

The Collaborative Innovation between Patents and Standards: A New Path to Solve the Legal Dilemma of COVID-19 Vaccine Patenting

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Abstract: As the COVID-19 pandemic continues, the rapid development and dissemination of safe, effective, and long-lasting vaccines have become global imperatives. Intellectual achievements must be fully respected and protected in order to have an effective and sustainable stimulating effect. Therefore, the granting of a patent on a COVID-19 vaccine is not inconsistent with its public goods status. However, there are many legal risks and conflicts of interest in the process of licensing the rights after patents are granted, and the current solutions to the legal dilemma of COVID-19 vaccine patents are inadequate. What remains promising, however, is that the collaborative innovation between patents and standards in the development of COVID-19 vaccines is a realistic legal and policy basis for promoting the public productization of COVID-19 vaccines. Therefore, this article proposes a synergistic solution to the legal dilemma of patents and standards for COVID-19 vaccines and suggests that both international legal and public policy support are needed to alleviate the dilemma, that efforts should be made to create a chartered innovation community based on contractual industrial alliances, and that the standard-essential patent system should be upgraded in an open innovation pattern.

1. Introduction

The COVID-19 pandemic concerns human health and fate.^[1] As of mid-March 2021, it has affected over 7.8 billion people worldwide, with about 120 million confirmed cases diagnosed and over 2.6 million deaths.^[2] Simultaneously, it has devastated economic and social development worldwide.^[3]

A COVID-19 vaccine is the key to ending COVID-19. Although some drugs are already available for emergency treatment, they treat the symptoms but not the cause, and only reduce the lethality of COVID-19.^[4] In unprecedented global mobilization against the virulent disease, international organizations, research institutions, and companies in several countries have efficiently advanced the development of COVID-19 vaccines and have obtained a series of remarkable technical results in just a few months as a priority response to COVID-19. The Consortium for Epidemic Preparedness Innovation (CEPI), Oxford University's Jenner Institute, Sanofi Pasteur, Johnson and Johnson, the University of Queensland, and the Chinese Academy of Sciences have all been involved. Several major technology lines are being developed simultaneously, including Inactivated Viral Vaccine, Protein Subunit Vaccine, Recombinant Viral Vector Vaccine, Nucleic Acid Vaccine (DNA Vaccine, RNA Vaccine), and Live Attenuated Viral Vaccine (LAVV). As of 18 February 2021, at least seven different vaccines across three platforms have been rolled out in different countries. At the same time, more than 200 additional vaccine candidates are in development, of which more than 60 are in clinical development.^[5]

COVID-19 vaccine development is a pioneering exploratory activity in advanced technology and requires breakthroughs in viral recombinant technology, oligonucleotide intramuscular formulation, nanoparticle formulation, and protein recombination. Ideal COVID-19 vaccines should employ a suitable delivery system, as well as adjuvants or immunomodulators, to induce a high level of mucosal immune response, and a balanced regulation of the type of vaccine-induced Th1/Th2

immune response to avoid immunopathological enhancement. COVID-19 vaccines should also have appropriate antigen target selection and antigen type pairing to balance conservativeness and functionality, to induce high levels of neutralizing antibodies, and to simultaneously remove antigenic epitopes that may cause harmful immune responses. In the long term, the development of a universal COVID-19 vaccine technology that induces a broad-spectrum cross-immune response may be the goal of scientific and industrial efforts to address the COVID-19 pandemic and other possible future outbreaks of different coronavirus sequence variants.

COVID-19 vaccine patents are closely related to the development of the pandemic.^[6] In terms of the current global COVID-19 vaccine patent application and grant status, popular technologies involve peptides, polynucleotide sequences, antigens, drug screening, antibodies, enzyme-linked immunosorbent assays, immunoassays, and so on. There is a high degree of consistency between the main market protection places and the applicant's place of origin for COVID-19 vaccine patents. According to the results retrieved from the database of Espacenet, it is found that COVID-19 vaccine patent applications were mainly originated from China (69 applications), Russia (5) and the United States (4), and many applicants used the Patent Cooperation Treaty route for patent placement (19). In view of the sharp increase in patent applications for vaccines in 2003 due to the outbreak of severe acute respiratory syndrome (SARS) at the end of 2002, it is expected that with the continued outbreak of COVID-19, there is also a possibility of a surge in patent applications for COVID-19 vaccines from 2021 to 2022.

The COVID-19 vaccine patent output boom is the most intuitive manifestation of knowledge innovation. However, a cautiously optimistic attitude should be maintained because behind the patent granting, there are hidden worries about the unfairness of benefit attribution and distribution, and there are also legal risks. The current situation regarding the distribution of rights and interests of vaccine research and development (R&D) results is rather complicated. On one hand, the R&D results of COVID-19 vaccines are beneficial to all mankind and should be shared to the maximum extent; on the other hand, the R&D of COVID-19 vaccines consume a large amount of human, material, and financial resources, and the relevant knowledge results need to be fully protected by the legal system. In practice, some countries, international organizations, and non-governmental organizations have adopted and advocated policies or initiatives such as compulsory licensing, patent commitments, and patent pools for the rights and interests of knowledge achievements. Some have also proposed solutions such as standard-essential patent (SEP) systems. However, objectively speaking, these are not sufficient to ensure that the knowledge outcomes of vaccine R&D are adequately protected while reconciling social public interest. Traditional intellectual property (IP) system solutions either appear to be overstretched or give a negative impression of stumbling blocks in encouraging the accessibility and affordability of drugs through innovation to fight COVID-19.^[7] In terms of positive incentive building and long-term development, the existing system for the protection of IP and other intellectual achievements is lacking and needs to be deeply reflected and improved upon.

