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The Negative Impact of Intellectual Property Protection on Vaccine Accessibility

• **Abstract** •

This article examines the tension between intellectual property protection and vaccine accessibility, demonstrating how patent law and trade secret regimes impede equitable access to vaccines as global public goods. Through analysis of international legal frameworks and recent pandemic case studies (Ebola, Zika, COVID-19), the research reveals that stringent IP protections create monopolistic pricing, suppress competition, and enable concealment of critical health information. While acknowledging patents' role in incentivizing innovation, the article argues that uniform twenty-year patent terms and indefinite trade secret protection contradict vaccines' essential social function. The study proposes reforms including investment-proportional patent durations, excluding vaccines from trade secret protection, implementing price controls, and establishing state subsidy programs. The article concludes that balancing innovation incentives with universal health access requires reconceptualizing vaccines as social goods requiring specialized legal regimes that prioritize fundamental human rights over commercial interests.

Keywords: Vaccine Patents, Intellectual Property Law, Right to Health, Global Public Goods, Health Equity.

Introduction

In legal doctrine, vaccines are recognized as "Global Common Goods" or "Global Public Goods", with ensuring equitable access thereto constituting a universal human interest (Boschiero, 2022, pp. 180–210). This characterization stems from the direct nexus between vaccine accessibility and the fundamental rights to health and life, as vaccines fortify human immunity against disease, impede

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disease transmission, or, in certain instances, effectuate complete recovery from illness.[1] Human rights and patent or trade secret law intersect at a critical juncture, as they represent conflicting interests.[2] For instance, pharmaceutical companies, in consideration of their invested expenditures and time, possess the legal prerogative to protect their innovations—a prerogative they exercise through intellectual property protection mechanisms: patents and trade secret protection "Medical Patents and the Right to Health—from Monopoly Control to Open Access Innovation and Provision of Medicines" (Cullet and Yuanquiong, 2018, pp. 5–29). Legal protection of innovations typically materializes through information confidentiality, monopolistic pricing structures, and analogous measures. Conversely, individuals possess a fundamental right to accessible healthcare, while states bear positive obligations to respect, protect, and ensure access to the right to health (WHO, 2008, pp. 3–11). Consequently, it is manifest that protecting vaccines under the aegis of intellectual property law engenders manifold ethical, moral, and legal dilemmas. Therefore, this article evaluates the merits and demerits of protection mechanisms for vaccines as objects of intellectual property law, which exert tangible influence on both public interests and private interests in practice.

Protection Mechanisms for Vaccines as Objects of Intellectual Property Law

Intellectual property law enables individuals to legally appropriate and protect products created through intellectual labour and cognitive application, including innovations—in this particular context, vaccines (Tikaradze, 2015, p. 117).

A vaccine denotes any biological preparation derived from living organisms that enhances immunity against disease and/or inhibits it (prophylactic vaccines) or, in certain cases, treats disease (therapeutic vaccines) (WHO, 2008, pp. 3–11). The designation and objective of every vaccine is singular—to attenuate the virus/bacteria such that the vaccine recipient can develop immunity without actual infection exposure (De Abrantes, 2016, p. 528). Precisely for this reason, free and universal access to vaccines as recognized global common goods is of paramount importance.

[1] Basic Concept of Vaccination available at http://www.phrma-jp.org/wordpress/wp-content/uploads/old/library/vaccine-factbook_e/1_Basic_Concept_of_Vaccination.pdf, pp. 12–28.

[2] Ibid., pp. 19–20.

Vaccines, as sophisticated biopharmaceutical products, are typically subject to two principal intellectual property protection mechanisms (Gregersen, 1994, pp. 63–64). Patent protection and trade secret regimes—which, in conjunction, constitute a formidable multilayered security system. Additionally, supplementary protection regimes exist, encompassing regulatory data exclusivity, emergency authorizations, licensing arrangements, and IP sharing mechanisms (Cullet and Yuanquiong, 2018, pp. 5–29).

