MITCHELL | HAMLINE School of Law

Cybaris®

Volume 15 | Issue 1 Article 4

2024

Disharmony in Patent Law: A Comparative Study of Patent Eligibility of Biological Subject Matters Between China and the United States

Xiongying Tu

DISHARMONY IN PATENT LAW: A COMPARATIVE STUDY OF PATENT ELIGIBILITY OF BIOLOGICAL SUBJECT MATTERS BETWEEN CHINA AND THE UNITED STATES

Xiongying Tu[*]

[*] The author is a licensed patent agent and a *J.D.* candidate of Mitchell Hamline School of Law. His biographical information can be found on LinkedIn at: https://www.linkedin.com/in/xiongyingtu/.

I. INTRODUCTION

Since negotiating the Word Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) during the 1986–94 Uruguay Round, the global intellectual property environment has become more predictable and consistent. [1] The TRIPS Agreement establishes standards for the availability, scope, and use of seven forms of intellectual property, namely copyrights, trademarks, geographical indications, industrial designs, patents, layout designs for integrated circuits, and undisclosed information (trade secrets). [2] However, it is important to note that the TRIPS Agreement sets the minimum level of protection, allowing for disharmony in certain intellectual property (IP) rights.[3]

One area where disharmony exists pertains to the eligibility of biological subject matters for patents, such as disease treatment and diagnosis methods, animals and plants, genetic resources, and stem cells.[4] Different countries have adopted varying approaches in this regard, influenced by their culture, customs, and developmental status. This disharmony allows countries to adopt IP regimes that align with their needs and socio-economic conditions.

However, disharmony can create challenges for global companies, as they may have to navigate different patent laws and regulations in different countries to protect their interests. This is particularly true in the case of biological subject matters, as standards appear to differ from one jurisdiction to another.

---

[1] Daniel R. Cahoy & Lynda J. Oswald, *Is Legal Harmonization Always Better? The Counter-Case of Utility Models*, 58 AM. BUS. L.J. 525, 526–27 (2021).
[2] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 183, 33 I.L.M. 1197 [hereinafter TRIPS Agreement].
[3] J.H. Reichman, *Universal Minimum Standards of Intellectual Property Protection Under the TRIPS Component of the WTO Agreement*, 29 INT'L L. 345 (1995).
[4] The term "disharmony" in this paper does not imply conflict, strife, or discordance. Instead, it signifies that different countries do not employ equivalent levels, scope, or criteria for protection.

Given the United States' position as the largest global economy and China's emergence as the second largest economy, both countries hold significant roles in international business and intellectual property protection. The United States (U.S.) has raised concerns regarding inadequate protection of foreign intellectual property rights in China. However, the Chinese government has undertaken substantial efforts to enhance IP protection and align its patent system with international standards.[5]

It is important to recognize that China and the U.S. have distinct cultural and traditional backgrounds. China has a long-standing community-based culture and tradition that emphasizes social value and collective benefits.[6] Conversely, the U.S. has a property rights-based culture and tradition that strongly emphasizes protecting and rewarding individual inventors and innovators.[7]

Therefore, conducting a comparative analysis of the treatment of biological subject matters in Chinese and U.S. patent law is valuable to understand how cultural, customary, and developmental differences influence their approaches to protecting such subject matters. This comparison can provide insights into the underlying rationale behind their choices and in exploring potential avenues for harmonizing the two patent systems.

The first part of this paper will examine the divergent aspects of eligible biological subject matters in the Chinese and U.S. patent law systems. It will shed light on their respective approaches, focusing on areas such as methods of treating or diagnosing human and animal diseases, plants and animals, genetic resources, and human stem cells. An analysis

---

[5] WIPO, *China's Commitment to Strengthening IP Judicial Protection and Creating a Bright Future for IP Rights*, WIPO MAG. (June 2019), https://www.wipo.int/wipo_magazine/en/2019/03/article_0004.html [https://perma.cc/4NT8-RJ8F].

[6] Zhang Lihua, *China's Traditional Cultural Values and National Identity*, CARNEGIE ENDOWMENT FOR INT'L PEACE (NOV. 21, 2013), https://carnegieendowment.org/2013/11/21/china-s-traditional-cultural-values-and-national-identity-pub-53613 [https://perma.cc/W99Z-V26K].

[7] Todd Martin, *Patentability of Methods of Medical Treatment: A Comparative Study*, 82 J. PAT. & TRADEMARK OFF. SOC'Y 381 (2000).

of these differences can give a better understanding of their contrasting approaches.

The second part of the paper will delve into potential areas for harmonization that can promote global IP protection and facilitate innovation in biotechnology and related industries. Exploring opportunities for aligning the Chinese and U.S. patent systems will contribute to creating a more cohesive and efficient framework for biotechnological innovation on an international scale.

II. DIFFERENCES IN ELIGIBLE BIOLOGICAL SUBJECT MATTER BETWEEN CHINA AND U.S. PATENT LAW

Both China and the U.S. are signatories of the TRIPS Agreement, which establishes minimum criteria for patentability. [8] According to Article 27.1 of the TRIPS Agreement, inventions in all technological fields, whether products or processes, are eligible for patent protection.[9]

In China, patentable subject matter is defined in Article 2.1 of China Patent Law as any new technical solution relating to a product, method, or any improvement thereof.[10] This definition is further elucidated by the China Patent Examination Guidelines, [11] which interprets a "technical solution" as a collection of technical means that use natural laws to solve technical problems. [12] Technical means are usually embodied by technical characteristics.[13]

---

[8] WIPO IP Treaties Collection, https://www.wipo.int/wipolex/en/treaties/parties/231 [https://perma.cc/N2S2-9Z68]; Reichman, *supra* note 3, at 351–52.
[9] TRIPS Agreement, *supra* note 2, at art. 27.1.
[10] Zhonghua Renmin Gongheguo Zhuanli Fa (中华人民共和国专利法) [Patent Law of the People's Republic of China] (effective October 17, 2020), art. 2, http://english.cnipa.gov.cn/col/col3068/index.html [https://perma.cc/KY47-2SGS] [hereinafter China Patent Law].
[11] Zhuanli Shencha Zhinan (专利审查指南) [Patent Examination Guidelines] (effective January 15, 2021), China National Intellectual Property Administration, http://zjpaa.cn/upload/attachments/draft/2c9f82a5-797e3aa0-017a-e6fac48b-0037.pdf [https://perma.cc/B95R-MNL5] [hereinafter China Patent Examination Guidelines].
[12] *Id.* at Part 2, Chapter 1, § 2, at 84.
[13] *Id.*

On the other hand, section 101 of U.S. Patent Law (35 U.S.C.) defines patentable subject matter as "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."[14] The "machines, manufactures, and compositions of matter" are commonly referred to in practice (in shorthand) as "things" or "products."[15]

Thus, the patentable subject matter in the U.S. and China are defined broadly, aligning with the "product and process" categories outlined in TRIPS Agreement Article 27.1.

TRIPS also permits member countries to exclude certain specific inventions from patentability. Article 27.2 of the TRIPS Agreement allows the exclusion of inventions contravening *ordre public* or morality, safeguarding human, animal, or plant life or health, and preventing significant environmental harm.[16] Additionally, TRIPS Agreement Article 27.3 permits member countries to exclude (a) diagnostic, therapeutic, and surgical methods for human or animal treatment, and (b) plants and animals from patentability.[17]

Thus, while the TRIPS Agreement establishes minimum criteria for patentability, individual member countries have the autonomy to determine which specific inventions they exclude from patent eligibility. China and the U.S. diverge significantly in their approaches to exceptions, including what is excluded from patentable subject matter and how such exclusions are implemented.

A. The Statutory Exception Approach in China

China Patent Law employs a statutory exception approach, which is evident in two key provisions: Articles 5 and 25. [18] Together, these two provisions establish a

[14] 35 U.S.C. § 101.
[15] Digitech Image Techs., LLC v. Elecs. for Imaging, 758 F.3d 1344, 1348 (Fed. Cir. 2014).
[16] TRIPS Agreement, *supra* note 2, art. 27.2.
[17] *Id.*
[18] China Patent Law, *supra* note 10, art. 5 at 25.

framework for determining nonpatentable subject matters in China.

Article 5.1 of China Patent Law introduces statutory exceptions to Article 2.1 by excluding from patentability those inventions that conflict with laws, social morality, and public interests. The term "social morality" refers to ethical principles and behavioral norms that are widely recognized and accepted within the territory of China.[19] Specific cultural backgrounds influence its meaning, which evolves over time and across different regions.[20] Examples of inventions falling under the "social morality" exception include non-medical artificial human organs or substitutes, procedures altering the genetic integrity of human reproductive systems or individuals, human cloning or related methods, industrial or commercial applications involving human embryos, and methods that alter the genetic integrity of animals in ways that inflict suffering on them without substantial medical benefits to humans or animals.[21]

Article 5.1 of China Patent Law aligns with TRIPS Agreement Article 27.2, as the concept of "social morality" in China can be considered similarly to the notion of "*ordre public* or morality" of the TRIPS Agreement. Both provisions aim to establish limitations on patentability based on ethical and societal considerations. While the TRIPS Agreement uses the term "*ordre public* or morality," China Patent Law utilizes the concept of "social morality" to achieve a similar purpose. These terms encompass principles and norms that reflect societal values and interests, allowing for the exclusion of inventions that may conflict with these concerns. Therefore, the adoption of "social morality" in Article 5.1 of the China Patent Law aligns with the objective of TRIPS Agreement Article 27.2, ensuring that patent protection is subject to certain limitations in accordance with ethical and moral considerations.