Based on collaborative innovation theory, this article seeks to find a public policy that connects intellectual property rights (IPR), which stimulate innovation with pharmaceutical products to protect public health, through the "externally acceptable and internally diverse" governance approach of patent and standard collaboration. To this end, this article analyzes the following legal risks and conflicts of interest in the licensing of COVID-19 vaccine patents: compulsory or automatic licensing of patents may discourage innovation; patent commitments or patent openness are mainly self-conscious expedient measures; the transfer model of collaborative R&D results may lead to the entanglement of rights and interests; the construction of semi-closed patent pools may aggravate the patent jungle phenomenon; and the rules of SEPs must consider patent hold-ups and reverse patent hold-ups. This article finds that the development of a COVID-19 vaccine reflects the development trend of patent-standard collaboration, which has a realistic legal and policy basis that is conducive to promoting the public productization of COVID-19 vaccines. Further, this article provides suggestions for the collaboration of patents and standards to solve the legal dilemma of patenting COVID-19 vaccines. These suggestions address the institutional shortcomings of the

aforementioned solutions to the legal dilemma of COVID-19 vaccine patents.

2. Legal Dilemma of Covid-19 Vaccine Patents: Risks, Conflicts, and Positions

2.1. Possible Legal Risks of Licensing COVID-19 Vaccine Patents

2.1.1. Abuse of Patent Rights and Tragedy of the Anticommons

Consequences of the expansion of the governance function and rights boundaries of IP policy tools are not always controllable. The granting of COVID-19 vaccine patents in large quantities may form a patent thicket and create a tragedy of the anticommons. As far as the governance function is concerned, once a patent is granted, the patentee has effective control over the corresponding technical achievements during the validity of the patent, and can either use it themselves or authorize others to use it. The patent holder can set conditions for use, such as a clause prohibiting the use of the invention under certain circumstances. They can also restrict usage by charging high fees for access to the technology, or they can refuse to license the patent and thus become its sole provider. In addition, the way patents are licensed may affect other technologies because some technologies require the use of existing patented technology to operate. Thus, a patent holder's decision has the potential to have a significant ripple effect on the use of other technologies and on R&D within the technology field. The key point is that the decision to license such patented technologies to other manufacturers is entirely at the discretion of the patent holder, notwithstanding the COVID-19 pandemic.^[8] Prior to the pandemic, several scholars^[9] had pointed out the tragedy of the anticommons problem that results from patent licensing in the biomedical field. For example, in 2009, John B. Classen patented the idea of linking infant vaccines to late-stage immune dysfunction. Classen Immunotherapies, a company operated by Classen, sued Biogen, a company engaged in research on immunization procedures and subsequent medical conditions, in court.^[10] John B. Classen was accused of patent hooliganism for failing to contribute substantive research results and "freezing" other research related to immunization and diabetes for his own personal financial gain, thus impeding the development of the immunization protocol. This is a clear tragedy of the patent commons, as he not only failed to contribute substantial research results but also "froze" other research related to immunity and diabetes to seek personal financial gain and discouraged innovation by other researchers in this field. Could this tragedy have been avoided in the development of COVID-19 vaccines?

Patent abuse has been around for a long time and is evident in the current COVID-19 pandemic. For example, regarding the case of the patent technology battle over the COVID-19 test, BioFire, the company sued by Labrador, released three COVID-19 test products based on FilmArray technology. Labrador claimed that BioFire's tests infringed Theras' patents (United States Patents 8,283,155 and 10,533,994). They asked the court to enjoin the company from manufacturing these products, and, if they could not be enjoined from infringement, required the defendants to pay ongoing royalties to Labrador.^[11] Although this challenge was abandoned over strong public opposition, it highlights the potential for patent holders to limit available diagnostic tests. Another example is the patent litigation over 3D-printed respiratory wearable parts. During the height of the Italian epidemic, the patent holder of 3D-printed respiratory parts had prevented others from using the same technology to make these parts. These claims were subsequently denied by the individuals involved, and were refuted by the patent holder.^[12] However, if the patentee prevents others from copying their patented product, it is perfectly legal to do so.^[13] There is also a potential dispute over the patent for COVID-19 vaccines. There is widespread concern that patents could be used by patent holders as a vehicle for profiteering, resulting in unaffordable costs for COVID-19 prevention and treatment.^[14] For example, the mRNA vaccine developed by Moderna requires the use of a key technology, lipid granules, because RNA injected directly into the human body causes a violent reaction and thus requires a lipid granule to encase the RNA in the human body. Arbutus Biotechnology, Inc. is the patent owner of this technology, holding United States Patent US8058069B2, and the invention name is "Novel Formulation for Accounting Delivery." The patent battle between the two parties has been ongoing for many years, and patent invalidation was

initiated in early 2019. This is because this delivery formulation is needed not only for the COVID-19 vaccine but for all mRNA vaccines. Based on social public interest pressure, Arbutus has not issued an injunction against Moderna, but Moderna must pay a license fee, which leads to a reduced profit margin for future vaccines produced by Moderna. With relatively stable procurement prices in the domestic market, there will inevitably be price adjustments in overseas markets to expand profit margins, which may significantly increase the financial burden on developing countries to purchase COVID-19 vaccines, thus reducing the number of vaccinations for those populations.

2.1.2. Using Patent Advantages to the Detriment of Public Interest

Patent exclusivity protection generates monopolistic profits. If a patent owner decides to license or provide the technology at a price that far exceeds the cost of production, the price of the patented medical product will remain high, causing damage to public health interests. A study in the United States shows that the average AIDS patient who continues treatment will live for another 24 years, during which time they will have to pay more than \$600,000 in medical costs: an average of \$25,200 per year.^[15] Such high medical costs are unaffordable for most AIDS patients, especially those in developing countries. Although some countries and international organizations subsidize these costs, there are many restrictions on the amount, scope, and timing of subsidies, and drug prices remain high. In another recent example, the cost of Remdesivir, once considered the most promising treatment for COVID-19, was initially determined to be about \$3,200 per six-day course of treatment, while its production cost was estimated to be less than \$6 per six-day course, with the patent holder undoubtedly enjoying a huge profit margin.^[16]

The high prices of patented pharmaceutical products, although unfair to patients (as a vulnerable group), have objective reasons. Private pharmaceutical companies play a huge role in bringing disease treatment products and methods to market, and their innovation is indispensable. Statistically, the success rate of developing a completely new drug is not high, and the total cost of investment averages at about \$400 million when losses from the risk of project failure are added. Companies and the scientists who work for them are economic actors who rationally expect to achieve a reciprocal or even superior return between the human, material, and financial resources invested in upfront R&D and the output of the R&D results. Without strong protection of innovation results, there is no economic justification for investment. Prices that are higher than the cost of raw materials, production equipment, and management of the production process of a drug represent a way to compensate for the cost of development and the cost of past failures. After all, without the economic benefits as a direct motivating mechanism for R&D and risk compensation guarantee mechanisms, both patients and those with potential needs will ultimately not have access to life-saving drugs, including vaccines with disease-preventing effects.

