STEM CELLS IN SPACE

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I. INTRODUCTION

Stem cell research in space presents unprecedented opportunities that surpass terrestrial limitations. This Technology Explainer highlights foundational principles of stem cell science, explores the unique advantages space provides for advancing this research, and raises key legal and policy considerations as the field evolves.

II. STEM CELLS: FOUNDATIONS & THERAPEUTIC POTENTIAL

This Section introduces the fundamental properties and therapeutic potential of stem cells, providing a basis for understanding how space-based research can address terrestrial challenges.

A. PROPERTIES

Stem cells possess two key properties: *self-renewal*, the ability to divide and replicate; and *differentiation*, the ability to become various specialized cell types in the body.[1] These abilities support tissue regeneration, development, maintenance, and repair throughout the body.

B. STEM CELL TYPES

1. *Pluripotent Stem Cells*

Pluripotent stem cells, including embryonic stem cells (ESCs), possess the ability to differentiate into nearly any cell type—from neurons to cardiac cells to muscle cells. This versatility establishes them as foundational "blank slate" or "master builder" cells. ESCs' capacity for self-renewal and differentiation was first demonstrated in 1998 when scientist Jamie Thomson successfully isolated and cultivated ESCs in a laboratory setting.[2]

ESCs are derived from the inner cell mass of blastocysts, which are tiny clusters of cells formed just days after fertilization. Blastocysts are donated by *in vitro* fertilization (IVF) clinics with fully informed consent and under strict ethical guidelines; if not

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[1] Irving L. Weissman, *Stem Cells: Units of Development, Units of Regeneration, and Units in Evolution*, 100 CELL 157, 157–68 (2000).

[2] James A. Thomson, Joseph Itskovitz-Eldor, Sander S. Shapiro, Michelle A. Waknitz, Jennifer J. Swiergiel, Vivienne S. Marshall & Jeffrey M. Jones, *Embryonic Stem Cell Lines Derived from Human Blastocysts*, 282 SCIENCE 1145, 1145–47 (1998).

donated for research, these blastocysts are discarded as medical waste.[3] Scientists gain critical insights into tissue formation, regenerative processes, and disease mechanisms by transforming these otherwise-discarded cell masses into research tools.

ESCs exist only in the earliest stages of development and disappear before birth. This distinguishes them from tissue-specific adult stem cells, which persist throughout life.[4] Research into ESC biology has been pivotal in uncovering essential mechanisms of tissue regeneration and has informed subsequent innovations such as induced pluripotent stem cells (iPSCs).[5]

2. *Induced Pluripotent Stem Cells*

Induced pluripotent stem cells (iPSCs) are adult cells artificially reprogrammed to return to a pluripotent state, thereby mimicking many of the properties of embryonic stem cells (ESCs).[6] First developed in 2007, this technique showed that somatic (non-reproductive) cells—such as skin fibroblasts—can be coaxed back into a pluripotent state by introducing specific transcription factors, or proteins that regulate gene expression.[7] In theory, iPSCs can differentiate into specialized cells, much like ESCs. However, because this technique is relatively new, the question remains of whether iPSCs perfectly replicate all aspects of ESCs.[8] iPSCs may exhibit genetic or epigenetic aberrations, potentially disrupting their normal function.[9]

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[3] Bernard Lo & Lindsay Parham, *Ethical Issues in Stem Cell Research*, 30 ENDOCRINE REV. 204, 204–13 (2009).

[4] Weissman, *supra* note 1.

[5] Kazutoshi Takahashi & Shinya Yamanaka, *Induction of Pluripotent Stem Cells from Mouse Embryonic and Adult Fibroblast Cultures by Defined Factors*, 126 CELL 663, 663–76 (2006).

[6] *Id.*

[7] Kazutoshi Takahashi, Koji Tanabe, Mari Ohnuki, Megumi Narita, Tomoko Ichisaka, Kiichiro Tomoda & Shinya Yamanaka, *Induction of Pluripotent Stem Cells from Adult Human Fibroblasts by Defined Factors*, 131 CELL 861, 861-72 (2007).

[8] Daisy A. Robinton & George Q. Daley, *The Promise of Induced Pluripotent Stem Cells in Research and Therapy*, 481 NATURE 295, 295–305 (2012); Adekunle Ebenezer Omole & Adegbenro Omotuyi John Fakoya, *Ten Years of Progress and Promise of Induced Pluripotent Stem Cells: Historical Origins, Characteristics, Mechanisms, Limitations, and Potential Applications*, 6 PEERJ 4370 (2018).