[19] China Patent Examination Guidelines, *supra* note 11, pt. 2, ch. 1, § 3.
[20] *Id.*
[21] *Id.*

Article 25 of China Patent Law introduces additional statutory exceptions to Article 2.1.[22] It prohibits the granting of patent rights for the following: (1) scientific discoveries; (2) rules and methods for intellectual activities; (3) methods for the diagnosis or treatment of diseases;[23] (4) animal and plant varieties.

Article 25(1) and (2) somewhat correspond to the three judicially created exceptions in the U.S.: laws of nature, natural phenomena, and abstract ideas.

Article 25(3) and (4) align with TRIPS Agreement Article 27(3), which allows member countries to exclude from patentability: (a) diagnostic, therapeutic, and surgical methods for the treatment of humans or animals, and (b) plants and animals. The following sections provide a more detailed discussion of these exceptions.

B. The Judicial Exception Approach in the U.S.

In contrast, U.S. Patent Law does not impose an *ordre public* or morality barrier. U.S. Patent Law is rooted in the Constitution's intellectual property clause, which grants Congress the power "[t]o promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." [24] This clause does not encompass considerations of *ordre public* or morality. Instead, its primary focus is on fostering innovation and creativity for the advancement of science and useful arts.

The 1952 Patent Act defined patentable subject matter as anything under the sun that is made by man.[25] Although

[22] China Patent Law, *supra* note 10, art. 2 at 25.
[23] The scope of the term "diseases" is limited to human and animal diseases. According to the China Patent Law, methods for treating and diagnosing plant diseases can be granted patent protection. In addition, instruments or devices used to implement disease diagnosis and treatment methods, as well as substances or materials used in disease diagnosis and treatment methods, can be subject to patent rights, regardless of whether they are intended for treating or diagnosing human, animal, or plan diseases.
[24] U.S. CONST. art. I, § 8, cl. 8.
[25] S. REP. NO. 19-79, at 4 (1952); H.R. REP. NO. 19-23, at 6 (1952).

the Act was later amended to narrow the patent-eligible subject matter to "process, machine, manufacture, or composition of matter," Congress intended for patent law to have a broad scope, as evidenced by the legislative history.[26] The Court has only introduced three judicial exceptions to patent-eligible subject matters: laws of nature, natural phenomena, and abstract ideas.[27] These judicial exceptions are considered to be fundamental principles that are "part of the storehouse of knowledge of all men . . . free to all men and reserved exclusively to none."[28] Thus, the purpose of these judicial exceptions appears to be preventing the granting of patents for natural products and concepts that are inherently fundamental or too broad to warrant exclusive rights. This ensures that patents are granted for genuine inventions that yield practical, tangible benefits while preventing the exploitation of patents to monopolize or preclude the advancement of science and technology.[29]

When it comes to patenting biological subject matters, such as animals, bacteria, and cells, one of the main issues revolves around determining whether these forms of life fall within the four categories of patentable subject matter and whether they fall under any of the judicial exceptions. Prior to *Chakrabarty*, the widespread belief was that living subject matter was not eligible for patenting, either because it did not fit into a statutory category or because it was considered a judicial exception to patent eligibility.[30]

In 1980, the Court ruled that a live microorganism could be considered a "manufacture" or "composition of matter" and is therefore eligible for patent protection.[31] This landmark decision established that the presence of living matter does not affect the patent eligibility of an invention.

---

[26] Diamond v. Chakrabarty, 447 U.S. 303, 308–09 (1980); ERIC C. BENSON, 1 PATENT LAW PERSPECTIVES § 1.1 (2023).
[27] Diamond v. Diehr, 450 U.S. 175, 185 (1981).
[28] Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948); see also Le Roy v. Tatham, 55 U.S. 156, 175 (1852) ("A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right.").
[29] Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 71 (2012).
[30] U.S. PATENT & TRADEMARK OFFICE, MPEP § 2105 (9th ed. February 2023).
[31] *Chakrabarty*, 447 U.S. at 309–10.

Consequently, it became possible to patent living subject matter, including cells, microbes, and animals.

As a result of the 1980 ruling, the U.S. has adopted a broad approach to patentability, allowing for a wide range of biological subject matters to be considered for patents, provided they do not fall within the three judicially created exceptions. This expansive scope encompasses almost all biological subject matters. Thus, when comparing the U.S. patent system to that of China, it can be observed that the U.S. provides a broader latitude for the patentability of diverse biological subject matters.

III. METHODS FOR THE DIAGNOSIS AND TREATMENT OF DISEASES

A. Humanitarian and Social Ethical Approach in China

Article 25(3) of China Patent Law explicitly excludes methods for the diagnosis or treatment of diseases from patentability. The term "diagnosis and treatment methods of diseases" refers to the process of identifying, determining, or eliminating the causes of diseases in living human or animal bodies. [32] Thus, this term encompasses diagnostic, therapeutic, and surgical methods for the treatment of humans or animals, as outlined in TRIPS Agreement Article 27(3).

This exclusion is rooted in humanitarian considerations and social ethics, recognizing that doctors should have the freedom to choose from various methods and conditions during the diagnosis and treatment process.[33] Additionally, within Chinese culture, there is a strong emphasis on collective well-being and the belief that healthcare and medical knowledge should be accessible to everyone. Excluding diagnostic and therapeutic methods from patentability serves the purpose of ensuring that these essential healthcare services remain accessible to the public and are not hindered by patent monopolies. This approach promotes the availability of affordable healthcare while

[32] China Patent Examination Guidelines, *supra* note 11, pt. 2, ch. 1, § 4.3.
[33] *Id.*

stimulating competition in the implementation of new treatment and diagnostic techniques. Furthermore, these methods, which directly involve living human or animal bodies and industries, cannot be exploited under traditional Chinese culture. Therefore, patent protection does not cover diagnostic and therapeutic methods of treating diseases in China.

However, the exclusion of methods for treatment and diagnosis from patent protection also poses certain challenges. There are cases where patent protection is necessary, particularly when significant investments, amounting to billions of dollars for some instances, are required to develop new treatment and diagnostic methods.[34] Without the incentive of patent protection, investors and inventors may be deterred from pursuing innovation in these areas. Even if they choose to pursue innovation, they may opt to keep their advancements as trade secrets, restricting public access to valuable information. As a result, this can hinder further research and development in these crucial areas. Striking a balance between promoting accessibility and providing adequate incentives for innovation will be a key consideration in addressing these challenges effectively.

B. Innovation-Incentive Approach in the U.S.

Contrary to China, the U.S. embraces an innovation-incentive approach when it comes to methods of disease treatment and diagnosis.[35] This approach places a strong emphasis on promoting and advancing medical technology, research, and healthcare practices. It ensures that practical medical inventions, particularly those related to treatment and diagnosis, receive appropriate patent protection to stimulate and uphold a culture of innovation.

Under U.S. Patent Law, methods of treatment and diagnosis of diseases are patentable subject matter as long as

[34] Joseph A. DiMasi, et al.*, Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J HEALTH ECON., 20, 20–33 (2016).
[35] Maggi Robert, Comment, *From Patients to Patents: The Disappearing I of Innovation*, 53 ST. MARY'S L. J. 1203, 1205–06.

they exhibit a significant distinction from laws of nature, natural phenomena, or abstract ideas.[36] Although the Supreme Court's decisions in *Mayo v. Prometheus* and *Alice v. CLS Bank* have led to increased scrutiny of patent applications involving the judicial exceptions,[37] recent developments indicate an increased willingness to grant patents for medical methods that meet the eligibility requirements. The federal circuit decision in *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals* (2018) has provided clarification on the patent eligibility of claims that apply natural relationships in a practical manner.[38] This decision affirms that method of treatment or diagnosis claims that applies a natural relationship to a specific disease using a specific compound at specific doses may be considered patent-eligible without the need for the inclusion of non-routine or unconventional steps.[39]

IV. HUMAN-CREATED ANIMALS AND PLANTS

A. The Human-Nature Harmony Approach in China

Under Article 25(4) of China Patent Law, new varieties of animals and plants are ineligible for patent rights, even if they meet the criteria of novelty, inventiveness, and utility as human creations through research and technological processes.[40]

The exclusion of animals and plants from patentability may reflect a unique perspective shaped by the cultural, customary, and developmental status of China. China has a rich cultural heritage deeply rooted in reverence for nature and living beings, which includes human beings, animals, and

[36] The U.S. is one of the few countries that permits patenting methods of treatment and diagnosis of human and animal diseases.
[37] Brian R. Dorn, *Mayo v. Prometheus: A Year Later*, 4 ACS MED. CHEM. LETTERS, 572, 572–73 (2013).
[38] Vanda Pharms. Inc. v. W.-Ward Pharms. Int'l Ltd., 887 F.3d 1117, 1136 (Fed. Cir. 2018).
[39] *Id.* at 1135–36.
[40] China Patent Law, *supra* note 10, art. 25.

plants. [41] Traditional Chinese philosophies, such as Confucianism, Buddhism, and Taoism, emphasize the harmony between humans and the natural world.[42] Animals and plants are seen as part of the natural ecosystem, and their commodification through patents may be viewed as a disruption to this balance. Thus, the exclusion of animal and plant patentability appears to align with the cultural belief in preserving the natural order and respecting the intrinsic value of animals and plants.

