
[205] CENTREDOC REPORT, *supra* note 19, at 11.

likely lead to frequent WTO disputes over discriminatory licensing regimes. The primary policy response would be to fully implement NSCEB recommendations to expand the International Technology Security and Innovation (ITSI) Fund and create reciprocal biological data-sharing agreements with allies.[206]

D. Scenario 3: Breakout Enhancement (Lower Probability)

This low-probability, high-impact scenario posits a "Sputnik moment" for biology. One nation, likely China, given its tolerance for high-risk research and stated interest in "population improvement,"[207] achieves a strategically decisive heritable enhancement. This could manifest as one of the threats envisioned by the NSCEB: the development of "'super soldiers' with genetically enhanced physical capabilities."[208] This concern is substantiated by official U.S. government assessments that the People's Liberation Army (PLA) has funded projects on "human performance enhancement" and identified "human-machine integration as a potential game changer for future combat platforms."[209] This analytical convergence is highlighted in other strategic assessments, which note that governments are exploring biotechnologies for military applications, including "enhancing the physical capabilities of soldiers."[210] The announcing state frames it as a "public health triumph," but its military implications trigger a "crash program" by the rival, which casts aside all ethical restraints under the pressure of national survival.[211] Leading indicators would include a sudden surge in patent filings by an institution like the Chinese Academy of Sciences clustered around neuro-enhancement, alongside intelligence reports of unregulated in vivo trials.

---

[206] NSCEB FINAL REPORT, *supra* note 1, at 140 (Recommendation 6.1.a) and 143 (Recommendation 6.1.d).
[207] *Id.* at 25.
[208] *Id.* at 16.
[209] ISAB REPORT, *supra* note 24, at 56.
[210] SHINOMIYA & TANAKA REPORT, *supra* note 2, at 10.
[211] DAVID HOLLOWAY, STALIN AND THE BOMB: THE SOVIET UNION AND ATOMIC ENERGY, 1939-1956 (1994) (describing the Soviet crash program following Hiroshima).

Such a breakout would lead to widespread invocation of the TRIPS Agreement's national security exception to break patents and the imposition of total export bans on all relevant technologies.[212] The primary policy levers would be emergency treaty proposals at the U.N. and an immediate, fully funded "Manhattan project" for biological countermeasures.

E. Scenario 4: Normative Snap-Back (Lower Probability)

A catastrophic event, a "global Thalidomide moment" for gene editing, triggers a wave of public revulsion so intense that it forces political action.[213] A publicly documented failure in a human trial, perhaps caused by unforeseen consequences like the "megabase-scale deletions" or persistent "mosaicism" observed in animal models,[214] or the "accidental release of dangerous pathogens,"[215] could create a global activist movement that overcomes the security dilemma. Indicators would be the formation of broad civil-society coalitions demanding a ban, national referenda on human enhancement, and rapid treaty negotiation under U.N. mandates.[216] Public pressure would become so immense that it drives states to negotiate a binding international treaty with strict prohibitions and intrusive verification mechanisms,[217] leading to a new legal framework analogous to the Biological Weapons Convention but with an empowered verification body.[218] The U.S. policy would be to take the lead in creating a "Geneva Convention for Germline Genetics."

---

[212] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 73(b), Apr. 15, 1994, 1869 U.N.T.S. 299 (allowing measures to protect essential security interests).
[213] Neil Vargesson, *Thalidomide-Induced Teratogenesis: History and Mechanisms*, 105 BIRTH DEFECTS RES. PART C 140 (2015) (recounting the thalidomide disaster and regulatory reforms).
[214] Kim et al., *supra* note 151, at 295 (discussing risks such as large deletions and mosaicism).
[215] ISAB REPORT, *supra* note 24, at 42 (warning about accidental release of dangerous pathogens).
[216] NAT'L ACADS. OF SCI., ENG'G & MED., *supra* note 6.
[217] *Id.*
[218] Biological Weapons Convention, *supra* note 194.

F. Policy Dashboard: Early-Warning Indicators for Strategic Monitoring

To remain strategically agile, the National Biotechnology Coordination Office (NBCO) proposed in Part IX must actively monitor leading indicators to discern which future is materializing. This dashboard should include:

- **Patent Landscape Shifts:** Divergence in patent filing internationalization rates and clustering around specific applications (e.g., therapeutics vs. agricultural).[219]
- **Industrial Policy:** Foreign government subsidies and policies aimed at creating "national champions" or "industrial clusters" for biotechnology, including "discriminatory review and approval processes, price controls, export financing, and procurement policies."[220]
- **Regulatory Weaponization:** Changes to national export control lists for dual-use biotechnologies or the strategic use of domestic regulatory approvals to advantage local firms.
- **Clinical Activity:** Clinical trial registrations, or credible intelligence reports of unregistered trials, involving human germline modification, noting that trial activity in China has recently "outpac[ed] all other countries" in key areas.[221]
- **Public Opinion Shifts:** Significant changes in public opinion survey data regarding the acceptability of therapeutic versus enhancement applications.
- **Erosion of Ethics:** Legislative or executive actions in other nations designed to weaken or bypass national research ethics boards.