However, during the COVID-19 pandemic, an easily available, affordable, and effective COVID-19 vaccine is a matter of global public interest that needs to be prioritized as a matter of human health and fate. Even if the need for economic efficiency is further justified, it is intolerable for companies and R&D organizations to maintain high prices for vaccines that contain patents. There seems to be a consensus that IP laws should not be a stumbling block in the fight against the COVID-19 pandemic.^[17] We find that governments are attempting to bridge the decades-long gap between market incentives and public health interests by moving away from a profit-driven model to encourage the development and production of drugs to combat mass infectious diseases.^[18]

2.1.3. Transnational Patent Disputes and Fears of a Humanitarian Crisis

Developing countries face a humanitarian crisis that results from vaccine patent blackmail. In addition to the risks and difficulties aforementioned, the production and distribution of COVID-19 vaccines require crossing political, geographic, and cultural barriers that are cloaked in IPR. Currently, there is insufficient capacity for COVID-19 vaccines, and developed countries and regions such as the United States, the European Union, Japan, and Canada, which account for 12% of the world's population, have pre-ordered the vast majority of the 5.35 billion doses.^[19] Most developing countries have been forced to "wait in line" and face the dilemma of having no way to

purchase the vaccines. The issue of how to make vaccines available to all countries is becoming a global concern. Once a vaccine is licensed, it is often marketed in a way that de facto excludes certain populations, even leading to global "vaccine nationalism," where developing countries are excluded from the distribution of newly-developed (or first-in-manufacture) vaccines. For example, Merck's anti-HPV vaccine, Gardasil, has more than 80 patents in the United States, but patent barriers have prevented access to the vaccine in developing countries.^[20] If, in the future, COVID-19 vaccines encounter transnational "patent sniping" in the process of worldwide application, then the step-by-step settlement or judicial procedures will be tantamount to the party in control of the technology cloaking itself in the garb of legality to slow down or even hinder the spread of the vaccine, which will not only damage public interest but will also lead to a humanitarian crisis.

2.2. External Manifestations of the Conflict over Patent Licensing for COVID-19 Vaccines

2.2.1. Market Players are Profit-seeking in Nature, which Makes Them Crave a Monopoly Status

The incentive of the patent system is to grant the inventor exclusive rights for a certain period to obtain the economic benefits brought about by the new technology so as to compensate for the initial investment, although there is a great uncertainty whether the balance between this price and the investment is achieved. The normal R&D cycle of a vaccine is about 14 years, during which the hardware costs of experimental facilities and equipment, human resources costs, and so on, need to be paid. The cost of marketing the results after they are developed is significant, and the increase in Good Manufacturing Practice (GMP) and clinical trial standards have caused funding for vaccine development to soar to unprecedented levels, with an investment of \$850 million currently required to obtain a new vaccine approval.^[21] In addition, there is another cost to vaccine development that is difficult to ignore: the opportunity cost/failure cost. Only 9.6% of drugs advanced from clinical phase I to market approval from 2006 to 2015, and nearly 70% of drugs in development phase I were declared failures. Therefore, the monopolistic position of vaccine patents is often the key to recovering the investment of vaccine developers from a long and costly development cycle. Once mass production starts after huge investment, companies are often reluctant to openly share their knowledge under a single incentive model that relies only on financial gain due to the dual consideration of "return to profit" to protect their own wealth, and the constant vigilance of potential competitors to encroach on the market share.

In the past, it has been difficult to get the private sector interested enough in a vaccine for a viral pandemic. One concern that pharmaceutical companies face is that if they develop a vaccine, they will face enormous political pressure to make it cheaply available.^[22] The key point is clear: vaccines should be both profitable and universally available, and this requires a systematic collection of innovative policies to achieve both goals.^[23] The government's obligation to guarantee citizens' right to health through the provision of various social services is clear, but the vision of the private groups (e.g., pharmaceutical companies) that seek to maximize profits by requiring them to lower the price of drugs, such as vaccines, to provide them to the public when they have the advantage of the market share is contradictory to both the capital system and the pursuit of profits. A further contradiction is that the existing governmental funding programs generally continue to take the form of individual commissions or facilitated multiparty collaborations to advance technology and product development activities. Companies, for their part, are unlikely to commit significant resources to product development efforts that are not yet production-ready due to their pursuit of profit.^[24]

Scientific research institutions also have a need to realize their value, although they do not pursue purely economic interests. The publication of papers or patent applications to complete research projects or to establish academic status is common in academia in all countries. However, the process of resolving the structure of the SARS-CoV-2 virus requires a very different way of working, with vaccine development, manufacturing, and marketing companies and researchers working in complementary fields needing to collaborate and share information as vaccines and

drugs move into clinical trials.^[25]

2.2.2. Conflicting Rules of Vaccine Patents in Some Countries and Regions

Differences in national strategies and rules regarding vaccine patents have also objectively contributed to the creation of the COVID-19 vaccine patent conflict. In the United States, the high reliance of policymakers on private companies to innovate in the production of therapies and vaccines contrasts sharply with the international community's commitment to public-private partnerships. European countries, however, are more inclined to promote the development and dissemination of COVID-19 vaccines through public interest organizations.