Some scholars argue that cultural beliefs should not be the sole basis for excluding animal and plant patentability because the commercialization of these living beings has occurred for thousands of years through activities like buying, selling, and using them for commercial and consumer purposes.[43] However, it is important to distinguish between commercial activities involving animals and plants and granting patent monopolies. Traditional Chinese culture and customs perceive plants and animals as more than mere property, whereas patent law primarily concerns property rights and their protection. China's cultural context and philosophical traditions have played a significant role in shaping its approach to patent law and the consideration of animals and plants as integral components of a broader natural order.

China's rich history also encompasses extensive agricultural practices, in which farming and animal husbandry have held significant importance. Throughout generations, farmers and breeders have relied on traditional knowledge, selective breeding, and shared resources to improve animal and plant breeds. The communal nature of these practices fosters a culture of collective ownership and shared benefits, which may be incongruent with the notion of exclusive patent rights. "A basic tenet of patent law is ownership and the ability

---

[41] Wei Jiang & Haoran Zhang, *Traditional Chinese Culture and the Construction of Ecological Civilization: From Cultural Genes to Practical Behaviors — Case Studies in Confucianism, Buddhism and Taoism*, 8(2) CHINESE J. URB. & ENV'T STUD. 1 (2020).

[42] *Id.*

[43] Ke Geng, *Should China Provide Intellectual Property Protection for Genetically Modified Animals*? 23 NW. J. INT'L L. & BUS. 467, 472 (2003).

to exclude as a reward for revealing an inventor's new technology."[44] The ownership and exclusivity of patent law contradict collective ownership and shared benefits.

In addition, China, with its large population, faces significant agricultural demands. Ensuring food security and accessibility to animal and plant genetic resources is a paramount concern.[45] The exclusion of animals and plants from patent protection serves the public interest by safeguarding the availability of diverse animal and plant varieties, especially those essential for sustaining agricultural productivity and meeting the nutritional requirements of the population.

However, this exclusion presents challenges, as there are instances where patent protection for certain genetically engineered animal disease models or disease-resistant and drought-tolerant plants may incentivize innovation, attract research investment, and facilitate technology transfer. "A fundamental trait of patent law is its reliance on economic motivation and reward as a means to encourage innovation, development, and dissemination of technology."[46] Striking a balance between preserving cultural values, meeting agricultural needs, and fostering technological advancement remains an ongoing consideration in China.[47]

B. The Property Rights Approach in the U.S.

The Lockean labor-based justification stands as a principle underpinning the U.S. patent system.[48] Stemming from John Locke's theory, this justification posits that patents ought to be awarded to inventors who invest their intellectual and creative efforts in developing novel inventions.[49] Locke's

---

[44] Martin, *supra* note 7.
[45] Yan Zhang & Xiaoyong Lu, *A Comprehensive Evaluation of Food Security in China and Its Obstacle Factors*, 20 INT'L. J. ENV'T. RSCH. & PUB. HEALTH 451, 451–52 (2022).
[46] Martin, *supra* note 7, at 381.
[47] Geng, *supra* note 43, at 467.
[48] Justin Hughes, *The Philosophy of Intellectual Property*, 77 GEO. L.J. 287, 365–66 (1988).
[49] *Id.* at 296–97.

theory extends to human-created animals and plants, connecting them to the notion of property rights, where an individual's labor and creativity are transformed into ownership.

In addition, the U.S. Constitution bestows exclusive rights upon the discoveries of new animals and plants as a way to reward inventors for their creative efforts in advancing science and useful arts. Article I, Section 8, Clause 8 of the U.S. Constitution holds particular importance in this regard. This clause bestows upon Congress the explicit power "To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[50]

Thus, unlike China, the U.S. allows for the patent protection of new animal and plant varieties with only certain exceptions. Naturally occurring animals or plants, as well as discoveries of new animal species or plant varieties, may not be eligible for patent protection. The U.S. patent system emphasizes the recognition of innovation and human intervention in the creation or modification of living organisms. It underscores the significance of active human contribution when determining patentable subject matter within the biological realm.

New plant varieties can be protected by plant patents granted to anyone who has invented or discovered and asexually reproduced a new and distinct variety of plant, other than a tuber-propagated plant or a plant found in an uncultivated state.[51] The term "asexually reproduced" means that plants can be reproduced without the need for seed, such as through cuttings, grafting, or tissue culture.[52] To be eligible for a plant patent, the new variety must be novel, non-obvious, and stable.[53] Once granted, the plant patent provides the

[50] U.S. CONST. art. I, § 8, cl. 8.
[51] U.S. PATENT AND TRADEMARK OFFICE, MPEP § 1601 (9th ed. Feb. 2023).
[52] *Id.*
[53] *General Information About 35 U.S.C. 161 Plant Patents*, UNITED STATED PATENT AND TRADEMARK OFFICE (Sept. 22, 2017), https://www.uspto.gov/patents/basics/apply/plant-patent#heading-4 [https://perma.cc/X2ZH-XN8P].

owner with the exclusive right to reproduce, use, and sell the protected plant for a period of twenty years from the date of filing the patent application.[54]

It should be noted that there can be an overlap between the protection of plant patents and utility patents, and certain plant varieties such as genetically modified plants may be eligible for both types of patents.[55] Utility patents safeguard new and useful processes, machines, articles of manufacture, and compositions of matter, which can encompass plants that have been genetically modified through human intervention.

While plant patents are one way to protect new plant varieties in the U.S., plant breeders also have the option to seek protection under the Plant Variety Protection Act (PVPA). [56] The PVPA provides legal protection to plant breeders who develop new varieties of sexually or asexually reproduced plants that are distinct, uniform, and stable.[57] A plant breeder can apply for a certificate of protection that gives him/her exclusive rights to market and sell their varieties for up to twenty-five years, depending on the type of plant.[58] During this time, others cannot use the protected variety without the plant breeder's permission.

One of the key advantages of the PVPA over plant patents is that the PVPA covers sexually reproduced plants, which cannot be protected by plant patents. This means that breeders of crops like wheat, corn, and soybeans can still obtain legal protection for their new varieties. Additionally, the PVPA provides broader protection for asexually reproduced plants, such as fruit trees, than plant patents.[59]

---

[54] 35 U.S.C. § 163; 35 U.S.C. § 154(a)(2).
[55] Jonathan D. Carpenter, Note, *Intellectual Property: The Overlap Between Utility Patents, Plant Patents, and PVPA, and Trade Secrets and the Limitations on that Overlap,* 81 N.D. L. REV. 171, 171–72 (2005).
[56] *Id.* at 176–77.
[57] Benjamin Berkowitz, *Plant Variety Protection Act Now Covers Asexually Reproduced Plants*, JD SUPRA: FOLEY & LARDNER LLP (May 21, 2019), https://www.jdsupra.com/legalnews/plant-variety-protection-act-now-covers-95762/ [https://perma.cc/ZCS2-X5KB].
[58] *Id.*
[59] *Id.*

In contrast to China, new animal varieties in the U.S. can be protected by utility patents. This differs from China's approach, which restricts animals as nonpatentable subject matter. One prominent example of an animal variety protected by a utility patent is the oncomouse, a genetically engineered mouse used in cancer research. Researchers at Harvard University developed the first oncomouse in the 1980s, and the patent (U.S. Patent 4,736,866) was issued in 1988.[60] The patent covered both the mouse itself and the method for producing it. Since then, the United States Patent and Trademark Office has granted numerous utility patents for other genetically modified animals, including pigs, cows, and sheep.

Utility patents for new animal varieties grant the patent owner exclusive rights to manufacture, use, and sell the patented animal variety for a period of twenty years, similar to plant patents.[61] This form of patent protection holds significant value for companies engaged in the development of new pharmaceuticals and medical treatments that rely on animal models for testing and research purposes.

However, there has been debate and controversy in the U.S. regarding the patentability of animal varieties.[62] Those who oppose the idea of patents on animals and their genetic material argue that it raises ethical and moral concerns.[63] This is particularly true when it comes to the use of animals in research and testing, where patents can be seen as a way of commodifying living beings and treating them as mere property.[64] Opponents of animal patents also argue that patent protection could exacerbate this issue by incentivizing

[60] Carolyn Brown, *Patenting Life: Genetically Altered Mice an Invention, Court Declares*, 163 CMAJ 867 (2000); Michael Fuller, *Twenty Years of Transgenic Animals: Are Some Inventions SO Important as to NOT Be Entitled To Full Patent Protection?*, 30 WORLD PAT. INFO. 139, 140 (2008).
[61] 35 U.S.C. § 154 (2015).
[62] James R. Chiapetta, Comment, *Of Mice and Machine: A Paradigmatic Challenge to Interpretation of the Patent Statute*, 20 WM. MITCHELL L. REV. 155, 158–59 (1994).
[63] *Id.* at 177–178.
[64] Rebecca Dresser, *Ethical and Legal Issues in Patenting New Animal Life*, 28 Jurimetrics J. 399 (1988), http://nationalaglawcenter.org/wp-content/uploads/2013/06/dresser_ethical.pdf [https://perma.cc/2NSG-23N6].

researchers to prioritize profits over ethical considerations.[65] In addition, they point out that animals are not mere objects or machines but living beings with their own rights and dignity.[66]

On the other hand, supporters of animal patents argue that patent protection is necessary to incentivize innovation and research.[67] They argue that without the possibility of patent protection, companies and researchers may be less likely to invest time and resources into developing new animal varieties or genetic modifications.[68] In addition, supporters of animal patents argue that patent protection can help to ensure that important scientific discoveries are widely available and accessible.[69] Without patent protection, they argue, there is a risk of keeping important discoveries secret or restricting them to a small group of researchers or companies.[70]

Thus, while U.S. Patent Law allows for a relatively broad range of patentable biological subject matter, there are important ethical considerations that arise. These considerations include the potential for monopolistic control over genetic resources, the impact on access to essential technologies or therapies, and the ethical implications of patenting living organisms.