By systematically mapping these indicators, the United States can better anticipate shifts in the strategic landscape, shaping the future of germline governance rather than merely reacting to it.

---

[219] CENTREDOC REPORT, *supra* note 19.
[220] ISAB REPORT, *supra* note 24, at 12.
[221] *Id.* at 18.

IX. TOWARD A STRATEGIC FUTURE: POLICY RECOMMENDATIONS FOR U.S. LEADERSHIP

The preceding analysis reveals significant U.S. vulnerabilities rooted in a fragmented innovation ecosystem, a dynamic that stands in stark contrast to China's coordinated, state-led approach.[222] However, the United States retains unparalleled advantages: a world-leading private sector, a deep network of advanced democratic allies, the rule of law, and an "open innovation ecosystem [that] attracts top talent from across the globe."[223] A coherent domestic strategy can and must leverage these assets to secure leadership while upholding democratic values. The following recommendations synthesize this Article's analysis with the urgent warnings of the NSCEB report and other government advisory bodies to offer a comprehensive strategy for winning the germline gambit.[224]

A. Immediate Actions: Closing Critical Gaps

Establish a National Biotechnology Coordination Office (NBCO). As its "primary institutional recommendation," the NSCEB calls for Congress to "establish a National Biotechnology Coordination Office (NBCO) within the Executive Office of the President."[225] The President should act swiftly on this by Executive Order. This office must be explicitly modeled on the National Security Council, with a mandate and the presidential authority to direct, not merely coordinate, biotechnology strategy across the network of agencies in the U.S. government. Its core function is to remedy the institutional failures that have led to the "piecemeal and uncoordinated"

---

[222] NSCEB FINAL REPORT, *supra* note 1.
[223] *Id.* at 9.
[224] *See generally id.*
[225] *Id.* at 11 (Recommendation 1.1.a), 44.

approach that defines U.S. strategic fragmentation (aligning with NSCEB Recommendation 1.1 a).[226]

The primary challenge will be the inevitable bureaucratic friction from established agencies guarding their equities.[227] Critics will also argue that such a body adds another layer of bureaucracy that could stifle the agile, bottom-up innovation at which the U.S. excels.[228] To overcome this, the NBCO's authority must be unambiguous and consistently backed by the President. Its goal should not be to micromanage research, but to set national priorities, deconflict agency efforts, and review departmental budgets to ensure they align with a unified general biotechnology strategy.

Launch an Emergency Biomanufacturing Resilience Initiative. Congress should immediately pass a Biomanufacturing Resilience Act, appropriating the at least $15 billion over five years recommended by the NSCEB to mitigate the U.S.'s critical manufacturing dependence on China.[229] These funds must be structured as public-private partnerships aimed at building secure, domestic, end-to-end manufacturing capacity for the complex materials essential for gene therapies, such as viral vectors and plasmids.

The primary counterargument to this initiative is that it constitutes protectionist industrial policy that distorts the free market.[230] This critique, however, fundamentally misreads the strategic landscape. The goal is not purely economic efficiency but national security resilience. The most successful historical precedent is SEMATECH, a government-industry consortium created in the 1980s that successfully countered Japanese dominance in the semiconductor industry by pooling

---

[226] *Id.* at 42.
[227] GRAHAM T. ALLISON & PHILIP ZELIKOW, ESSENCE OF DECISION: EXPLAINING THE CUBAN MISSILE CRISIS 295-97 (2d ed. 1999) (describing the bureaucratic politics model).
[228] Fuad Hasanov & Reda Cherif, *The Pitfalls of Protectionism*, BENNETT INST. FOR PUB. POL. BLOG (July 9, 2024), https://www.bennettinstitute.cam.ac.uk/blog/pitfalls-of-protectionism/ (arguing that protectionist policies often lead to inefficiency and corruption).
[229] NSCEB FINAL REPORT, *supra* note 1, at 10, 39 (Recommendation 2.3.a) and 164 (allocating $800 million for pre-commercial bioindustrial facilities as part of a $15.142 billion strategic investment package).
[230] Jagdish Bhagwati, *The Case for Free Trade*, 261 SCI. AM. 42 (1989) (outlining the benefits of open trade).

resources and de-risking domestic manufacturing.[231] A similar approach is required for biotechnology, which must be understood as critical national infrastructure.