During the COVID-19 outbreak, the United States federal and state governments relied on innovation from the private industry to identify and accelerate the development of promising COVID-19 drug candidates and vaccines through government-supported private sector R&D programs and targeted, commissioned R&D relationships. On April 17, 2020, the National Institute of Health announced a collaborative study between United States federal researchers and 16 pharmaceutical companies, called the “Accelerating COVID-19 Therapeutic Interventions and Vaccines” (ACTIV) project,^[26] which aims to develop a collaborative framework to prioritize vaccine and drug candidates, streamline clinical trials, harmonize regulatory processes, and leverage all Regeneron Pharmaceuticals (REGN), who have signed a \$450 million agreement with the American government's Operation Warp Speed program to provide the government with a COVID-19 vaccine. REGN's COVID-19 neutralizing antibody, REGN-COV2, also represents a corporate strategy. Under the University and Small Business Patent Procedures Act of 1980 (Baidoo Act), the government has the authority to direct any of these companies to license their funded inventions to a third party if the government determines that the companies have not done enough to reasonably address an epidemic.

European countries have a different approach to advancing the development and spread of COVID-19 vaccines. The leaders of Italy, France, Germany, and Norway, as well as the European Commission in early May 2020 called for any innovative tool, therapy, or vaccine to be shared fairly and equitably, as it would be a unique global public good in the 21st century if we could develop a vaccine to be produced worldwide.^[27] At a virtual meeting of the World Health Assembly (WHA) in May 2020, the European Union introduced a draft resolution called “WHA73: COVID-19 Response,”^[28] urging the WHA to voluntarily collect IPR as part of a plan to ensure “equitable access” to vaccines, therapies, and other medical products to combat the pandemic. The draft resolution also recommends the WHA, as the policy-making body of the World Health Organization (WHO), to work closely with the World Intellectual Property Organization, Medicines Patent Pool, United Aid, United Nations Children's Fund, Alliance for Innovation in Epidemic Protection, Global Fund to Fight AIDS, and Vaccine Alliance in the fight against the pandemic. By implementing this resolution, the European Union provides a viable pathway to establish a relevant patent pool.^[29] Objectively speaking, the overall solidarity of European countries is higher than that of the United States at the strategic level, if the efficiency of the single outcome output is put aside.

2.2.3. The International Community's Vision: The COVID-19 Vaccine as a Public Good

The divergence between private incentives and public health in pandemic preparedness and response has tended to widen in recent years. Approaches to knowledge production and dissemination are necessary, especially in global health, where market interest is often lacking, and countries must also do a better job of supporting publicly funded institutions and scientists that are engaged in translational research. That is, instead of assuming that the only way to advance vaccines and other products is to patent and license them to the private sector; government laboratories, funding agencies, and universities should consider expanding their scope. For example, regarding the case of the Ebola vaccine, rVSV-ZEBOV, the Canadian government, its researchers, and other public funding agencies injected significant costs and efforts, from sponsoring early research to conducting clinical trials.^[30] The public sector-led supply of reasonably priced drugs, from R&D through production and regulatory approval, represents a social public interest option. The case of the Ebola vaccine (rVSV-ZEBOV) demonstrates that this public option is not merely

theoretical; rather, the public sector has the capacity to do much more than conduct purely basic research. For example, given sufficient resources, public sector laboratories can be involved in the full process of basic research to application, thus addressing the many technical challenges of making a clinical-grade vaccine.

The COVID-19 vaccine is a drug of public interest that is similar to, if not more urgent than, the Ebola vaccine. Therefore, previous innovation and IP policies should be revised. As aforementioned, France, Germany, and Italy have previously made strong calls for solidarity and consider any COVID-19 vaccine as a "global public good."^[31] China has a similar attitude. On October 8, 2020, China signed an agreement with the Global Alliance for Vaccine Immunization (GAVI) to join the new "Crown Pneumonia Vaccine Implementation Program" (COVAX). Once the Chinese vaccine is developed and operational, it will be provided to developing countries as a global public good, with priority.

2.3. Basic Position: Granting Patents for COVID-19 Vaccines Does Not Contradict Its Public Goods Positioning

Before a study is eligible for industrialization, it must have a good preliminary research foundation, and most of its R&D should have significant breakthroughs in terms of cost reduction and efficiency improvement in the industrialization of vaccine products to production and preparation.^[32] This is the key point of focus for patent-granted technology because an indispensable element of a patent grant is that it must have utility. IPR is not the issue but rather the mode and means of application. There is no evidence that IP protection constitutes a "substantial barrier" to epidemic-related drugs and technologies. Exempting patent protection is an extreme measure to address an unproven problem. We maintain that IPRs are a driver of innovation and competition, that they are the best way to safeguard drug and vaccine development against a virus, and that patenting new vaccines is a necessary incentive for innovation.

However, it is indisputable that COVID-19 vaccines, which contain numerous proprietary technologies, need to be public goods. The current R&D costs of COVID-19 vaccine companies are borne entirely, or to a large extent, by taxpayers, thus these vaccines belong to the public. For example, the mRNA technology that Moderna and Pfizer relied on to develop their vaccines received federal assistance from the National Institute of Health. Moderna received \$2.5 billion in funding for its vaccine research and orders, both before and after. The company acknowledges that \$1 billion of that would have been sufficient to cover the full cost of R&D. Pfizer also received \$455 million from the German government for its R&D. According to statistics, the United States and the European Union placed nearly \$6 billion in orders with the company. AstraZeneca Pharmaceuticals received more than \$2 billion in R&D and booking funds. In the case of receiving funding, the attribution of IPRs are applied according to the agreement, if there is an agreement. If there is no explicit agreement, or if there is room for further interpretation of an agreement, then the interpretation that is most useful in the interest of public health should be made. However, this does not prevent the relevant rights holders from continuing to retain their IPR. That said, there is a distinction between the manner in which rights are confirmed and the manner in which they benefit. The granting of a patent on a COVID-19 vaccine is consistent with its public goods character. The World Trade Organization (WTO) has paid comprehensive attention to trade measures related to the pandemic, and vaccines, as public goods, require international cooperation for mutual benefit. By making vaccines public goods, we are planting seeds of hope in the global governance system and are promoting their development in an equitable manner. If the traditional rules of the game of "winner-takes-all" are maintained, the pandemic will exacerbate the disparity between countries and directly or indirectly harm the interests of all stakeholders. We have not seen any substantial change in the current solution.