[9] Yosef Buganim, Styliani Markoulaki, Niek van Wietmarschen, Heather Hoke, Tao Wu, Kibibi Ganz, Batool Akhtar-Zaidi, Yupeng He, Brian J. Abraham, David Porubsky, Elisabeth Kulenkampff, Dina A. Faddah, Linyu Shi, Qing Gao, Sovan Sarkar, Malkiel Cohen, Johanna

3. *Adult Stem Cells (Tissue-Specific Stem Cells)*

Adult stem cells, or tissue-specific stem cells, are present in various tissues throughout the adult body. Certain tissue categories have specialized "repair mechanisms" to fix themselves when damaged. For instance, liver stem cells can regenerate liver tissue, while muscle stem cells repair muscle fibers. Their differentiation potential is typically restricted to the tissue type from which they originate; for example, liver stem cells cannot produce muscle fibers, nor can muscle stem cells regenerate liver tissue.[10] A specific type of adult stem cell—cancer stem cells—is particularly relevant throughout this article and thus merits further explanation.

Cancer occurs when cells in the body begin to divide uncontrollably, forming tumors and spreading throughout the body.[11] Often referred to as the "evil twin" of normal stem cells, cancer stem cells share the same capacities for self-renewal and differentiation. However, unlike normal stem cells, cancer stem cells evade regulatory signals and exploit these abilities to drive unchecked division and tumor propagation.[12] Scientists suspect that, in rare cases, the body's natural self-repair process misfires, leading to the emergence of cancer stem cells.[13]

C. THERAPEUTIC POTENTIAL OF STEM CELLS FOR CANCER AND UNMET CLINICAL NEED

Cancer remains an enduring and significant public health challenge. Approximately 40.5% of individuals will be diagnosed with cancer during their lifetimes, and it is the second-leading cause

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Goldmann, Joseph R. Nery, Matthew D. Schultz, Joseph R. Ecker, Andrew Xiao, Richard A. Young, Peter M. Lansdorp & Rudolf Jaenisch, *The Developmental Potential of iPSCs Is Greatly Influenced by Reprogramming Factor Selection*, 15 CELL STEM CELL 295, 295–309 (2015).

[10] Weissman, *supra* note 1.

[11] Derrick J. Rossi, Catriona H. M. Jamieson & Irving L. Weissman, *Stems Cells and the Pathways to Aging and Cancer*, 132 CELL 681, 681–96 (2008).

[12] Justin D. Lathia & Huiping Liu, *Overview of Cancer Stem Cells and Stemness for Community Oncologists*, 12 TARGETED ONCOLOGY 387, 387–99 (2017).

[13] Alysha K. Croker and Alison L. Allan, *Cancer Stem Cells: Implications for the Progression and Treatment of Metastatic Disease*, 12 J. OF CELLULAR AND MOLECULAR MED. 374, 374-390 (2007).

of death in the United States.[14] Persistently high rates of cancer-related mortality have driven efforts to detect cancer-causing mutations at early stages and to understand how tissue-specific cancer stem cells evade the immune system.[15] While these efforts have led to the development of life-extending therapies, such strategies are rarely curative for advanced cancers.[16] This underscores a critical unmet need for innovative therapies that can halt cancer progression and overcome immune evasion (the process by which cancer cells avoid detection and destruction by the immune system).

This unmet need has catalyzed the development of innovative therapeutic approaches, with stem cell research emerging as a particularly promising avenue in areas where conventional cancer treatments have yet to fully succeed.[17] Recent advancements in stem cell research, such as breakthroughs achieved through space-based experiments, offer promising solutions to these challenges.[18] Cancer serves as a compelling example of this potential due to its prevalence and prominence in space-based research.

III. STEM CELL RESEARCH IN SPACE

A. WHY MICROGRAVITY?

The success of new immune-based and regenerative therapies often depends on how effectively the immune system functions—a concept known as immune fitness, or the ability to detect and respond to threats. Microgravity and low-Earth orbit (LEO) environments create unique conditions that significantly alter stem cell behavior in ways unattainable on Earth, which can, in turn, affect immune fitness and therapeutic outcomes.