In addition, it is essential to address the delicate balance between promoting innovation and safeguarding the public interest. Within the U.S. patent system, ongoing discussions revolve around finding the right equilibrium that encourages innovation while ensuring public access to essential technologies or resources. This requires a careful

---

[65] Chiapetta, *supra* note 62, at 184.
[66] Robert P. Merges, *Intellectual Property in Higher Life Forms: The Patent System and Controversial Technologies*, 47 MD. L. REV. 1051, 1058–60 (1988).
[67] Dustin Mauck, *Animal Patents*, STATE BAR OF TEXAS ANIMAL LAW SECTION (June 7, 2011), https://www.animallawsection.org/animal-patents/ [https://perma.cc/DM7X-GC3C].
[68] *Id.*
[69] Elisabeth T. Jozwiak, Comment, *Worms, Mice, Cows and Pigs: The Importance of Animal Patents in Developing Countries*, 14 NW. J. INT'L L. & BUS. 620, 632–35 (1994).
[70] *Id.*

assessment of the potential social, economic, and ethical implications associated with granting patent rights in the field of biological subject matter.

V. GENETIC RESOURCES

Genetic resources are a unique subject matter for IP protection and have presented a challenge for IP systems since the modern life sciences began to develop in the mid-1970s.[71] On the one hand, there is a need to promote and incentivize innovation in the life sciences through IP protection, which can encourage the development of new products and technologies based on genetic resources and associated traditional knowledge. On the other hand, there is a need to protect biological diversity and the traditional knowledge of the communities that rely on these resources and to ensure that the benefits of innovation are shared equitably with these communities.[72] This has led to the development of a range of IP regimes and legal frameworks that seek to balance these interests, including patent systems, plant variety protection systems, and the prior informed consent and benefit-sharing rules. These IP regimes and legal frameworks are largely under the umbrella of the TRIPS Agreement and the Convention on Biological Diversity (CBD).

The CBD's prior informed consent and benefit-sharing rules aim to protect genetic resources and associated traditional knowledge extracted from biological resources by requiring prior consent from the country of origin, region, or community before use. Additionally, these rules ensure that the country or region of origin receives equitable and appropriate economic benefits when using these resources and knowledge. To further clarify the implementation details and specific requirements of these rules, the CBD has established the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits

---

[71] *Genetic Resources*, WORLD INTELLECTUAL PROPERTY ORGANIZATION, https://www.wipo.int/tk/en/genetic/ [https://perma.cc/W5Y3-68DU].

[72] *Traditional Knowledge and the Convention on Biological Diversity*, CONVENTION ON BIOLOGICAL DIVERSITY (Oct. 19, 2021), https://www.cbd.int/traditional/intro.shtml [https://perma.cc/2A5V-QS93].

Arising from their Utilization.[73] Over 100 countries have joined this Protocol since its implementation in 2014, promoting the sustainable use and protection of biological resources and safeguarding the rights of the country or region of origin.[74] The effectiveness of these rules depends on each country's specific implementation and legal system. Under the provisions of the CBD, member countries should take appropriate measures to ensure the implementation and effectiveness of these rules.[75] To achieve this, member countries should develop domestic laws and policies that provide procedures for access, utilization, and sharing of genetic resources and associated traditional knowledge and establish institutions and mechanisms to ensure the implementation and monitoring of these rules.[76]

The legal and scientific communities have sparked controversy and debate over the eligibility of genetic resources for patents. Some argue that genes are a fundamental part of biodiversity and have significant economic value to countries, and thus that protecting genetic resources can help to prevent biopiracy.[77] Biopiracy refers to the unauthorized commercial exploitation of biological resources, traditional knowledge, and genetic resources by individuals, organizations, or companies without providing fair and equitable benefits to the countries or communities where these resources originated.[78] Biopiracy can result in exploiting indigenous communities and developing countries, which may not have the resources or legal protections to prevent their genetic resources from being exploited. However, one may contend that genetic resources are naturally occurring and that humans do not create them. Thus, they should be free

[73] Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, Oct. 29, 2010, UNEP/CBD/COP/DEC/X/1, https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf [https://perma.cc/HGU2-WG7R].
[74] *Id.* at 1.
[75] *Id.* at 14.
[76] *Id.* at 17.
[77] Yoonus Imran et al., *Biopiracy: Abolish Corporate Hijacking of Indigenous Medicinal Entities*, 2021 SCI. WORLD J. Art. ID 8898842, at 5.
[78] Cynthia M. Ho, *Biopiracy and Beyond: A Consideration of Socio-Cultural Conflicts with Global Patent Policies*, 39 U. MICH. J.L. REFORM 433, 436 (2006).

to exploit, which would help promote research and development.

A. Benefit-Sharing Approach in China

Although Article 25 of China Patent Law excludes animals and plants themselves from patentable subject matter, it does allow for the granting of patent rights for the production methods of animal and plant varieties. [79] Additionally, inventions based on or derived from materials of plants, animals, or other genetic resources are eligible for patent protection under China Patent Law.[80]

However, it is important to note that these inventions are subject to certain limitations imposed by national laws and international treaties, which aim to address concerns regarding the protection of genetic and other biological resources.

China is a member of the TRIPS Agreement and the CBD agreements and is committed to protecting its biological resources and associated traditional knowledge within the frameworks provided by both. As a developing country with a vast array of genetic resources and traditional knowledge, China has encountered a growing threat of biopiracy. [81] However, there is currently no international agreement that adequately addresses the issue of biopiracy and genetic resource protection, particularly in terms of equitable benefit-sharing between developing and developed countries. The CBD lacks enforceable mechanisms and obligatory commitments, and certain developed countries have chosen not to become parties to the CBD.[82] Although developing countries can protect their own genetic resources through

[79] China Patent Law, *supra* note 10, art. 25.
[80] *Id.,* art. 26.
[81] Hepeng Jia, *China Faces Uphill Battle Against 'Biopiracy'*, SCIDEV.NET (Apr. 23, 2003), https://www.scidev.net/global/news/china-faces-uphill-battle-against-biopiracy/ [https://perma.cc/DYP8-EFSD]; Wei-Ning Yang and Andrew Y. Yen, *The Dragon Gets New IP Claws: The Latest Amendments to the Chinese Patent Law*, 21 INTELL. PROP. & TECH. L. J. 18 (2009).
[82] Xuanyu Chen, *Analysis on the Protection of Genetic Resources from the Perspective of Intellectual Property*, 9 ADVANCES APPLIED SOCIO. 163, 167 (2019).

domestic legislation, this can only be within the sovereignty of the country. To protect its genetic resources, China has introduced clauses in its patent law on the protection of genetic resources in accordance with the TRIPS Agreement and the CBD rules. These clauses require patent applicants to disclose the source and genetic origin of any genetic resources used in their inventions, as well as any traditional knowledge associated with those resources.[83] In addition, the law requires that patent holders negotiate with the Chinese government regarding the sharing of any benefits arising from the use of these resources. The most relevant of these provisions in China Patent Law are Articles 5.2 and 26.5.[84]

Article 5.2 of China Patent Law provides that "no patent right shall be granted for any invention where the acquisition or utilization of the genetic resources, on which the development of the invention relies, violates the provisions of laws or administrative regulations."[85] This provision is for the protection of genetic resources.

Article 26.5 of China Patent Law provides, "where an invention is developed relying on genetic resources, the applicant shall indicate, in the application documents, the direct and original sources of such genetic resources; where the applicant fails to indicate the original source, he or she shall state the reasons thereof."[86] This provision requires an applicant to describe the source of genetic resources.

Article 5.2 and Article 26.5 serve to protect genetic resources and prevent biopiracy by requiring applicants to disclose the source of the genetic resources used in their inventions and ensuring that patents are not granted if the acquisition or utilization of genetic resources violates the law or administrative regulations.[87] By requiring disclosure of the original sources of genetic resources, these provisions help ensure transparency and accountability in the patenting

[83] China Patent Law, *supra* note 10, art. 5, 26.
[84] *Id.*
[85] *Id.*
[86] *Id.*
[87] China Patent Examination Guidelines, *supra* note 11, at Part 2, Chapter 1, § 3.2.

process and promote the fair and equitable sharing of benefits arising from using genetic resources. China has also established various administrative measures and legal frameworks to strengthen the protection of its genetic resources, such as the National Catalogue of Biological Genetic Resources and the Regulations on the Administration of the Import and Export of Endangered Species. These measures and frameworks are designed to promote the sustainable use and protection of China's genetic resources while also ensuring that the benefits derived from these resources are shared equitably with the country or region of origin.

Thus, despite the absence of a comprehensive international agreement addressing biopiracy and genetic resource protection, China has taken proactive steps to incorporate clauses in its patent law, which align with the principles of the TRIPS Agreement and the CBD. China's efforts reflect its determination to safeguard its genetic resources and associated traditional knowledge while promoting responsible and sustainable use of these valuable assets.