3. The Existing Solutions and Shortcomings of the Legal Dilemma of Covid-19 Vaccine Patenting

3.1. Compulsory or Automatic Licensing of Patents may Discourage Innovation

In view of the potential impact of patents on global equitable distribution, the scope of rights of patent holders needs to be reconsidered. This can be achieved through compulsory licensing. The compulsory licensing provision first appeared in the Paris Convention for the Protection of Industrial Property in 1883, which hoped to prevent patent holders from abusing their rights by establishing a compulsory licensing system to ensure a balance between the interests of patent holders and public interest, so as to reflect social justice and fairness. Article 30 of The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), the "Exceptions to the Grant of Rights," is a factual provision for compulsory licensing, and Article 31, combined with Article 27(2), that does not grant patents, together constitute the basic framework of the compulsory licensing system under the TRIPS Agreement. Subsequently, the Doha Declaration on Public Health, the Resolution on the Implementation of the TRIPS Agreement, and Paragraph 6 of the Doha Declaration on Public Health have made further provisions. Compulsory licensing of patents carries certain economic or political interests, and there are already precedents. In as early as 1997, the AIDS epidemic triggered a major debate on public health and patented drugs, and both developed and developing countries wrestled with this issue within the framework of the WTO, who finally agreed to allow developing countries to use the compulsory licensing system to produce patented drugs in the event of a public health crisis, and to allow countries or regions without pharmaceutical capacity to import them.

However, compulsory licensing cannot solve the problem of sharing rights and interests in intellectual achievements. It is only a deterrent; a last resort to be considered when negotiations with the patentee result in difficulties in reaching an agreement. Although many safeguards are provided for compulsory licensing, some of these provisions still suffer from a lack of clarity in legal interpretation because many ambiguous terms are not well explained and lack specific definitions. Article 31(b) of the TRIPS Agreement states that a member may apply compulsory licensing when it is in either a state of national emergency or in a state of extreme urgency. However, in practice, the understanding of what constitutes a state of national or extreme urgency differs between countries, and if countries are allowed to make interpretations based on their own interests, then there is a possibility of abusing rights from the legislative level.

The prospects for profits from COVID-19 vaccines are not as broad as for other pharmaceutical products that require ongoing use. Vaccines are single-use consumer products with long-term effects, and even with significant IP protection, they are less profitable than drugs or treatments that require repeat purchases. If a system of compulsory licensing of patents, pharmaceutical patent exemptions, and so on, is applied to COVID-19 vaccine patents, it may cause a backlash from those who have (or will have) a vested interest. Equally important is the duration and scope of compulsory licenses. Countries should ensure the continued validity of national compulsory licensing provisions. This is because even if an exemption is passed, it is unclear how long it will last; for example, until the end of the COVID-19 pandemic or a later date. Therefore, it is also critical to have effective national compulsory mechanisms in place if other public health issues require them. Such licensing measures and their shortcomings need to be analyzed from a global public health perspective. On October 2, 2020, India and South Africa submitted a proposal to the WTO for a temporary waiver of certain provisions of the TRIPS Agreement that propose suspending IPR obligations related to prevention, containment, and control.

3.2. Patent Commitments or Patent Openings are Largely Self-Conscious Stopgap Measures

Patent commitments are voluntary commitments by patent holders to limit enforcement or other usages of their patent holdings; a mechanism that has been implemented in the field of automotive software.^[33] Patent commitments are a more modest approach in recognition of the premise of IP ownership. The "Open COVID Pledge" program is an inspiring experiment and exploration that calls on relevant organizations to make their key IP available free of charge to fight COVID-19 by encouraging innovation and reducing restrictions on IP access and research, leading to the development of new tools to combat COVID-19.^[34] This system design demonstrates how flexible licensing strategies can be used to facilitate technology transfer to promote public interest goals

within the dynamic context of IP, and is therefore more appropriate for implementation in the context of a public health emergency such as the current pandemic.

With the COVID-19 pandemic sweeping the world, there is a new awareness of the monopolistic nature of patents, and there are calls for patent sharing based on public interest needs.^[35] Patent commitments have considerable potential to be used to alleviate the market access problems posed by COVID-19 vaccine patents, but they require more national support and public understanding to maximize the profitability of patent holders. Yet even if the framework of the current knowledge transfer rules is retained to the maximum extent possible, resistance to patent commitments or openness is being pursued. Coordinating patent commitments typically require more lead time, including time for patent layout and for committing to patent certainty. During a pandemic, every day counts, and patent commitments may not be as effective as they could be if they lack ongoing management. Therefore, it is important to seek to align interests between IP holders and potential users.^[36]

3.3. The Transfer Mode of the R&D Results of Project Cooperation can Easily Lead to Entanglement Constraints of Rights and Interests

Collaboration between enterprises and university research institutes to develop vaccines against COVID-19 is currently quite common. For example, AstraZeneca and the University of Oxford have developed the AZD-1222 vaccine, which contains a recombinant adenoviral vector expressing the SARS-CoV-2 echinocandin and is now available on the market. Merck & Co. is developing two vaccine candidates using different viruses to deliver antigenic DNA through its acquisition of the vaccine company Themis, and its collaboration with the nonprofit organization IAVI. ExpreS2ion Biotechnologies, a Danish company, is leading a dedicated task force of European pharmaceutical company developers to address COVID-19. Further, a COVID-19 vaccine (Vero cells) has been developed by the Wuhan Institute of Biological Products Co., while a recombinant COVID-19 vaccine (adenovirus vector) has been developed by the Institute of Biological Engineering, Institute of Military Medical Research, and Academy of Military Sciences in collaboration with Kangxino Biological Co. The output of the R&D results through project collaboration inevitably involves the allocation of IPR and interests.