Vaccine Patents

Vaccines constitute innovations within the sphere of medical patents, to which—both in Georgia and globally—a standard of patent protection exclusion applies. For instance, Georgian law recognizes that patents shall not be granted for innovations pertaining to surgical, therapeutic, and diagnostic methods for treating humans and animals. This provision does not extend to devices and substances employed in such methods.[3] An analogous provision appears in the principal European patent instrument (European Patent Convention, EPC),[4] though unlike Georgian legislation, the EPC references exclusion not merely of treatment methods but of treatment modalities from patent protection. Unlike the EPC's stringent protection, the TRIPS Agreement grants member states the prerogative (rather than obligation) to exclude methods for treating humans and animals from patent protection, motivated by the recognition that this sphere constitutes "a matter of public interest." The United States maintains no statutory restriction regarding exclusion of medical patents from legal protection; however, a provision exempts physicians from legal liability arising from patent infringement, thereby limiting patent rights protection for medical methods.[5] Australia's patent legislation merits mention, as it is considered among common law jurisdictions the sole nation lacking statutory prohibition on medical patent issuance (Mitnovetski and Nicol, 2004, p. 476).

Notwithstanding the foregoing, it is acknowledged that vaccines as final products, along with their various constituent components, are subject to patent protection (De Abrantes, 2016, pp. 532–534).

[3] Article 17, paragraph 'b' of the Law of Georgia on Patents.
[4] Article 53(c) of the European Patent Convention.
[5] The United States Patent Act, 35 U.S.C. § 287(c).

The Problem of Vaccines as Patent Objects

Vaccines as patent objects are considerably complex and differ from other patent objects. Primarily, four vaccine types exist, and their types/varieties may influence patentability.[6] Furthermore, patents may be granted not solely for the final result (the vaccine itself) but also for its constituent elements (e.g. products used in vaccine preparation, vaccine application methods, DNA upon which the vaccine is based, creation methods, etc.). Consequently, a single vaccine as a final product may be subject to one or multiple patents (De Abrantes, 2016, pp. 532–534). The existence of multiple patents on a single vaccine naturally creates significant accessibility obstacles, as all measures necessary for licensing patent-protected vaccines must be undertaken twice or more, increasing both costs and licensing acquisition timelines.

Scientific circles and legal scholars have long disputed vaccine patentability.[7] Proponents argue that vaccines, as among the costliest innovations, cannot be incentivized nor can investors be persuaded to commit substantial investments without reasonable profit expectations (Kaplan and Marcowitz-Bitton, 2022, pp. 430–435). However, whether such protection satisfies public interest and fulfils vaccines' social purpose remains contentious. For instance, during the 2014-2016 Ebola outbreak, NewLink possessed a patent license from the Canadian government for the most effective Ebola vaccine, costing the company USD 205,000 (Santos, 2021, pp. 124–125). The company failed to ensure successful vaccine trials; when the Ebola epidemic commenced, NewLink declined both to continue trials and to transfer the license to another company. Ultimately, this company received USD 30 million for license sale with an additional USD 20 million contingent upon successful trial completion.[8] This example vividly illustrates the problematic aspects of patent protection extension to vaccines, including price escalation, temporal delays, and so forth—even when the "incentive" element has been surmounted.

The Zika vaccine commercialization case likewise exemplifies obstacles that patent protection can create for vaccine accessibility. Although an American governmental organization developed the Zika vaccine, private sector investment was necessary for conducting trials and achieving final vaccine results, which should have occurred through license issuance to a private company. While U.S. legisla-

[6] History of Vaccines, *What do vaccines do? Different Types of Vaccines*, available at https://historyofvaccines.org/vaccines-101/what-do-vaccines-do/different-types-vaccines

[7] Ibid.

[8] Ibid.

tion neither explicitly prohibits nor encourages exclusive patent license issuance, commercial competition for the Zika vaccine's exclusive license persisted for nearly one year (Santos, 2018, pp. 652–665), consequentially correlating with market competition absence, price escalation, and delayed global vaccine accessibility.

This problem was similarly pertinent during the COVID-19 pandemic—the world's most extensive pandemic to date, spanning 2020–2022. In February 2020, U.S. Health Secretary Alex Azar, when questioned whether potential vaccines would be universally accessible, explained that all measures were being undertaken to ensure vaccine accessibility; however, price control would be impossible because private sector investment was essential, thus price control would not ensure "desired outcome" achievement (Togoh, 2020). On October 2, 2020, India and South Africa petitioned the World Trade Organization to waive various provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS),[9] including patent protection articles. Patent protection suspension for COVID vaccines materialized only in 2021, enabling vaccine production method sharing; all companies possessing appropriate technology and infrastructure received COVID vaccine production capability (Naik, 2021, pp. 4516–4519). Patent protection relaxation yielded immediate results: specifically, the first vaccine wave was scarcely accessible and, for instance, Georgian citizen vaccination occurred on a "first-come, first-served" principle, with only one specific firm's vaccine available, whereas subsequently five companies' vaccines emerged and accessibility significantly increased.[10]

The aforementioned examples demonstrate that extending intellectual property legal protection mechanisms—patent protection—to vaccines, on one hand, incentivizes new vaccine innovation and biotechnology/biomedicine development; however, on the other hand, it undermines vaccines' primary social function fulfilment, fails to ensure accessible pricing, restricts competition, and consequently creates obstacles to health rights accessibility.