Stem cells are especially sensitive to environmental cues—such as microgravity, radiation, and noise—which determine how cells grow, differentiate, and ultimately support treatment efficacy.[19]

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[14] *Cancer Statistics,* NAT'L. CANCER INST. (May 9, 2024), https://www.cancer.gov/about-cancer/understanding/statistics [https://perma.cc/6RG3-K77X].

[15] Elizabeth H. Blackburn, *Cancer Interception*, 4 CANCER PREVENTION RSCH. 787, 787–92 (2011).

[16] Michael F. Clarke, *Clinical and Therapeutic Implications of Cancer Stem Cells*, 380 NEW ENG. J. MED. 2237, 2237–2245 (2019).

[17] Blackburn, *supra* note 15.

[18] Clarke, *supra* note 16.

[19] Francine E. Garrett-Bakelman, Manjula Darshi, Stefan J. Green, Ruben C. Gur, Ling Lin, Brandon R. Macias, Miles J. McKenna, Cem Meydan, Tejaswini Mishra, Jad Nasrini, Brian D. Piening, Lindsay F. Rizzardi, Kumar Sharma, Jamila H. Siamwala, Lynn Taylor, Martha Hotz

Illustrating how local microenvironments drive the formation of specific lineages, substrates that mimic specific tissue environments—such as those resembling brain tissue—can promote the development of neural stem cells.[20]

Microgravity further modifies cell signaling pathways, gene expression, and protein activity, offering unique opportunities for investigation.[21] Research at Stanford University has demonstrated that chronic stress on Earth—whether immune or environmental—can diminish the efficacy of therapeutic interventions and increase susceptibility to infection and cancer progression.[22] Microgravity in space may also present stressors such as reduced mechanical forces and heightened radiation, but it can reveal valuable insights into cell growth and differentiation.[23]

Vitaterna, Maryam Afkarian, Ebrahim Afshinnekoo, Sara Ahadi, Aditya Ambati, Maneesh Arya, Daniela Bezdan, Colin M. Callahan, Songjie Chen, Augustine M. K. Choi, George E. Chlipala, Kévin Contrepois, Marisa Covington, Brian E. Crucian, Immaculata De Vivo, David F. Dinges, Douglas J. Ebert, Jason I. Feinberg, Jorge A. Gandara, Kerry A. George, John Goutsias, George S. Grills, Alan R. Hargens, Martina Heer, Ryan P. Hillary, Andrew N. Hoofnagle, Vivian Y. H. Hook, Garrett Jenkinson, Peng Jiang, Ali Keshavarzian, Steven S. Laurie, Brittany Lee-McMullen, Sarah B. Lumpkins, Matthew MacKay, Mark G. Maienschein-Cline, Ari M. Melnick, Tyler M. Moore, Kiichi Nakahira, Hemal H. Patel, Robert Pietrzyk, Varsha Rao, Rintaro Saito, Denis N. Salins, Jan M. Schilling, Dorothy D. Sears, Caroline K. Sheridan, Michael B. Stenger, Rakel Tryggvadottir, Alexander E. Urban, Tomas Vaisar, Benjamin Van Espen, Jing Zhang, Michael G. Ziegler, Sara R. Zwart, John B. Charles, Craig E. Kundrot, Graham B. I. Scott, Susan M. Bailey, Mathias Basner, Andrew P. Feinberg, Stuart M. C. Lee, Christopher E. Mason, Emmanuel Mignot, Brinda K. Rana, Scott M. Smith, Michael P. Snyder & Fred W. Turek, *The NASA Twins Study: A Multidimensional Analysis of a Year-Long Human Spaceflight*, 364 SCIENCE EAAU8650 (2019).

[20] Sophia Shaka, Nicolas Carpo, Victoria Tran, Carlos Cepeda & Araceli Espinosa-Jeffrey, *Space Microgravity Alters Neural Stem Cell Division: Implications for Brain Cancer Research on Earth and in Space*, 23 INT'L. J. OF MOLECULAR SCI. 14320 (2022).

[21] Daniela Grimm, Markus Wehland, Thomas J. Corydon, Peter Richter, Binod Prasad, Johann Bauer, Marcel Egli, Sascha Kopp, Michael Lebert & Marcus Krüger, *The Effects of Microgravity on Differentiation and Cell Growth in Stem Cells and Cancer Stem Cells*, 9 STEM CELLS TRANSLATIONAL MED. 882, 882–94 (2020).