According to Article 2 of the CBD, genetic resources refer to genetic material of actual or potential value, whereas genetic material means any material of plant, animal, microbial, or other origin containing functional units of heredity.[88] In contrast, the "genetic resources" in China Patent Law mean the material obtained from a human body, animal, plant, or microorganism that contains functional units of heredity and is of actual or potential value.[89] The "functional units of heredity" mean genes or DNA/RNA fragments with genetic functions.[90] Thus, the scope of "genetic resources" in China's patent law is broader than in the CBD as it encompasses the human body.

[88] Convention on Biological Diversity, June 5, 1992, 1760 U.N.T.S. 79, 143; 31 I.L.M. 818 (1992), https://www.cbd.int/convention/articles/?a=cbd-02 [https://perma.cc/27LE-RFPY].
[89] China Patent Examination Guidelines, *supra* note 11, pt. 2, ch. 1, § 3.2.
[90] *Id.*

B. Unrestricted Access Approach in the U.S.

The U.S. is not a party to the CBD and the Nagoya Protocol.[91] The U.S. has historically recognized that genetic resources are a heritage of humankind and, consequently, should be accessible without restriction.[92] This stance might be rooted in the belief that unrestricted access to genetic resources promotes innovation and scientific advancement.

As a developed country, the U.S. has robust pharmaceutical industries. The potential impact of the CBD on the U.S.' commercial interests has raised concerns. U.S. biotech companies are concerned about the potential mandate to share their intellectual property rights associated with genetic resources with other countries.[93] The U.S. has argued that technology access and transfer under the CBD must be consistent with the adequate and effective protection of intellectual property rights.[94]

There are widespread concerns that joining the CBD would entail greater responsibilities to assist poorer nations and safeguard their natural resources, which could strain the U.S.' resources.[95] Furthermore, there are some concerns that joining the CBD would lead to more environmental regulations in the U.S.[96] Despite this need to balance its commercial and environmental protection interests, the U.S. has actively

---

[91] Convention on Biological Diversity, *List of parties*, https://www.cbd.int/information/parties.shtml. [https://perma.cc/ZW8G-7T8A]
[92] Kuei-Jung Ni, *Legal Aspects of Prior Informed Consent on Access to Genetic Resources: An Analysis of Global Lawmaking and Local Implementation Toward an Optimal Normative Construction*, 42 VAND. J. TRANSNAT'L L. 227, 229 (2021); U.N. Food & Agricultural Organization [F.A.O.] Conference, 22nd Session, Nov. 23, 1983, International Undertaking on Plant Genetic Resources, art. 1, F.A.O. Conference Res. 8/83, U.N. Doc. C/83JRep., available at https://www.fao.org/3/aj370e/aj370e.pdf [https://perma.cc/4YWZ-LR6V] [hereinafter Undertaking].
[93] Benji Jones, *Why the US Won't Join the Single Most Important Treaty to Protect Nature*, Vox (May 20, 2021, 10:00 am), https://www.vox.com/22434172/us-cbd-treaty-biological-diversity-nature-conservation [https://perma.cc/R27J-NBLA].
[94] Robert F. Blomquist, *Ratification Resisted: Understanding America's Response to the Convention on Biological Diversity, 1989-2002*, 32 GOLDEN GATE U. L. REV. 493, 537 (2002).
[95] Jones*, supra* note 93*.*
[96] *Id*.

participated in the efforts of the CBD and strongly supports the convention's objectives.[97] This suggests that while the U.S. has reservations about specific provisions of the CBD, it recognizes the importance of international cooperation in conserving biodiversity and achieving sustainable development.

VI. HUMAN STEM CELLS

Human stem cells have been the subject of controversy regarding their eligibility for patent.[98] Human stem cells can differentiate into many different cell types and be used for various medical treatments. However, the issue with stem cells is that they are often derived from human embryos, raising ethical concerns.[99] This has led to restrictions on the patentability of certain types of stem cells, particularly human embryonic stem cells.[100]

Human stem cells include three primary categories: human embryonic stem cells (hESCs), induced pluripotent stem cells (iPSCs), and human parthenogenetic stem cells (hpSCs). hESCs are derived from the inner cell mass of blastocyst-stage embryos and exhibit unlimited proliferation ability and pluripotency to differentiate into the three primordial germ layers (ectoderm, mesoderm, and endoderm) and then develop into any human tissue (excluding the placenta).[101] The hESCs also have the totipotency of induced differentiation *in vitro* and *in vivo*, which brings about the possibility of addressing diseases that cannot be cured with

---

[97] Jesse Walter, *Explanation of Position for the Adoption of the Implementation of the Convention on Biological Diversity and its Contribution to Sustainable Development Resolution*, United States Mission to the United Nations (November 23, 2021), https://usun.usmission.gov/explanation-of-position-for-the-adoption-of-the-implementation-of-the-convention-on-biological-diversity-and-its-contribution-to-sustainable/ [https://perma.cc/Y5VY-Z9Q5].

[98] Kathleen Doody, *The Moral, Ethical, and Legal Controversy Surrounding Pluripotent Stem Cell Research*, 48 LOY. L. REV. 267 (2002).

[99] Bernard Lo & Lindsay Parham, *Ethical Issues in Stem Cell Research*, 30 ENDOCRINE REVS. 204 (2009).

[100] Jiajv Chen & Wei Li, *Rethink the Patentability of Human Embryonic Stem Cell Research Findings: Relaxation Based on Benefit Weighing*, 16 STEM CELL REPS., 1868–73 (2021).

[101] Antonio Romito & Gilda Cobellis, *Pluripotent Stem Cells: Current Understanding and Future Directions*, 2016 STEM CELLS INT., 1–20 (2016).

traditional medical techniques and repairing damaged and aged organs.[102] iPSCs are created without the destruction of human embryos, and they are derived directly from adult somatic cells by reprogramming them into a pluripotent state.[103] hpSCs are formed by parthenogenesis (e.g., by chemically stimulating unfertilized oocytes), which also does not involve the destruction of human embryos.[104]

On one end, human stem cells are of significant commercial and academic interest because they can potentially be used to treat many diseases that do not have a cure or other viable treatment.[105] Treatment of Parkinson's disease is one example.[106] On the other end, instrumentalization and commercialization of human stem cells raise significant legal, moral, and cultural challenges, not only about the innate value of human life but also about the potential diminution of the status of the embryo, oocyte, and human tissues. For example, hESCs encountered ethical concerns because their generation may destroy an embryo.[107]

As will be discussed in the following section, each of these types of stem cells have unique legal and ethical considerations regarding patent eligibility.[108] hESCs are the most ethically controversial of all stem cells because of the special moral and cultural significance attached to the human embryo.[109]

A. The Social Morality Approach in China

According to Article 5.1 of China Patent Law, the human body at any stage of formation or development,

---

[102] Chen & Li, *supra* note 100, at 1868.
[103] Sonya Davey et. al., *Interfacing of Science, Medicine and Law: The Stem Cell Patent Controversy in the United States and the European Union*, 3 FRONT CELL DEV BIOL. 1 (2015).
[104] *Id* at 1.
[105] Fiona M. Watt & Ryan R. Driskell, *The Therapeutic Potential of Stem Cells*, 365 PHIL. TRANSACTIONS ROYAL SOC'Y B 155 (2010).
[106] Mohamed A Zayed et. al., *Stem-Cell-Based Therapy: The Celestial Weapon against Neurological Disorders*, 11 CELLS 3476 (2022).
[107] Lo & Parham, *supra* note 99.
[108] Davey, et al., *supra* note 103, at 1.
[109] Lo & Parham, *supra* note 99.

including human reproductive cells, fertilized eggs, embryos, and individuals, is not patentable subject matter.[110] However, this provision does not articulate whether stem cells obtained from human embryos are considered patentable under China Patent Law.

Confucianism is deeply ingrained in Chinese society, shaping many aspects of Chinese philosophy, ethics, and social values. Confucianism can be described as a humanistic philosophy or attitude that underscores the intrinsic value and significance of human beings. It greatly emphasizes moral values, social harmony, and the cultivation of virtues. Thus, the moral concern for human life underlies China's current legal and ethical frameworks.

China's ethical concerns regarding human stem cells have arisen from issues such as human cloning and potential harm to human genetic consistency.[111] These concerns are rooted in the cultural belief in the value of human life and the preservation of human dignity. China's cultural values, including those influenced by Confucianism, emphasize the importance of human dignity and value. This cultural perspective underscores the need to protect the integrity and uniqueness of human genetic material. As such, China refused to authorize the use of these commercial hESCs at the early stage. [112] In 2001, China National Intellectual Property Administration (CNIPA) declined to grant a patent to a method of preparing embryoid from primary hESCs (No. 22325) filed by the Wisconsin Alumni Research Foundation on the grounds that extraction of hESCs would inevitably damage the embryos, although the applicant indicated that the cultured hESCs came from commercial lines.[113]

However, the patentability of hESCs has been subject to dynamic adjustment based on benefit weighing and the conception of human beings. A series of adjudication rules are being established, but China has adopted the civil law system,

[110] China Patent Law, *supra* note 10, art. 5.
[111] Chen & Li, *supra* note 100, at 1869.
[112] *Id.* at 1871.
[113] *Id.*

and the precedents in the examination practices are of reference value only.[114] China's stance on this matter was not clearly defined until the publication of revised Guidelines for Patent Examination in 2020, which reflected changes in the definition of "human beings."[115]