Addressing Obstacles Caused by Vaccine Patenting

According to the research's developed reasoning, as noted, beyond innovation promotion, patents also serve the societal purpose of encouraging new innovation

[9] Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) available at https://www.sakpatenti.gov.ge/media/page_files/trips_1.pdf

[10] See, Coronavirus (COVID-19) Vaccinations – statistics by country and year available at https://ourworldindata.org/covid-vaccinations

disclosure, thereby ensuring technological information's broad dissemination/utilization (Barfield and Calfee, 2007, pp. 1–33). To balance existing risks countervailing this benefit—concerning innovation accessibility restrictions, price escalation, competition reduction, etc.—legal scholars examine various possibilities.

Patent protection duration reduction has been designated as one means of averting vaccine patenting's potential adverse consequences (Kaplan and Marcowitz-Bitton 2022, pp. 444–450). According to TRIPS Agreement Article 33, the general patent term comprises twenty years. This protection duration resulted from extensive negotiations and inter-state consensus, universalizing patent protection duration across 164 nations worldwide.[11] Nevertheless, some scholars maintain that patent terms should not be universal but rather determined individually for each innovation according to the time, resources, and investment expended on that specific innovation (Lester and Huan, 2019, pp. 787–790). Moreover, this perspective's proponents believe that determining patent protection duration commensurate with innovation's invested resources would resolve both excessive patent protection and insufficient legal protection for vaccines (innovations). For instance, under current regime conditions guaranteeing twenty-year patent protection, developed nations increase prices through early vaccine procurement, and no restriction mechanism exists within this timeframe (Kaplan and Marcowitz-Bitton, 2022, pp. 444–450). Shorter patent protection duration would enable other companies to commence production, consequently affording developing nations access to scientific benefits.[12]

To reduce vaccine transactional costs (correspondingly, final product accessibility) and clarify licensee patent utilization rights acquisition ambiguity, doctrine proposes extending not property protection standards to patents but rather liability regime/rules characteristic of tort law in common law jurisdictions (Rutschman, 2021, pp. 128–132). Specifically, it is recognized that property rights approximate absolute rights categories, and their restriction is permissible solely in exceptional circumstances explicitly defined by statute, in exchange for prior and just compensation.[13] Regarding liability regime/rules doctrine, damage causers are not constrained by prohibitions against others' rights, provided they fully and justly compensate inflicted damages (Kaplow and Shavell, 1995–1996, pp. 754–757). This approach was provoked by recent U.S. Supreme Court decisions noting that patents are not identical to property rights, and absolute protection characteristic

[11] World Trade Organization, *Amendment of the TRIPS Agreement* available at https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm

[12] Ibid.

[13] Decision of the Supreme Court of Georgia dated April 20, 2022, in case No. 1349-2019.

of property rights may not fully extend thereto.[14] Advocates for such modification assert that relaxing property rights protection standards for vaccines as patent objects carries dual implications: on one hand, acknowledging political economy in contemporary biotechnology development, which predominantly relies upon private company involvement's paramount role in biotechnology advancement. on the other hand, applying liability regime/rules doctrine, even very narrowly, during vaccine development and trial stages would significantly facilitate accessible vaccine creation, particularly in extreme situations such as the COVID pandemic (Rutschman, 2021, pp. 133–134). To substantiate this approach's efficacy, doctrine cites examples wherein one specific vaccine's biotechnological foundation, which may itself constitute a separate patent protection object, may serve as a foundation for vaccines against other diseases.[15]

Therefore, for vaccines, legalizing innovation utilization freedom even in exchange for damage compensation and/or establishing patent protection duration commensurate with investments is essential for both accessible vaccine creation and biotechnology development and disease treatment efficacy promotion purposes.