Solutions like the Bayh-Dole Act in the United States suffer from an inherent deficiency in the allocation of rights and interests. The Bayh-Dole Act recognizes the issue of patent rights vesting in project assignees; however, in some cases, while inventors and assignee institutions are presumed to have legal titles, the government retains a non-exclusive, non-transferable, and irrevocable license to the invention in question.^[37] Now, more than 40 years later, the controversy over the Act's role in promoting innovation, regulating competition, and market access continues unabated. Some scholars have called for giving governmental authority agencies additional authority to limit the content and boundaries of the rights of patentees of publicly funded research when commercialization of the invention is required in the public interest.^[38] Other scholars have pointed out that the ownership and use of IPR of research project results under the Baidoo Act does not guarantee the use of established patents by researchers in non-commercial research, and the ubiquitous patent rights indirectly consume relevant social resources.^[39]

Patent exclusivity agreements that are derived from collaborations hinder competition. Private sector involvement is common in the late stages of R&D, especially in the biopharmaceutical sector. However, in this type of IPR transfer, exclusivity agreements impede competition and create strong control over the market, which, in turn, leads to higher prices and unnecessary losses. When such inefficiencies occur in public goods like vaccines, exclusive licensing arrangements need to be carefully evaluated, and if exclusivity is not necessary but is licensed, the situation may enter a policy arrangement that is not conducive to innovation.^[40]

The aforementioned Ebola vaccine—the application of which was delayed and entangled due to the market foresight of some rights holders involved—was synthesized by a Canadian government research institute in the early 2000s and patented in 2003 as an rVSV-ZEBOV vaccine candidate against Ebola. With no private sector interest in further investment, the vaccine candidate was

licensed through an IP agreement to NewLink Genetics, a United States company who did not move forward with the development process but instead shelved it. The company refused to license the patent until the Ebola outbreak in 2014, and only signed a licensing agreement with global drug giant Merck after pressure from the WHO and others. The rVSV-ZEBOV vaccine was originally patented to NewLink for \$205,000, and the company received a \$30 million transfer fee from Merck when it transferred the patent, while another \$30 million was collected before clinical trials began. If the vaccine is licensed to market, NewLink will also receive a portion of the draw from the market profits. The company's actions are essentially a parasitic exploitation of public sector R&D and IP, and the company has harmed public health interests by both blocking continued development of the patented product and refusing to license it to institutions capable of conducting R&D when an unexpected public health crisis occurs.

3.4. The Construction of Semi-Closed Patent Pools may Aggravate the Patent Jungle Phenomenon

Patent alliance, also called patent pool or patent pooling, refers to an agreement between two or more patent owners to license one or more of their patents to each other or a third party. Traditionally, a patent pool is a bundle of all patents for licensing and has a uniform licensing fee, and the resulting revenue distribution is based on the ratio of the number of patents held by each member. Taking the DVD industry's 6C alliance as an example, its IPR licensing is centralized and intensively managed, and the alliance members agree that the IPR management agency for the alliance is a civil agent that authorizes third-party companies to use the IPR, and that the licensee is limited to using the licensed patents for the production and sale of specific products. Regardless of whether the third-party licensee companies are willing to produce, use, and sell DVDs that comply with the standard regulations, each patent-holding company must agree to grant the third-party licensee a non-exclusive right to use its essential DVD patents on an equal, reasonable, and non-discriminatory (RAND) negotiation basis.^[41] The IP policy of the patent pool may be determined by all members, based on the characteristics of the industry, and the members of the patent pool will absorb all patents containing essential claims to the maximum extent possible, based on the principles of voluntariness and good faith, in order to avoid conflicts of interest and disputes over IPR within the collaborative organization.^[42]

In the pharmaceutical and health industries, the Medicines Patent Pool, the first public health patent pool for HIV drugs, tuberculosis, and hepatitis C, was created in 2010 by a United Nations-supported non-profit organization seeking to increase access to HIV, hepatitis C, and tuberculosis treatments.^[43] The WHO has consistently encouraged the sharing of IP, know-how, data under broader technology transfer, and other knowledge resources to ensure equitable global access to much-needed health technologies.^[44] On May 29, 2020, the WHO and Costa Rica joined forces to launch and initiate the COVID-19 Technology Access Pool (C-TAP) by expanding the coverage of the COVID-19 Technology Pool, first advocated by the President of Costa Rica in March 2020.^[45] Thirty countries and multiple international partners and institutions have now agreed to support the C-TAP initiative so that COVID-19 vaccines, testing reagents, treatments, and other health technologies are available to all. The organization is now working to facilitate patent sharing and streamline access to proprietary information to accelerate the fight against COVID-19.^[46] However, it cannot be ignored that the patent pool is commonly understood to be semi-closed, and that there is an internal technology substitution. One scholar examined the development of patent pools in 20 industries and their impact on patents, and found a 16% decline in patent filings. They argued that patent pools allow competing companies to merge their patents, and suggested that unregulated patent pools may impede innovation by weakening competition to improve alternative technologies.^[47] Other IPR and knowledge gaps can also impede downstream industry access to trade secrets and accumulated experiences in vaccine production, management, and so on, and can create considerable invisible barriers to other generic companies that manufacture vaccines.^[48] This distinguishes vaccines from small molecule drugs, which are often more easily replicated by third parties without the need for additional knowledge of, for example,

manufacturing processes.^[49] The role of patents should be considered along with other potential barriers to accessing knowledge outcomes.^[50]

3.5. SEP Rules Need to Consider Patent Hold-ups and Reverse Patent Hold-ups

A SEP refers to a patent that no other non-patent technology can replace in the standard, and the essential patent is often embodied in the patent of invention. Specifically, the patented technology must be directly related to a certain product or production method to which the standard applies. However, due to the single nature of this technical route, which results in the essential patent technology in the field of the technical standard in an indispensable position, no other non-patent technology can replace it, and only the technology identified as an essential patent can be included in the technical standard.^[51] According to the American National Standards Institute's (ANSI) Essential Requirements for a fair process, a standard proposal does not, in principle, preclude the inclusion of a patent in its drafting if it is technically proven that the standard will be revised to involve patented technology.^[52] When IP is incorporated into a standard and becomes an SEP, the monopolistic nature and status of the patent is magnified by virtue of the standard. Not only does it protect the IPR holder from infringement but it even has a cascading effect on all market players that are covered by the standard. This makes it impossible for users of the standard to bypass such patents; they can only be on the weaker side of the game of rights and interests, and are destined to be passively subjected to the clampdown of non-market-based unfair means. An SEP holder may abuse the standard-setting process by creating a de facto threshold restriction for the party by implementing the standard through a patent. The threat of bans and other tactics by SEP holders have potential anti-competitive effects, even if the standard-setting organization (SSO) requires the contract to be licensed on fair, reasonable, and non-discriminatory (FRAND) terms. While some policymakers and SSOs have embraced ex ante licensing negotiations as a means of preventing obstruction, there are other non-monetary solutions to consider.^[53]