Embryological studies have shown that embryonic primordial chordate striations emerge after fourteen days of development and subsequently differentiate into various tissues and organs.[116] This stage marks the formation of the human body with a definite body plan, indicating the beginning of the human individual.[117] Thereby, the Australian philosopher Norman Ford argues that human beings in the real sense do not exist until the fourteenth day after the germ cell forms.[118] China eventually adopted this definition of human beings. This new understanding of human beings provides policy support for revising the patentability of hESC-related inventions, thus establishing a foundation for developing stem cell biotechnologies in China.[119]

The 2020 Examination Guidelines introduced several important revisions regarding the patentability of stem cells.[120] In *Part II, Chapter 1, Section 3.1.2 Inventions and creations in violation of the law*, the following is added: "[h]owever, if an invention involves the separation or extraction of stem cells from a human embryo that is within 14 days of fertilization and has not undergone in vivo development, it should not be rejected solely on the grounds of violating social morality."[121]

Furthermore, "industrial or commercial application of human embryos" is explicitly excluded from subject matter

---

[114] Xuekai Xie et. al., *From Strict Moral Standards to Ethical Neutrality: a Policy-Guided Shift in the Patentability of Human Embryonic Stem Cells in China*, 11 STEM CELL RSCH. & THERAPY 1, 6 (2020).
[115] *Id.*
[116] Chen & Li, *supra* note 100, at 1868.
[117] *Id.*
[118] Michael J. Coughlan, *When Did I Begin? Conception of the Human Individual in History, Philosophy and Science by Norman M. Ford*, 3 BIOETHICS 333 (1989).
[119] Chen & Li, *supra* note 100, at 1872.
[120] *Id.*
[121] *Id.*

eligibility as seen in *Part II, Chapter 1, Section 3.1.2*.[122] This new exclusion clarifies that inventions involving stem cells derived from human embryos over fourteen days of fertilization or that have undergone *in vivo* development are not considered patentable due to violating social morality.[123]

In *Part II, Chapter 10, Section 9.1.1 Examination of Subject Matter According to Article 5*, the following deletions and insertions have been made to the guidelines:

> ~~9.1.1.1 Human embryonic stem cells~~
> ~~No patent shall be granted for human embryonic stem cells or a preparation method thereof in accordance with the provision of Article 5.1.~~
> 9.1.1.21 Human Body at any Stage of Formation or Development
> Human body at any stage of formation or development, including human reproductive cells, fertilized eggs, embryos, and individuals, falls under the patent-ineligible inventions under Article 5.1. Human embryonic stem cells are not human bodies at any stage of formation or development. [124]

These revisions confirm the legitimacy of patenting hESCs obtained from a human embryo that is within fourteen days of fertilization and that has not undergone *in vivo* development. In addition, stem cells further derived or obtained from these hESCs are no longer considered a violation of morality. This ends the previous practice of tracing the source of hESCs to determine their patent eligibility.[125]

---

[122] *Id.*
[123] *Id.*
[124] Liaoteng Wang et. al., *A Comparative Look at Patent Subject Matter Eligibility Standards: China Versus the United States*, IPWATCHDOG, (Jun. 12, 2020, 07:15 AM), https://ipwatchdog.com/2020/06/12/comparative-look-patent-subject-matter-eligibility-standards-china-versus-united-states/id=122339/#:~:text=Section%20101%2C%20Chinese%20Patent%20Law,5.1%2C%20and%20a%20number%20of [https://perma.cc/K9DF-HU4X].
[125] Chen & Li, *supra* note 100, at 1872.

B. The Alice/Mayo Test Approach in the U.S.

In contrast, the U.S. Patent Act does not impose a morality-based barrier to patenting human stem cells.[126] Instead, U.S. Patent Law adopts a different approach by disregarding *ordre public* or morality and focusing instead on excluding the judicially created exceptions: laws of nature, natural phenomena, and abstract ideas.[127] Laws of nature and natural phenomena, as identified by the courts, include naturally occurring principles/relations and nature-based products that are naturally occurring or that do not have markedly different characteristics compared to what occurs in nature.[128]

In 1998, the University of Wisconsin's Wisconsin Alumni Research Foundation (WARF) obtained the first patent for hESCs in the U.S. (U.S. patent number 05843780).[129] WARF received two additional U.S. stem cell patents between 1998 and 2006.[130] However, when WARF attempted to patent hESCs in Europe, the European Patent Office rejected the patent applications based on moral grounds.[131] Unlike the U.S., where morality is not explicitly considered in the patent examination process, Europe incorporates moral considerations into its patent examinations.[132]

The ethical concerns surrounding the eligibility of embryonic stem cells for patents have not been the primary focus in the U.S. Instead, the opposition has centered around

---

[126] Jacob S. Sherkow & Christopher T. Scott, *Stem Cell Patents and the America Invents Act*, 16 CELL STEM CELL 461 (2015).
[127] Diamond v. Diehr, 450 U.S. 175, 185 (1981).
[128] U.S. PATENT & TRADEMARK OFFICE, MPEP § 2106.04(b) (9th ed. February 2023).
[129] Primate Embryonic Stem Cells, U.S. Patent No. 5,843,780, (December 1, 1998).
[130] Stephen Kintz, *Stem Cell Monopoly: The Debate Over Wisconsin Alumni Research Foundation's Stem Cell Patents*, PATEXIA (May 13, 2012), https://services.patexia.com/feed/stem-cell-monopoly-the-debate-over-wisconsin-alumni-research-foundation-s-stem-cell-patents [https://perma.cc/P5US-NL3U].
[131] Jenny Shum, *Moral Disharmony: Human Embryonic Stem Cell Patent Laws, Warf, and Public Policy*, 33 B.C. INT'L & COMPAR. L. REV. 153, 156 (2010).
[132] David B Resnik, *Embryonic Stem Cell Patents and Human Dignity*, 15 HEALTH CARE ANALYSIS 211 (2007).

the monopoly created by the broad scope of the patents.[133] The patents held by WARF grant exclusive rights that cover both the stem cells themselves and the methods for generating these cells.[134] As a result, WARF effectively gained a monopoly over all primate embryonic stem cells within the U.S.[135]

In 2013, Consumer Watchdog (CW) filed an appeal with the U.S. Court of Appeals for the Federal Circuit against one of WARF's embryonic stem cell patents.[136] CW referenced the June 2013 U.S. Supreme Court ruling in *Association for Molecular Pathology v. Myriad Genetics*, which concluded that human genes cannot be patented because they are considered a "product of nature."[137] CW contended that hESC culture falls within this "product of nature" exception.[138]

However, in 2014, the Court of Appeals for the Federal Circuit dismissed CW's appeal on the grounds of lack of proper standing, as CW failed to demonstrate any specific "injury in fact" resulting from the patents.[139] The Federal Circuit in this appeal did not address the patentability issues of the WARF patents, leaving uncertainty regarding future disputes over the patentability of stem cells.[140]

Nevertheless, the fate of hESC patents remains uncertain, and there is an ongoing risk of stem cells becoming ineligible for patent protection. The significant changes in the legal landscape may shape how future issues get decided in the U.S. The debates surrounding stem cells will likely center

---

[133] Maryn Wilcoxson, *A Lesson Learned from Myriad: The Affordable Care Act as both an Incentive and an Alternative for Invalidating Stem Cell Patents*, 48 IND. L. REV. 723, 743 (2015).
[134] *Id.* at 738–39.
[135] Maureen L. Condic & Mahendra Rao, *Alternative Sources of Pluripotent Stem Cells: Ethical and Scientific Issues Revisited,* 19 STEM CELLS & DEV. 1121 (2010).
[136] Consumer Watchdog v. Wis. Alumni Rsch. Found., 753 F.3d 1258, 1260 (Fed. Cir. 2014).
[137] Ren-How Harn, *Keeping the Gates Open for Human Embryonic Stem Cell Research*, 13 CARDOZO PUB. L. POL'Y & ETHICS J. 525, 534.
[138] *Id.* at 540–41.
[139] *Consumer Watchdog*, 753 F.3d at 1260–61.
[140] *Id.*

around the comparisons between original and cultured stem cells.

C. Human Stem Cells vs. Human Organisms

The America Invents Act (AIA), passed in September 2011, specifically excludes human organisms from patentable subject matter.[141] However, the AIA does not define the term "human organism."[142] As a result, it does not explicitly address whether "human stem cells" are considered part of the category of "human organisms."

The legislative history of AIA contains a testimony that acknowledges the prior issuance of patents on stem cells by the U.S. Patent Office.[143] This testimony clarifies that the proposed exclusion aimed to prohibit claims directed to human organisms, including human embryos and fetuses.[144]

However, if the U.S. Supreme Court were to construe "human stem cells" as falling within the category of "human organisms" in the future, the resulting implication would be that human stem cells could no longer qualify as patentable subject matter.[145]

D. "Product of Nature" Exception

The Supreme Court's decisions in *Association for Molecular Pathology v. Myriad Genetics, Inc.*[146] and *Ariosa Diagnostics, Inc. v. Sequenom, Inc*.[147] have significantly

---

[141] Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, § 33(a), 125 Stat. 284, 340 (2011).
[142] Davey, et al., *supra* note 103, at 3.
[143] 157 CONG. REC. 1179 (2011) (testimony of Rep. Dave Weldon previously presented in connection with the Consolidated Appropriations Act, Pub. L. No. 108-199, § 634, 118 Stat. 3, 101 (2004), and later resubmitted with regard to the AIA); *see* 149 CONG. REC. 2417 (2003) ("[T]he U.S. Patent Office has already issued patents on genes, stems cells, animals with human genes, and a host of non-biologic products used by humans, but it has not issued patents on claims directed to human organisms, including human embryos and fetuses. My amendment would not affect the former, but would simply affirm the latter.").
[144] *Id.*
[145] Davey, et al., *supra* note 103, at 3.
[146] Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013).
[147] Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371 (Fed. Cir. 2015).

impacted the eligibility of biological subject matter in the U.S. These decisions expanded the "product of nature" exception, thereby imposing limitations on the scope of what can be patented for biological subject matters.