[22] Firdaus S. Dhabhar, *Enhancing Versus Suppressive Effects of Stress on Immune Function: Implications for Immunoprotection and Immunopathology*, 16 NEUROIMMUNOMODULATION 309, 309–10 (2009).

[23] Jeffrey S. Willey, Richard A. Britten, Elizabeth Blaber, Candice G.T. Tahimic, Jeffrey Chancellor, Marie Mortreux, Larry D. Sanford, Angela J. Kubik, Michael D. Delp & Xiao Wen Mao, *The Individual and Combined Effects of Spaceflight Radiation and Microgravity on Biologic*

Microgravity enables researchers to observe how stem cells grow, differentiate, and behave free from typical mechanical constraints by removing physical forces like shear stress and compression.[24] This "force-free" environment can expose fundamental processes that remain hidden under gravity-driven stresses; however, studies also indicate that microgravity may reduce the differentiation potential of these cells.[25] Nonetheless, the unique conditions of microgravity provide important insights into stem cell biology and immune fitness and can inform the design of new treatments in space and on Earth.[26] Researchers at the University of California, San Diego Sanford Stem Cell Institute (UCSD SSCI) are investigating how conditions such as microgravity and increased radiation aboard the International Space Station (ISS) might drive chromosomal alterations, immune dysfunction, and stem cell responses related to cancer.[27]

B. IMPLICATIONS OF BEHAVIOR IN MICROGRAVITY

Changes in microgravity influence the behavior of hematopoietic stem cells—adult stem cells responsible for generating blood and immune cells—and may contribute to stress-induced cellular changes that could lead to a premalignant or cancerous state.[28]

The 2019 NASA Twins Study highlighted how environmental stress is a key driver of immune dysfunction and the generation of cancer stem cells.[29] The Twins Study compared astronaut Scott Kelly, who spent a year in space, with his twin brother Mark—also an astronaut—who remained on Earth. One key finding was that

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Systems and Functional Outcomes, 39 J. OF ENV'T SCI. & HEALTH PART C TOXICOLOGY & CARCINOGENESIS 129, 129–79 (2021).

[24] Elizabeth A. Blaber, Hayley Finkelstein, Natalya Dvorochkin, Kevin Y. Sato, Rukhsana Yousuf, Brendan P. Burns, Ruth K. Globus & Eduardo A. C. Almeida, *Microgravity Reduces the Differentiation and Regenerative Potential of Embryonic Stem Cells*, 24 STEM CELLS & DEV. 2605, 2605–2621 (2015).

[25] *Id.*

[26] *Id.*

[27] Nicholas St. Fleur, *Q&A: Meet the Scientist Sending Tumors into Space*, STAT (May 6, 2024), https://www.statnews.com/2024/05/06/cancer-drug-development-space-station-catriona-jamieson/ [https://perma.cc/AG5K-AF36].

[28] Luisa Ladel, Jessica Pham, Larissa Balaian, Kathleen Steel, Isabelle Oliver & Catriona Jamieson, *Modeling Premalignant Transformation of Hematopoietic Stem Cells in a Nanobioreactor in Microgravity*, 140 BLOOD 2982, 2982–83 (2022).

[29] Garrett-Bakelman et al., *supra* note 19.

spaceflight led to changes in Scott's gene expression, immune system, and cognitive function, highlighting the significant impact of long-term space travel on human health.[30] LEO exposure induced signs of accelerated cell aging and immune dysfunction in the astronauts.[31] These dramatic results highlight the potential of space-based research to dissect mechanisms of immune dysfunction and cancer stem cell generation within a compressed time frame, paving the way for faster development of innovative therapies.[32] By subjecting cancer cells to experimental drugs under unique space conditions, researchers can observe faster cellular responses and refine treatments more quickly, accelerating the development of cancer therapies for delivery to patients on Earth.[33]

C. SCIENTIFIC TECHNIQUES AND APPLICATIONS

Researchers use advanced imaging, molecular analysis, and bioengineering to investigate how stem cells respond to conditions in microgravity. This space-based research has accelerated the identification of critical factors that drive progression of cancer and other diseases, as well as various aspects of cellular aging, immune dysfunction, and tissue regeneration.[34]