In the unprecedented global vaccine R&D race, COVID-19 vaccine frontier R&D entities are engaged in an open battle over how to use vaccine technology patents to gain first-mover advantages and block rivals.^[54] The existing SEP rules cannot address the balance between IPR and public interest for COVID-19 vaccines. Through data searches, we were surprised to find that, in addition to using traditional patent pools, technology barriers, and inter-licensing agreements, some companies are already experimenting with the double-edged sword of SEPs to achieve a long-term "winner-takes-all" in the future NIC vaccine market. Traditional SEP rules can both create and reverse patent hold-ups. Unlike, for example, the 5G wireless communication system, vaccine product categories are diverse and of single-function, and the process of vaccine R&D and production generates a large amount of clinical trial data, genetic profile data, and information on non-patentable disease diagnosis and treatment methods. In addition, the administrative approval process is cumbersome and strict, so if the SEP rules are directly applied, both the licensor and the licensee have many means to block another party from obtaining the relevant knowledge in a timely manner. In this global public health emergency, the need for efficient, extensive, and thorough communication of vaccine-related knowledge is paramount. The lengthy negotiation and benefit exchange game is obviously not conducive to knowledge spillover and flow. The aforementioned legal risks and dilemmas caused by patents must find a new and viable solution.

4. Feasibility of Patent and Standard Collaboration in Solving the Legal Difficulties of Covid-19 Vaccine Patents

4.1. The Development Trend of Patent-Standard Collaboration is Reflected in the R&D of COVID-19 Vaccines

In innovation environments that have differentiated policies, it is necessary to have a deeper understanding of the opportunities and challenges brought by open innovation.^[55] The core idea behind open innovation, which requires both patents and standards to break down previous application barriers and institutional barriers, is to make scientific information, data, and outputs

more widely available and more reliably utilized with the active participation of all stakeholders. IP-protected technologies in standards should be given adequate and reasonable protection to safeguard the interests of IP owners. Simultaneously, the relevant IPR holders should be prevented from abusing their dominant market position, such as by charging unreasonably high fees to implementers of standards or by discriminating among implementers of standards to impede the market competition.^[56]

Open innovation is the result of the game between market interests and social public interests, and is the process of technological innovation in which market players simultaneously use internal and external complementary resources to achieve innovative knowledge results.^[57] Scientific management, rational use, and comprehensive protection of IPRs are some of the core elements of open innovation theory. Compared with other high-tech industries, the R&D, commercialization, and other innovation activities of modern biotechnology industry are characterized by high investment and low imitation cost, and no other economic and technological fields can rely as much on the protection of patents and other IPR as the biotechnology industry.^[58] The “Biological Innovation for Open Society” program, launched in 2004, is a useful attempt to apply the open resource innovation model to the industrial field.^[59] Under the influence of open innovation theory, the academic community has successively proposed the theoretical terms of “open biotechnology,” “open-source biotechnology,” and so on. These terms have been advocated to solve the problem of the lack of resources for groups and researchers, to ensure the accessibility of biotechnology tools needed for research and innovation, and to realize “public free resources + patents + technology secrets.” It is an ideal model for open resource management and IPR protection.^[60]

In the vaccines field, there has been a convergence between patents and standards in an open innovation context. For example, it initially took 50 years from *Bacillus* being discovered as the causative agent of pertussis (in 1906 by Belgian bacteriologists and immunologists Baudet and Gengou) to its effective vaccine receiving a new drug certificate, largely because of the failure to standardize the product in many early trials. Only when some degree of standardization occurred did the development of an effective pertussis vaccine become feasible.^[61] There are now over 250 patents that are directly related to pertussis vaccines, with early patents being filed in 1958.^[62] This is, perhaps, an example of how patent and standard timelines overlap in the field of vaccine technology. On June 30, 2020, the Food and Drug Administration’s Center for Biologics Evaluation and Research (CBER) released the document “Guidance for Industry: Development and Licensing of COVID-19 Prophylactic Vaccines” to assist biopharmaceutical companies in the clinical development and regulatory approval of COVID-19 prophylactic vaccines. This document mentions several considerations for COVID-19 prophylactic vaccines in terms of chemistry, manufacturing, and quality control (CMC), as well as non-clinical data, clinical trials, and post-marketing safety evaluation.^[63] These considerations are undoubtedly closely related to the relevant cutting-edge technologies. Further, each aspect of vaccine development in China has corresponding technical specifications that are aligned with the WHO’s standards. China has published five guiding principles for vaccine development. On August 15, 2020, the Drug Review Center of the State Drug Administration (SDA) released the “Technical Guidelines for the Development of Novel Coronavirus Vaccines for Prophylaxis (for Trial Implementation)” and other guidelines. These guidelines were formed with reference to the target product characteristics issued by the WHO to strengthen guidance on clinical evaluations of COVID-19, and to promote the marketing of COVID-19 vaccines as soon as possible.

In terms of international standardization practice, there is an international organization for standardization (ISO) standard for viral nucleic acid assays, titled “Biotechnology—Requirements for Evaluating the Performance of Methods for Quantification of Nucleic Acid Target Sequences—qPCR and dPCR.”^[64] This standard provides general requirements for evaluating and ensuring the performance and quality of methods for the quantification of specific nucleic acid sequences. It applies to target sequences in nucleic acid molecules, including double-stranded DNA (dsDNA) and plasmid DNA, single-stranded DNA (ssDNA), complementary DNA (cDNA) and single-stranded RNA (ssRNA), and double-stranded RNA (dsRNA). In these criteria, correlations

with patents can be found. A search of patents worldwide revealed about 70 "Quantification Methods for Nucleic Acid Target Sequences," which included nucleic acid target sequence quantification of qPCR and dPCR methods. Moreover, we also found that "A Method for Preparing RNA Standard Material of SARS-CoV-2 Virus" (CN202010358042.8) also contains descriptions of qPCR and dPCR methods. Therefore, it can be tentatively concluded that in vaccine technology and industry, the integration of patents and standards does not appear to be abrupt.