Vaccines as Trade Secret Protected Objects

Trade secrets constitute an alternative means of protecting vaccines through intellectual property law (Menell, 2017, p. 13). Across jurisdictions, trade secret protection is regulated in certain instances by specialized legislation (e.g. U.S., Germany, etc.) or by general damage compensation provisions.[16] Georgia lacks specialized legislation for regulating trade secret-related legal issues; however, Article 1105 of the Georgian Civil Code explicitly stipulates that such rights belong to the industrial property regulation sphere (Dzamukashvili, 2002, pp. 350–355).

In recent years, trade secret protection objects' scope has expanded considerably. Georgian legislative framework recognizes only one norm regulating trade secrets,[17] though its definition has been refined through judicial practice. specifically, Georgia's Supreme Court deemed essential for information's trade secret qualification the cumulative infliction of damage upon interests such as commercial value and competitiveness.[18] In another case, the court added that trade se-

[14] Oil States Energy Selvs., LLC v. Greene's Energy Grp., LLC, 138 S, 2018.

[15] Ibid.

[16] Ibid.

[17] Article 272 of the General Administrative Code of Georgia.

[18] Decision of the Supreme Court of Georgia dated February 28, 2017, in case No. BS-33-32 (K-16).

crets may encompass information possessing commercial value or enabling profit generation based thereupon.[19] In the U.S., trade secret objects may comprise any information that is commercially valuable and requires reasonable efforts to maintain confidentiality.[20] European Union countries operate under a legally binding unified directive designating trade secrets as undisclosed information,[21] though substantively representing identical trade secret regulation.

Unlike patent protection, manufacturing-commercial trade secret rights violations may engender both civil legal liability (when constituting a delict) and criminal liability. Measures identical to those employed in unfair competition suppression may be adopted, including cessation of activities commenced through unfair competition results and product confiscation for the damaged party's benefit. Compensation may be demanded (and satisfied) including inflicted damages and lost revenue (Dzamukashvili, 2002, pp. 350–355).

In the U.S., trade secrets, unlike patents, are equated with property rights; state public dissemination of such information necessitates just compensation payment, while individual trade secret disclosure is ensured through general damage compensation provisions (Menell, 2017, pp. 10–13).

Trade Secret Regime's Impact on Vaccine Accessibility

It is recognized that trade secret regulatory legislation is premised upon "commercial morality" principles.[22] In a landmark case, the U.S. Supreme Court explained that federal patent-regulating legislation does not encompass trade secret protection. Maintaining commercial ethics standards and encouraging innovation constitute broadly declared policies beyond trade secret law.[23] Therefore, trade secrets may represent a form of innovation incentive mechanism, as even innovations ineligible for patent protection may be protected through trade secret regulatory norms (Arevadze, 2019). However, conversely, the fact that trade secret protection occurs indefinitely, without any registration, and no specific statutory enumeration of trade secret objects exists means that unscrupulous utilization of this instrument may yield reverse effects.

[19] Decision of the Supreme Court of Georgia dated January 16, 2007, in case No. 623-590 (K-06).

[20] United States Uniform Trade Secrets Act, 1979.

[21] Directive (EU) 2016/943, on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure.

[22] Eastman Co. v. Reichenbach, N.Y.S., 1892.

[23] Kewanee Oil Co. v. Bicron Corp. 416 U.S. 470, 1974.

Utilizing intellectual property law's protection mechanism—trade secrets—during vaccine creation/realization may occur in various forms. Specifically, clinical trial information, vaccine or constituent medication prices, information regarding unlawful corporate wrongdoing (e.g. animal vaccine testing, prohibited substance testing, or human vaccine testing procedure violations), vaccine production technology information enabling product decentralization, and information regarding biological resources necessary for vaccine and treatment method development may be kept confidential (Durkin et al., 2021, p. 130).

Each enumerated action may adversely affect health rights accessibility and the right for all to benefit from scientific progress. Unlike patent protection, which involves rigorous and detailed innovation verification for registration, trade secret cases are limited to minimal criteria, enabling companies to keep confidential—solely for their commercial purposes—significant information that, while not constituting innovation-scale novelty, is important for scientific advancement and universal health protection.