Equity & Access Caveat

A purely market-driven or national security-focused approach risks creating a world of genetic haves and have-nots, exacerbating inequality. Therefore, the policy structures proposed must incorporate mechanisms to address justice and equity. The NBCO, for instance, should be mandated to include a public engagement and health equity office, tasked with developing frameworks to ensure that therapies derived from federally supported research are accessible. This can include building upon existing "inclusive innovation" models, such as the non-exclusive licensing frameworks and patent pools promoted by institutions like the Broad Institute to facilitate widespread access to foundational CRISPR tools.[232]

B. Medium-Term Initiatives: Building Sustainable Advantage

Fund Strategic, High-Risk Research through ARPA-H. Congress must fully and consistently fund the Advanced Research Projects Agency for Health (ARPA-H),[233] directing it to pursue the high-risk, high-reward "moonshot" projects that the more incremental, peer-review-driven NIH system is structurally ill-suited to support. This aligns with the NSCEB's call to launch "grand research challenges to unlock leap-ahead capabilities," including investments in next-generation editing systems, novel delivery technologies, and the integration of AI with synthetic biology for predictive design.[234]

---

[231] WILLIAM B. BONVILLIAN & PETER L. SINGER, ADVANCED RESEARCH PROJECTS AGENCY-ENERGY: A NEW MODEL FOR ENERGY INNOVATION? 52-53 (2017) (describing SEMATECH as a successful government-industry partnership).

[232] *Regents of the Univ. of Cal. v. Broad Inst., Inc.*, *supra* note 49 (context for licensing models following the dispute).

[233] Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, 136 Stat. 49, 420 (codified at 42 U.S.C. §282d) (authorizing ARPA-H).

[234] NSCEB FINAL REPORT, *supra* note 1, at 12 (Pillar 4 title).

The primary implementation challenge is cultural, in that to succeed, ARPA-H must be protected from the bureaucratic tendency to make it "NIH-light."[235] The ARPA model is defined by a distinct culture: small, agile, and led by empowered program managers with significant autonomy to fund and terminate projects based on performance against ambitious milestones.[236] Maintaining this DARPA-like culture within the vast Health and Human Services bureaucracy will require constant vigilance.

Forge an Allied Biotechnology Framework. The State Department, in concert with the NBCO, must lead the establishment of an Allied Biotechnology Framework, acting on the NSCEB's directive to "mobilize the collective strengths of our allies and partners."[237] With key democratic partners, such as the European Union, the United Kingdom, Japan, and South Korea, the goal is to build a high-standards coalition that can collectively shape global norms and create secure, interoperable supply chains (as envisioned in NSCEB Pillar 6). This aligns with the State Department's own advisory recommendations to "develop a global biotech system in which a broad range of partners cooperates on scientific research and trade."[238]

The most significant obstacle will be harmonizing divergent legal and ethical frameworks, a challenge highlighted by jurisdictional complexities such as the European Patent Office's invalidation of certain foundational U.S. CRISPR patents.[239] Therefore, the initial focus should not be on a rigid treaty but on flexible commitments: co-developing common technical standards,

---

[235] William B. Bonvillian & Andrew L. Russell, *The Challenge of Building a New Health ARPA*, 35 ISSUES SCI. & TECH. 69, 72-74 (2019).
[236] Bonvillian & Singer, *supra* note 231, at 14-18 (discussing lessons from ARPA-E applicable to bioindustrial initiatives).
[237] NSCEB FINAL REPORT, *supra* note 1, at 13 (Pillar 6 title).
[238] ISAB REPORT, *supra* note 24, at 2-3 (presenting the scope of the report and key findings).
[239] Case T 844/18, *supra* note 98 (illustrating IP harmonization issues).

coordinating on export controls as recommended by the NSCEB, and establishing a joint strategic stockpile of essential biotech materials.[240]

C. Long-Term Positioning: Shaping the Future

Develop Human Capital through a National Defense Biotechnology Education Act. Modeled on the transformative National Defense Education Act of 1958,[241] this legislation must be designed not merely to produce more laboratory scientists, but to cultivate the elite corps of IP-savvy professionals necessary to win the global competition. The professional directory *IAM Strategy 300: The World's Leading IP Strategists* provides a definitive taxonomy of the required skills, identifying factions of experts in disciplines such as "intellectual asset management," "technology commercialisation," "licensing," and "M&A."[242] Success in the bio-revolution will be measured not just by publications, but by a nation's ability to field its own world-class experts capable of orchestrating the complex commercial and legal campaigns that define twenty-first-century technological leadership. The Act would therefore fund scholarships and university programs in biotechnology, biomanufacturing, and bioethics, directly addressing the "bioliteracy" gap identified by the NSCEB.[243] In exchange, recipients would commit to a period of service in a relevant government agency or federally designated critical industry partner, building the deep talent pipeline necessary for long-term leadership. This proposal echoes the urgent calls from multiple advisory bodies, including the Defense Science Board and the State Department's International Security Advisory Board, which recently concluded that a modern NDEA is a critical