In the *Myriad* case, the Supreme Court ruled that a naturally occurring DNA segment is a product of nature and not patent-eligible merely because it has been isolated from the rest of the human genome.[148] According to the *Myriad* decision, "isolated DNA has been cleaved (*i.e.*, had covalent bonds in its backbone chemically severed) or synthesized to consist of just a fraction of a naturally occurring DNA molecule."[149] Thus, the *Myriad* decision may imply that if a stem cell is isolated from the human embryo, it is likely not eligible for patent protection. Similarly, if a synthetic stem cell, such as iPSCs, closely resembles a naturally occurring human embryonic cell or lacks markedly different characteristics from those found in nature, it would also not be considered patent-eligible.

The *Myriad* decision seems to undermine the patent eligibility of hESCs since isolated and purified hESCs may be substantially identical to those found in human blastocysts.[150] This contention resonates with those who oppose patenting any part of the human body or interfering in the natural processes of human development.

E. "Law of Nature" Exception

Another significant issue arises regarding the patentability of methods involving human stem cells for diagnosing and treating diseases, as they often involve the law of nature. A notable example of this is the case of *Sequenom*.[151] Sequenom is the exclusive licensee of U.S. Patent No. 6,258,540, which claims priority to GB9704444 filed on March 4, 1997, by Oxford University Isis Innovation

[148] *Ass'n for Molecular Pathology*, 569 U.S. at 576.
[149] *Id.* at 587.
[150] *See id.*
[151] *Sequenom*, 788 F.3d at 1376–77.

Ltd.[152] The patent describes a method of using cell-free fetal DNA (cffDNA) in maternal plasma and serum (cell-free blood) to diagnose fetal abnormalities. cffDNA is naturally occurring extracellular fetal DNA that circulates in the bloodstream of pregnant women.[153] Claim 1 at issue states the following:

> A method for detecting a paternally inherited nucleic acid of fetal origin performed on a maternal serum or plasma sample from a pregnant female, which method comprises amplifying a paternally inherited nucleic acid from the serum or plasma sample and detecting the presence of a paternally inherited nucleic acid of fetal origin in the sample.[154]

In the U.S., a method claim is generally patentable if the composition of matter in the claims is patent-eligible, novel, and non-obvious or if the method steps are novel and non-obvious. However, in the *Sequenom* case, the U.S. Court of Appeals for the Federal Circuit decided that cffDNA was not patent-eligible, and the claimed method steps were obvious.[155]

While recognizing the significance of the *Sequenom* claims as a scientific breakthrough, the U.S. Court of Appeals for the Federal Circuit invalidated Sequenom Inc.'s patent on the grounds that the claim at issue merely applied newly discovered natural laws and phenomena in routine or conventional ways.[156] The court determined that cffDNA is a natural phenomenon and, as such, ineligible for patent protection.[157] It also concluded that the "applying" and "detecting" steps added only "well-understood, routine, and conventional activity" to the natural phenomenon because researchers were already familiar with and capable of performing the individual steps of fractionating blood, amplifying DNA, and detecting characteristics in amplified

[152] U.S. Patent No. 6,258,540 (issued July 10, 2001).
[153] *Sequenom*, 788 F.3d at 1376.
[154] *Id.* at 1373–74.
[155] Davey, et al., *supra* note 103, at 4.
[156] *Id.*; *Sequenom*, 788 F.3d at 1379–80.
[157] *Sequenom*, 788 F.3d at 1376.

DNA before the patent filing.[158] These routine and well-understood methods were insufficient to transform the claimed subject matter into a patentable application.[159]

Furthermore, there are concerns surrounding undue preemption, which refers to the fear that granting broad patents without appropriate limitations may foreclose future innovative applications by others.[160] Granting overly broad patents that cover basic building blocks of technology—abstract ideas, naturally occurring phenomena, and natural laws—might deter other researchers and companies from exploring potential novel applications or improvements in the field. This could stifle competition, hinder scientific progress, and limit the overall benefits that society can derive from these discoveries.

F. The Alice/Mayo Framework

The United States Patent and Trademark Office uses the Alice/Mayo Framework to determine subject matter eligibility for patent protection.[161] There are two criteria.[162] First, the claimed invention must fall into one of the four statutory categories.[163] Second, the claimed invention must not be directed to a judicial exception unless the claim as a whole includes additional limitations that amount to significantly more than the exception.[164]

The Alice/Mayo Framework is a two-step analysis.[165] Step 1 determines whether the claim is a process, machine, manufacture, or composition of matter, ensuring it meets the first criterion by falling within one of the four statutory categories. [166] Step 2, known as the Supreme Court's Alice/Mayo test, involves a two-part inquiry to identify claims

[158] *Id.* at 1377–78.
[159] Davey, et al., *supra* note 103, at 4.
[160] *Id.* at 1379.
[161] MPEP, *supra* note 128, § 2106.
[162] *Id.*
[163] *Id.*
[164] *Id.*
[165] *Id.*
[166] *Id.*

directed to a judicial exception (Step 2A) and then evaluate whether additional elements of the claim provide an inventive concept (Step 2B), also referred to as "significantly more" than the exception.[167] Steps 2A and 2B ensure the second criterion is met.[168]

In 2019, the United States Patent and Trademark Office revised Step 2A as a two-pronged inquiry.[169] The first prong "evaluate[s] whether the claim recites a judicial exception," while the second prong evaluates whether the exception is integrated into a practical application.[170]

The product of nature exception covers both naturally occurring products and those that do not have markedly different characteristics compared to what occurs in nature.[171] Therefore, isolated and chemically derived stem cells are prone to falling under the product of nature exception unless they exhibit markedly different characteristics in terms of structure, function, or other properties. Markedly different characteristics can be expressed through structural differences, functional characteristics, and other non-structural properties.[172] Various differences in structures, such as biological, pharmacological, physical, genetic, and chemical differences, can demonstrate markedly different characteristics.[173] Form or function can also provide markedly different characteristics.[174]

Interpreting what constitutes a marked difference remains challenging, particularly after *In re Roslin Institute*, where the U.S. Court of Appeals for the Federal Circuit ruled that differences resulting from environmental factors, uninfluenced by anyone's creative efforts, are not patentable.[175] Consequently, establishing markedly different

---

[167] *Id.*
[168] *Id.*
[169] 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50, 54 (Jan. 7, 2019).
[170] *Id.*
[171] MPEP, *supra* note 128, § 2106.04(b).
[172] *Id.* § 2106.04(c).
[173] *Id.*
[174] *Id.*
[175] In re Roslin Inst. (Edinburgh), 750 F.3d 1333, 1338 (Fed. Cir. 2014).

characteristics requires demonstrating differences that have arisen from the inventors' creative endeavors rather than occurring independently of their influence. Achieving this demonstration necessitates a thorough understanding of the stem cells' characteristics and molecular details. However, this requirement for additional scientifically unnecessary experimentation to showcase markedly different characteristics raises uncertainties, particularly considering the high cost of research and development in the field.

The fate of hESC and other human stem cell patents in the U.S. remains uncertain, as the outcome will depend on ongoing litigation and potential social movements.[176] Stem cell patent eligibility in the U.S. revolves around the competing interests of protecting innovation, promoting useful art, and safeguarding public welfare. This tension is evident in the legal landscape and debates surrounding hESC and other human stem cells. In contrast, stem cell patent eligibility in China revolves around similar competing interests of protecting innovation, promoting useful art, and safeguarding social morality. This suggests the possibility of convergence between the U.S. and China patent laws concerning stem cell patent eligibility.

VII. Future Potential Harmonization Between China and U.S. Patent Law Relating to Patent Eligibility of Biological Subject Matters Through Compulsory Licensing

The differences between China and the U.S.'s patent laws highlight their contrasting approaches to balancing culture and property rights. The U.S., where property rights are prominent in its culture, highly values patent rights. On the other hand, China's culture, deeply rooted in Confucianism, Taoism, and Buddhism, requires consideration of ethics and customs in their approach.