Consequently, developing reasoning that in such sensitive spheres as the medical field, employing simpler protection to circumvent patent protection's stringent provisions may adversely affect vaccine accessibility is grounded in sound judgment. This reasoning's endorsement is particularly relevant when this alternative mechanism—trade secrets—enables indefinite monopolization (confidentiality) of information not constituting patent objects. This reasoning was confirmed during the most recent and most extensive COVID pandemic worldwide, when in 2020 U.S. vaccine contracts were publicized, revealing that one company's contract explicitly granted rights to keep confidential vaccine production and creation know-how, trade secrets, and all types of clinical data.[24] The European continent was no exception; during this period, European Commission-publicized vaccine contracts granted companies extensive discretion to keep confidential information encompassing, inter alia, dosage required per injection, licensee prepaid fees, and vaccine market release schedules (Apuzzo and Gebrekidan, 2021).

Similar to reasoning developed regarding patent protection's negative influences, in this case too, even non-professionally it is evident that keeping confidential such information as vaccine dosage, licensing payment amounts, production quantities, production release plans, etc., does not serve health rights protection or scientific development but rather aims to maximize investor revenues at the

[24] See, S. Lupkin, *COVID-19 Vaccine Contract Accountability. HHS Released More Coronavirus Vaccine Contracts As Election Results Unfolded*, November 8, 2020 available at https://www.npr.org/sections/health-shots/2020/11/08/932793698/hhs-released-more-coronavirus-vaccine-contracts-as-election-results-unfolded

expense of restricting vaccine accessibility. Consequently, protecting them under trade secret auspices, at the expense of specific enterprise profit maximization, seriously harms vaccine accessibility and delays disease combat.

Eliminating Potential Problems Caused by Vaccine Trade Secret Protection

Meticulous fact verification often reveals that adequate and proper trade secret legislation interpretation excludes from trade secret protection vast information related to health (Durkin et al., 2021, p. 135). For instance, despite U.S. courts' endorsement of recognizing prices as trade secrets, doctrine contains persuasive arguments based on trade secret law theory and purpose that price alone should not be protected through such mechanisms (Feldman and Graves, 2020, pp. 106–114). In this case, price is merely a culmination point achieved through party negotiations and does not constitute information that may serve as a starting point for future development.[25] The same may be said regarding most clinical trial safety and efficacy data, as such information cannot confer competitive advantages nor be employed to sell other products or reduce competitor expenses (Morten and Kapczynski, 2021, pp. 180–190).

To reduce potential problems caused by vaccine trade secret protection, doctrine identifies several directions. All recommendations address issues requiring political-legal level state regulation; specifically, primarily, it is considered that trade secrets should not be regarded as fundamental human rights or constitutional rights, and international law endeavours to establish stronger trade secret legislative foundations should not be facilitated (Durkin et al., 2021, p. 136). For instance, if trade secrecy is protected through property rights regime, states will be perpetually constrained from requiring companies to share health-related data for achieved result improvement or new technology development.[26] Second, states must protect societal interests in healthcare and health rights-related matters by restricting trade secret extension, and trade secret disclosure should be permitted where public health protection occupies the opposite scale. This may occur through proportionality testing, recognizing public interest-containing information as exceptional, and/or mandating proactive publication of health and healthcare-related information.[27] Third, to reduce potential problems caused by trade

[25] Ibid.
[26] Ibid.
[27] Ibid.

secret protection, establishing high protection guarantees for whistleblowers has been proposed, which should encompass reasonable judgment standards for whistleblower protection for both unlawful and incorrect actions, minimizing potential adverse legal consequences for them, and creating appropriate infrastructure, resources, and disclosure channels that incentivize disclosure.[28]

Alternatives to Restricting Vaccine Intellectual Property Legal Protection

To increase vaccine accessibility, maintain balance between intellectual property law and moral obligations, and enable everyone, regardless of birthplace, to benefit from this scientific good, all subjects participating in vaccine creation, protection, and utilization cycles must assume certain obligations.

States must steadfastly fulfil assumed positive obligations—respect health accessibility rights, i.e., refrain from direct or indirect interference in this right; protect health accessibility rights—prevent third-party interference in this right; and fulfil it—develop relevant and timely legislation and create adequate legal mechanisms for rights protection (WHO, 2008, pp. 3–20). These positive obligations, inter alia, entail state obligations to ensure prevention of private sector's unjust influence on health accessibility rights (WHO, 2008, p. 26). Intellectual property law-protected objects are social products and possess primarily social functions; therefore, states are obligated, through creating relevant legal frameworks, to ensure accessible pricing for these products (UN Committee on Economic, Social and Cultural Rights, 2017, pp. 2–15). Furthermore, private sector representatives must assume certain moral and ethical obligations ensuring their prevention of human rights violations (Dickhut, 2017, p. 219). Specifically, private companies must study with due diligence and formulate human rights protection policies, assess their contemplated actions' potential impact scope on human rights (Impact Assessments), and effectuate their integration and performance tracking (WHO, 2008, pp. 3–39).