---

[240] NSCEB FINAL REPORT, *supra* note 1, at 146 (Recommendation 6.2.b) (calling for harmonized export controls).
[241] National Defense Education Act of 1958, Pub. L. No. 85-864, 72 Stat. 1580 (promoting STEM education).
[242] IAM STRATEGY 300, *supra* note 137, at 4 (describing sectors of expertise used to categorize leading professionals).
[243] NSCEB FINAL REPORT, *supra* note 1, at 122 (emphasizing the need for a bioliterate workforce).

national security imperative to produce the scientific workforce needed to compete with the PRC.[244]

Lead Ethically from a Position of Strength. The ultimate competitive advantage for a democratic society is its commitment to open, transparent, and ethically grounded governance. The United States must prove that its values enhance, rather than inhibit, responsible innovation. This requires proactively establishing citizen assemblies to build social consensus and using its leadership position within the Allied Biotechnology Framework to shape global norms. This course of action aligns with the NSCEB's core principle that for "humanity to benefit from progress in biotechnology, we want our democratic values to lead the way."[245]

X. CONCLUSION: THE STAKES OF THE GERMLINE GAMBIT

The competition between the United States and China for mastery of human germline editing is a fundamental contest over who will shape the next stage of human development. This Article has revealed how the iron logic of state competition has permeated this deeply ethical domain, creating a standard of strategic consequentialism where national advantage, not abstract principle, dictates state action. It has demonstrated how China, through a "whole-of-nation effort," has achieved near-parity in key metrics by executing a coordinated state-run strategy that skillfully exploits the vulnerabilities of the U.S.'s fragmented, market-driven innovation system.[246] The international governance vacuum enables this unconstrained competition, pushing both populations toward a dangerous and escalatory race. It is crucial to underscore that this framework

[244] ROLAND BERGER TRENDS, *supra* note 15, at 8 (showing a positive correlation between PISA outcomes and innovation rankings and stressing education for innovation).
[245] NSCEB FINAL REPORT, *supra* note 1, at 10 (asserting that democratic values should guide biotechnology leadership).
[246] *Id.* at 25.

is presented as descriptive, not prescriptive; it is an analysis of the powerful logic that is shaping state behavior, not an endorsement of that logic as a moral ideal.

The United States retains unparalleled advantages in breakthrough discovery, a network of advanced democratic allies, and immense economic vitality. The policy recommendations offered provide a roadmap for converting these inherent strengths into sustained, responsible leadership. This is not a call to abandon American values, but to recognize that a cohesive domestic strategy is the prerequisite for defending them on a global stage in the twenty-first century.[247] As the National Security Commission on Emerging Biotechnology (NSCEB) has made clear, the choice is not between innovation and values, but between leading with our values or ceding the future to those of our rivals.[248]

The stakes extend beyond general rivalry to the future of humanity itself. Will these technologies serve broad human flourishing or become tools for division and conflict? The germline gambit forces choices between competing values: security and openness, innovation and caution. How The United States navigates these choices will determine not only its own future but the trajectory of human evolution. The window for decisive action is narrowing.

The time to act on the Commission's urgent warnings is now. The germline gambit is a contest not only for technological primacy, but for authorship of the next chapter of the human story; history will judge harshly those who left that chapter to be written by others.[249]

---

[247] Jake Sullivan, Nat'l Sec. Advisor, *Remarks on Renewing American Economic Leadership at the Brookings Institution* (Apr. 27, 2023), https://bidenwhitehouse.archives.gov/briefing-room/speeches-remarks/2023/04/27/remarks-by-national-security-advisor-jake-sullivan-on-renewing-american-economic-leadership-at-the-brookings-institution/ (outlining U.S. industrial policy).

[248] NSCEB FINAL REPORT, *supra* note 1, at 10 (asserting that U.S. leadership should be guided by democratic values).

[249] JENNIFER A. DOUDNA & SAMUEL H. STERNBERG, A CRACK IN CREATION: GENE EDITING AND THE UNTHINKABLE POWER TO CONTROL EVOLUTION 251-253 (2017) (discussing the societal responsibilities accompanying germline gene editing).