At UCSD SSCI, investigators study cancer, liver, and neural stem cells to analyze how microgravity influences cellular behavior, providing insights that are difficult to achieve on Earth.[35] A team led by Dr. Catriona Jamieson focuses specifically on cancer stem cells, utilizing nanobioreactors—small, self-contained units that mimic the natural environment of cells to study their behavior

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[30] *Id.*

[31] *Id.*

[32] Qingfei Jiang, Jane Isquith, Maria Anna Zipeto, Raymond H. Diep, Jessica Pham, Nathan Delos Santos, Eduardo Reynoso, Julisia Chau, Heather Leu, Elisa Lazzari, Etienne Melese, Wenxue Ma, Rongxin Fang, Mark Minden, Sheldon Morris, Bing Ren, Gabriel Pineda, Frida Holm & Catriona Jamieson, *Hyper-Editing of Cell-Cycle Regulatory and Tumor Suppressor RNA Promotes Malignant Progenitor Propagation*, 35 CANCER STEM CELL 81, 81–94 (2019).

[33] Jessica Pham, Jane Isquith, Larisa Balaian, Luisa Ladel, Shuvro P. Nandi, Karla Mack, Inge van der Werf, Emma Klacking, Antonio Ruiz, David Mays, Paul Gamble, Shelby Giza, Jiya Janowitz, Trevor Nienaber, Tejaswini Mishra, Anna Kulidjian, Jana Stoudemire, Michael P. Snyder, Twyman Clements, Alysson R. Muotri, Sheldon R. Morris, Thomas Whisenant, Ludmil B. Alexandrov & Catriona H.M. Jamieson, *Accelerated Hematopoietic Stem Cell Aging in Space*, BIORXIV (2024), https://doi.org/10.1101/2024.01.28.577076.

[34] Garrett-Bakelman, *supra* note 19.

[35] *Id.*

in real time—to better understand how these cells react in microgravity and explore disease progression.[36] Through their research, the team has identified rebecsinib, a drug candidate, as a promising therapeutic option for advanced blood cancers.[37]

Rebecsinib targets ADAR1 (adenosine deaminase acting on RNA 1), an enzyme that edits RNA by converting adenosine to inosine, thereby altering genetic messages within cells.[38] This enzyme plays a critical role in regulating RNA, and its abnormal activity in cancer cells can promote cancer growth and help cancer stem cells evade immune detection.[39] By inhibiting ADAR1's RNA-editing activity, rebecsinib effectively disrupts this pathway, inhibiting cancer cell proliferation and positioning it as a strong candidate for future clinical trials.[40]

To gain deeper insights into rebecsinib's effects, the Jamieson group conducted experiments aboard the ISS during private missions.[41] The unique microgravity conditions allowed the team to study how rebecsinib interacts with cancer cells more effectively, revealing its potent anti-cancer properties and strong efficacy against triple-negative breast cancer organoids.[42]

Notably, the Jamieson team's experiments conducted in microgravity showed that changes in their cancer stem cells were driven primarily by microgravity rather than radiation.[43] Although further research is needed, these initial findings suggest that

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[36] Luisa Ladel, Jessica Pham, Larissa Balaian, Kathleen Steel, Isabelle Oliver & Catriona Jamieson, *Modeling Premalignant Transformation of Hematopoietic Stem Cells in a Nanobioreactor in Microgravity*, 140 BLOOD 2982, 2982–83 (2022).

[37] Leslie A. Crews, Wenxue Ma, Luisa Ladel, Jessica Pham, Larisa Balaian, S. Kathleen Steel, Phoebe K. Mondala, Raymond H. Diep, Christina N. Wu, Cayla N. Mason, Inge van der Werf, Isabelle Oliver, Eduardo Reynoso, Gabriel Pineda, Thomas C. Whisenant, Peggy Wentworth, James J. La Clair, Qingfei Jiang, Michael D. Burkart & Catriona H. M. Jamieson, *Reversal of Malignant ADAR1 Splice Isoform Switching with Rebecsinib*, 30 CELL STEM CELL 250, 250–63 (2023).

[38] *Id.*

[39] *Id.*

[40] Nicole Mlynaryk, UC San Diego First to Test Cancer Drugs in Space Using Private Astronaut Mission, UC SAN DIEGO TODAY (May 22. 2023), https://today.ucsd.edu/story/uc-san-diego-first-to-test-cancer-drugs-in-space-using-private-astronaut-mission [perma.cc/2L8L-YUYF].