However, culture, ethics, and customs have been evolving in China along with its economic development. In China, while animal and plant varieties may not be eligible for patent protection under its patent law, recent developments

[176] Davey, et al., *supra* note 103, at 4.

have introduced alternative avenues for their protection.[177] These developments recognize the significance of incentivizing research and development in new animal and plant varieties. For instance, new plant varieties can find protection under the Regulations on the Protection of New Plant Varieties in China, while new animal varieties can find protection under the Animal Husbandry Law.[178] Furthermore, China has allowed the legality of genetically modified plants and animals.[179]

Nevertheless, these alternative protections do not confer the same exclusivity rights as patents.[180] Consequently, they may not provide sufficient incentive for companies to invest in the development of genetically modified animals and plants within the industry.[181] The process of developing and commercializing genetically modified organisms typically requires significant financial investment and involves inherent risks and uncertainties.[182] The absence of comprehensive patent-like protection may discourage companies from fully engaging in these sectors.[183]

Additionally, methods of treating and diagnosing human and animal diseases are not eligible for patenting in China.[184] As a result, inventors and companies may opt to keep these methods as trade secrets for economic gain rather than sharing valuable information with peers and the public. This practice of safeguarding trade secrets can limit the dissemination of knowledge and advancements in the medical field. Furthermore, hospitals often compete with one another to attract patients by offering new diagnoses and treatment

[177] Geng, *supra* note 43, at 476, 483.
[178]中华人民共和国畜牧法 (Zhonghua Renming Gongheguo xumu hua) [Animal Husbandry Law of the People's Republic of China], (China's National People's Congress Standing Committee, effective 2022), Chapter 2, http://www.gov.cn/xinwen/2022-10/30/content_5722639.htm [https://perma.cc/464T-AJQQ].
[179] Jingang Liang et. al., *The Evolution of China's Regulation of Agricultural Biotechnology*, 3 aBIOTECH 237 (2022).
[180] Geng, *supra* note 43, at 477.
[181] *Id.*
[182] *Id.* at 468–72.
[183] *Id.* at 480–83.
[184] China Patent Examination Guidelines, *supra* note 11, Part 2, ch. 1, § 4.3.

methods. However, maintaining these methods as trade secrets can limit patients' access to the most recent advances in treatments and diagnostic methods. This, in turn, has the potential to hinder the progress of medical innovation and negatively impact patients' overall well-being.

Patents play a vital role in fostering technological innovation. They accomplish this by incentivizing individuals who make novel contributions in their respective fields through the promise of a monopoly that can yield financial benefits for the patent owner. Simultaneously, patent laws require inventors to share their invention disclosure with the public, ensuring that society as a whole benefits from technological innovation and progress. This dual purpose of patents—rewarding inventors while promoting widespread dissemination of knowledge—drives advancements and enables collective growth in various sectors.

China has made substantial investments in medical methods and genetic engineering to elevate its biotechnology industry on par with developed countries. [185] These investments demonstrate China's dedication to advancing scientific research, fostering innovation, and driving technological development within the medical and biotechnology industry.

In September 2021, China released the Outline to Boost China's Competitiveness in the Area of Intellectual Property for the next fifteen years. [186] This document outlines China's goal of establishing an intellectual property protection system that supports a world-class business environment, promotes an IP market operation mechanism conducive to

[185] ZHIHUA XIAO & WILLIAM A. KERR, *Biotechnology in China – Regulation, Investment, and Delayed Commercialization*, 13 GM CROPS & FOOD 88 (2022); *see also* Scott Moore, *China's Role in the Global Biotechnology Sector and Implications for U.S. Policy*, GLOBAL CHINA, https://www.brookings.edu/wp-content/uploads/2020/04/FP_20200427_china_biotechnology_moore.pdf [https://perma.cc/4S92-5SR2].

[186] *Goals Set for the Next 15 Years: The Outline to Boost China's Competitiveness in the Area of Intellectual Property (2021-2035)*, China National Intellectual Property Administration (CNIPA) Annual Report 2021, https://english.cnipa.gov.cn/module/download/down.jsp?i_ID=176465&colID=2936 [https://perma.cc/4GPF-FDLQ].

innovation-driven development, and cultivates a favorable cultural and social environment for the high-quality development of intellectual property by 2035.[187]

Thus, as China continues to progress, it might be essential to reevaluate and reassess its patent laws in response to evolving societal needs, advancements in medical research and genetic engineering, and the development of international trade. Balancing the preservation of cultural values and promoting innovation will be key considerations for China's future patent law reforms to achieve the goals in the Outline.

In this regard, considering the possibility of allowing the patenting of methods for treating and diagnosing diseases, as well as genetically modified plants and animals, could be an option for future reforms of the China Patent Law.

However, it is important to acknowledge the potential drawbacks of patent rights, as they inherently grant a monopoly to the patent holder. This can lead to higher prices and reduced affordability for accessing new inventions.[188] Moreover, exclusive patent rights for plant and animal varieties can impede access to these resources and run counter to the communal nature of Chinese culture.[189]

One potential solution to address these ethnic, cultural, and accessibility concerns is by implementing compulsory licensing when voluntary licensing is not available or is inadequate. Compulsory licensing allows a government or authorized entity to grant licenses for the use of a patented invention without the explicit consent of the patent holder.

Compulsory licensing can serve as a valuable tool to mitigate the negative impacts of patent monopolies by allowing for the licensing of patented technologies in specific

---

[187] *Id.*
[188] Kishore Khan, *Striking a Balance in Compulsory License Legislation*, 5 GEO. MASON J. INT'L COM. L. 221, 223 (2014).
[189] Geng, *supra* note 43, at 485–86.

circumstances, ensuring wider access and affordability.[190] By introducing compulsory licensing provisions tailored to medical treatment and diagnosis methods, genetically engineered animals and plants, genetic resources, and human stem cells, countries can uphold the respect for cultural values, ensure accessibility to innovations, and promote a more equitable sharing of the benefits derived from technology. It fosters an environment that encourages collaboration, knowledge exchange, and responsible innovation, benefiting society and the economy.

Compulsory licensing can address specific concerns about plant and animal-related technologies, especially in developing countries where food is a significant concern. By enabling local researchers, breeders, and farmers to utilize patented inventions at reasonable costs, compulsory licensing facilitates technology transfer, enhances food security, and supports economic development. This approach fosters a more inclusive and sustainable agricultural sector, by promoting equitable access to essential innovations, driving agricultural progress, and bolstering the livelihoods of farmers and communities alike.

It is also essential to strike a balance between the interests of patent holders and the broader public interest. Implementing compulsory licensing provisions for medical methods, plant, animal, genetic resource, or stem cell patents should involve transparent and fair mechanisms for determining reasonable compensation to patent holders, encouraging innovation, and addressing any potential adverse effects on investment and incentives for research and development.[191]

To effectively harmonize biological subject matters through compulsory licensing, international cooperation and harmonization efforts might also be crucial. Article 31 of the TRIPS Agreement permits compulsory licensing.[192] However,

---

[190] Cynthia M. Ho, *Patent Breaking or Balancing?: Separating Strands of Fact from Fiction Under TRIPS*, 34 N.C. J. INT'L. L. & COM. REGUL. 371, 379 (2009).
[191] *Id.* at 407–10; Khan, *supra* note 188, at 258.
[192] TRIPS Agreement, *supra* note 2, art. 31; Ho, *supra* note 78, at 491.

it requires that licensees have made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period. Nevertheless, the TRIPS Agreement can provide frameworks for discussions, negotiations, and the development of common standards and guidelines for compulsory licensing of plant and animal patents. [193] By embracing international cooperation and carefully designing compulsory licensing provisions, China may create an equitable and sustainable system for protecting its biological resources and inventions.

By navigating these factors thoughtfully, China may develop patent laws that harmonize with its rich cultural heritage while fostering innovation, safeguarding public interests, and promoting international trade.

VIII. CONCLUSION

Disharmonies in intellectual property rights allow countries to explore and discover a balanced approach that protects inventions while accommodating their unique cultures, customs, and economic circumstances. As evidenced by the comparison between China and the U.S., each country has implemented patent laws tailored to its specific context, values, and goals, while also complying with its international treaties.

China's exclusion of treatment and diagnosis methods from patent protection emphasizes the importance of accessibility to healthcare and collective well-being, promoting affordable options and preventing hindrance by patent monopolies. On the other hand, the U.S.'s allowance of patentability for these methods encourages medical innovation and provides incentives for research and development.

Similarly, China's exclusion of animal and plant patentability is influenced by a complex interplay of cultural, customary, and developmental perspectives, prioritizing

[193] Geng, *supra* note 43, at 478–79.

reverence for nature, traditional agricultural practices, and food security. While this may limit certain commercial opportunities, it underscores the importance of preserving cultural heritage, promoting shared benefits, and safeguarding access to genetic resources.

The protection of genetic resources poses a complex global issue, requiring a balance between promoting innovation and safeguarding biological diversity and traditional knowledge. China's proactive incorporation of clauses in its patent law to align with the CBD principles showcases its commitment to protecting genetic resources while ensuring equitable sharing of benefits. Conversely, the U.S., while not a party to the CBD, prioritizes unrestricted access to genetic resources, presenting its own challenges in international cooperation.

China's approach to human stem cell patentability, shaped by Confucian cultural values, prioritizes human dignity and genetic integrity, leading to strict regulations protecting human embryos. In contrast, the U.S. focuses on excluding judicially created exceptions, resulting in the granting of patents for human embryonic stem cells. Both approaches encounter unique challenges, with China's cultural emphasis potentially limiting scientific research and advancements, while the U.S. approach raises concerns about broad patents hindering future innovations.

As cultures and customs evolve with economic development, it becomes essential for China to continually assess and adapt its patent laws, striking a balance between cultural values, societal needs, and technological progress. This will ensure that China's approach to biological subject matter eligibility remains responsive to the changing demands of society, promoting an environment where innovation and progress can flourish in harmony with its cultures and customs.

A promising avenue to achieve this balance is by harmonizing eligibility of biological subject matters through compulsory licensing when voluntary licensing is not feasible or falls short. This avenue holds the potential to preserve

community cultural values, encourage knowledge sharing, and ensure the affordability and widespread availability of essential technologies while fostering innovation. Additionally, it can help streamline international trade, encourage cross-border trade and investment, and promote economic integration and cooperation.

ACKNOWLEDGMENT

This paper was derived from a study conducted to fulfill the course requirements of International and Comparative IP Law instructed by Professor Jay Erstling. The author received guidance from Professor Erstling during the preparation process.