Despite criticism developed in this work, complete removal of patent protection regimes for vaccines is unreasonable and cannot ensure just balance between intellectual property law subjects and other moral or ethical obligations, because patent protection factually encourages and facilitates vaccine innovation. Conversely, extending commercial regimes to vaccines in forms granting private companies rights to indefinitely keep confidential any type of vaccine innovation-related in-

[28] Ibid.

formation (not solely commercially valuable information), including information not subject to patent protection, necessitates excluding vaccines from trade secret regime protection and achieving inter-state consensus on this matter. Regarding patent protection, balancing parties' rights requires protection restriction; price control system establishment is essential, and for specific vaccines, according to invested investments, necessary resources, and their significance, upper limits for sale prices must be established (Dickhut, 2017, p. 231). Moreover, the twenty-year universal patent protection term must be removed and vaccine patents established according to invested investments. To maintain patent protection and ensure equitable vaccine accessibility, a state subsidy system may be established, investing state finances in innovating vaccines against diseases constituting public threats (Kaplan, 2022, pp. 444–450). This automatically ensures reduced need for investor solicitation and, consequently, vaccine sale price stabilization).

Conclusions

Extending intellectual property legal protection mechanisms—patent protection—to vaccines, on one hand, incentivizes new vaccine innovation and biotechnology/biomedicine development; however, on the other hand, it undermines vaccines' primary social function fulfilment. Vaccines are considered among the costliest innovations, whereby investors who commit substantial sums at vaccine creation's initial stages receive patent protection enabling them to unilaterally manufacture and sell at monopolistic prices they establish, failing to ensure accessible pricing, restricting competition, and consequently creating obstacles to health rights accessibility.

The perspective that, for vaccines, legalizing innovation utilization freedom even in exchange for damage compensation and/or establishing patent protection duration commensurate with investments is essential for both accessible vaccine creation and biotechnology development and disease treatment efficacy promotion purposes merits endorsement.

Vaccine trade secret regime protection, unlike patent protection, is considered more easily obtainable. However, in such sensitive spheres as the medical field, employing simpler protection to circumvent patent protection's stringent provisions may adversely affect vaccine accessibility. Endorsing this reasoning is particularly relevant when this alternative mechanism—trade secrets—enables indefinite monopolization (confidentiality) of information not constituting patent objects, i.e., invested valuable novelty.

Recognizing medical sphere-related innovations as property objects and establishing absolute control over their utilization, even under intellectual property law auspices, engenders manifold ethical and moral obstacles, as it is perpetually counterbalanced by highly protected public interest—health rights accessibility, which constitutes a fundamental human right guaranteed at both international and national levels.

Consequently, vaccines as common beneficial goods possessing real, immediate, and vital influence on human health and mortal or life-quality-deteriorating infection dissemination cannot be protected through such stringent legal regimes as patent and trade secret protection law. Complete commercialization of this specific intellectual property law object and extending stringent property regimes thereto manifestly contradicts human rights ethics; thus, alternative protection mechanism identification is necessary, which will achieve conflicting interest balancing without infringing fundamental human rights at property rights' expense.

To achieve the aforementioned objective, all subjects participating in vaccine creation, protection, and utilization cycles must assume certain obligations. Specifically: states are obligated, through creating relevant legal frameworks, to ensure accessible vaccine pricing. For this purpose, primarily inter-state consensus is necessary, and vaccine protection must be excluded from trade secret protection regimes, while private companies must be statutorily mandated to study with due diligence, formulate, and implement human rights protection policies during vaccine creation/realization processes. Furthermore, price control system establishment is essential, and for specific vaccines, according to invested investments, necessary resources, and their significance, both patent protection duration determination and vaccine sale price upper limit establishment must occur. Alternatively, as a strict exception, state paternalistic approach possibilities may be encouraged, and for universal vaccine accessibility and human life preservation purposes, state subsidy programs may be established, maximally reducing private investments in vaccine creation and monopolistic pricing's inevitable risk.

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