[41] Press Release, Int'l. Space Station Nat'l Lab'y, Second All-Private Astronaut Mission to the International Space Station Also Brings Compelling Science and Technology Demonstrations (May 11, 2023), https://issnationallab.org/press-releases/ax2-issnationallab-science/ [https://perma.cc/DU3Z-2VNU].

[42] St. Fleur, *supra* note 27.

[43] *Id.*

engineers could consider incorporating artificial gravity into long-term spaceflights to help counteract the effects of microgravity on cancer development.[44]

IV. POLICY AND LEGAL IMPLICATIONS

Space-based stem cell research challenges existing laws and policies, highlighting critical gaps that must be addressed to align with rapid scientific progress.

A. HEALTH AND REGULATORY LAW

Stem cell therapeutics developed in space may require adjustments to national and international clinical trials standards; microgravity-grown stem cells may exhibit different behaviors compared to those cultivated on Earth, potentially affecting their safety and efficacy. Regulatory agencies such as the U.S. Food and Drug Administration (FDA) must evaluate whether current guidelines can address these variations or if new protocols are necessary to meet the strict safety and efficacy standards required for Earth-based clinical trials.[45] Since stem cell therapies are classified as biologics under the FDA's regulatory framework, stem cell therapeutic drug sponsors must demonstrate their products' safety, purity, and potency and adhere to Good Manufacturing Practices (GMP) to ensure consistent quality and reliability.[46]

Novel biological products synthesized in space may pose health risks if they lead to the emergence of contaminants such as drug-resistant pathogens.[47] Comprehensive biosafety measures, such as environmental screening, equipment sterilization, and quarantine protocols, will be critical.

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[44] *Id.*

[45] *The Drug Development Process*, F.D.A., https://www.fda.gov/patients/learn-about-drug-and-device-approvals/drug-development-process [https://perma.cc/ANT4-QC9F] (last visited Dec. 31, 2024).

[46] *Pharmaceutical Quality Resources*, F.D.A., https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practice-cgmp [https://perma.cc/U828-2ETB] (last visited Dec. 31, 2024).

[47] Ágota Simon, Adriana Smarandache, Vicentiu Iancu & Mihail Lucian Pascu, *Stability of Antimicrobial Drug Molecules in Different Gravitational and Radiation Conditions in View of Applications during Outer Space Missions*, 26 MOLECULES 2221 (2021).

B. INTELLECTUAL PROPERTY LAW

Developing stem cell therapies in space involves complex international collaborations, which pose significant intellectual property challenges. As space-based stem cell research advances, cross-border collaborations will demand a unified global framework to address these issues. The ability to develop new drug formulations in microgravity presents opportunities to expand intellectual property portfolios, including novel compositions not currently addressed by existing legislation such as the Space Act.[48] However, creating compositions of matter in microgravity raises legal complexities about what qualifies as patentable and who holds the associated rights.

A relevant case in this context is *Diamond v. Chakrabarty*, which involved genetically engineering *E. coli* bacteria to synthesize enzymes capable of degrading crude oil, leading to a patent application for the modified organisms. The Court held that organisms genetically engineered through human intervention—such as *E. coli* bacteria modified to produce human insulin—are eligible for patent protection, provided that these modifications confer characteristics sufficiently distinct from their naturally occurring counterparts.[49]

In the context of outer research, the critical question arises as to whether organisms modified by microgravity environments exhibit distinct characteristics that differentiate them from their terrestrial counterparts, potentially affecting their biological processes and behavior. This inquiry necessitates a comprehensive analysis of whether microgravity-induced traits—such as expression of novel proteins or alterations in epigenetic markers—are sufficient to meet the "distinctness" threshold for patentability under prevailing patent law.[50]

V. CONCLUSION

The frontier of space-based stem cell research holds immense promise but demands rigorous scrutiny of attendant policy and legal challenges. While this discussion emphasizes the technological potential, advancing the field will require coordinated efforts among scientists, legal scholars, and policymakers to optimize benefits, mitigate risks, and promote equitable and sustainable progress.

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[48] 51 U.S.C. § 20135(b).
[49] Diamond v. Chakrabarty, 447 U.S. 303, 310 (1980).
[50] 35 U.S.C. § 112(b).