4.2. The Collaboration between Patents and Standards Has a Realistic Legal and Policy Basis

The conceptual and institutional requirements of the synergistic development of patents and standards can set the boundary of the rights of each party without forcing them to give up or restrict their rights under the condition of ensuring the overall public safety of human beings. The combination of IPR with standards can optimize competition in emerging markets and play a beneficial role in boosting reinvention in new industrial fields. Standards are also an important means to improving the efficiency of knowledge utilization, since knowledge utilization in the form of IPR licensing and transfer may be costly. If the costs of communication and negotiation between the demander of knowledge results and the IPR holder are too high, or if the economic strength is weak and the information is asymmetric, then the technology demander will have difficulty in obtaining authorization from the IPR holder. Moreover, due to the existence of technical dependency, no IPR can be truly utilized in substance, thus it can be inferred that the public at the end of the industrial chain cannot obtain real benefits from the technological progress. In cross-licensing, blanket licenses are offered or patent pools are formed in favor of competition. Many of these issues are likely to be extremely important in future, especially with the rise of standards development as an important part of the commercialization process for new technologies.^[65] Finding ways for patents and standards to coexist peacefully is critical, at least in terms of the development and subsequent widespread adoption of COVID-19 vaccines. Fortunately, the rules for the development and application of COVID-19 vaccines are "de facto standard" in nature, and can be applied outside of the established rules for SEPs. Further analysis of the WHO's existing public documents on COVID-19 vaccines reveals that these documents contain encouraging and promotional technical guidelines that are aimed at the harmonization of actions. That is, they are not international standards that are ISO-certified and strictly enforced but rather internal organizational norms with relatively loose technical specifications written in vague language.

The collaborative innovation between patents and standards has a realistic public policy basis. On February 15, 2020, the Chinese government issued a document,^[66] Article 3 of which stipulates that patent applications and trademark registrations related to the prevention and treatment of COVID-19 shall be given priority examination upon request. Subsequently, the State Intellectual Property Office issued a patent grant notice on August 11, 2020 which granted a patent for "a new recombinant coronavirus vaccine using human replication-defective adenovirus as a carrier" (Patent Application No. 2020193587.8). This is the first patent for a COVID-19 vaccine in China, and the applicants are the Military Medical Research Institute of the Chinese People's Liberation Army Academy of Military Sciences and Kangxino Biological Co. At the end of 2020, 32 patents on COVID-19 vaccines have been published in China, and 3 have been granted. However, China is also promoting the standardization of COVID-19 vaccine development and application, and has implemented technical guidelines throughout the process of vaccine development and application. From the domestic perspective, there are strict legal, regulatory, and technical standard requirements for the marketing and application of vaccines. Before a vaccine can enter clinical trials, three aspects of research must be completed: research on pharmacological aspects, research on efficacy, and research on safety. For each aspect of vaccine development, there are corresponding technical specifications to follow, and these regulations and technical requirements are in line with the requirements that are prevailing internationally by the WHO.

Patents and standards can synergistically play an important role in promoting R&D efficiency, and such a path is feasible. As aforementioned, China's SDA released five guidelines, including the

"Technical Guidelines for the Development of Vaccines for Novel Coronavirus Prophylaxis (Trial)," with reference to the target product characteristics issued by the WHO. Taking these Chinese guideline as an example, the clinical study of COVID-19 vaccines should focus on specific indicators related to the vaccine production process and the immunopathological response, in addition to the conventional observation indicators. This includes: (1) indicators related to the vaccine production process, such as safety observations related to new adjuvants/new excipients, vectors, and so on; (2) detection indicators related to immunopathological reactions, such as humoral immunity and/or cellular immunity related to the mechanism of ADE/VED occurrence. The method of the above observational content should be retrieved from no less than 2,000 relevant patents worldwide. In other words, the standard-setting and implementation of vaccines cannot be separated from the technical contents that are contained in the patents and that naturally fall into the scope of their claims.

4.3. The Collaborative Innovation between Patents and Standards Facilitates the Promotion of Public Productization of COVID-19 Vaccines

The IPR system is designed to stimulate the healthy development of innovation that is sustainable by means of empowerment and the balance of interests. The protection and enforcement of IPRs should facilitate technological innovation, technology transfer, and dissemination; should contribute to the common interests of creators and users of technological knowledge; and should contribute to the balance of socioeconomic welfare and rights and obligations. Granting IPR to the creator (or the transferee) of innovative knowledge results allows them the possibility to profit through use, license, or transfer, which can effectively stimulate the subsequent output of new knowledge. The consideration for granting IPR is the disclosure of information on innovative knowledge, and such disclosure also requires practicality so that competitors within the same industry can thoroughly understand and grasp its technical core, and can provide technical and tactical references for their own competitive strategies, thus promoting the application of technological innovation in society. Thus, the existence of IPR will not only be a means to hinder innovation but also a catalyst to promote technological innovation and technology diffusion.

Standards are a kind of "macro/strategic + micro/tactical" composite economic development method through mandatory or recommended ways to promote unified technical requirements in extremely detailed product areas. Companies that organize product production in accordance with technical requirements can effectively improve production efficiency and maximize product quality and stability, and can thus indirectly achieve the purpose of reducing the production cost of the whole industry, limit industrial duplication, and promote social welfare at the strategic level. Although the specific contents and behavioral adjustment methods of the IPR and standard systems are designed differently, they are designed to protect and stimulate innovation and to safeguard public interest, respectively. Standardization can alleviate the conflict between the monopolistic characteristics of patents and the essential attributes of a public good. Basic standards can have a significant impact, mainly because the unified nature of standards will eliminate conflicting product design lines so that market players naturally provide standardized products. It can be argued that there is complementarity between IPRs and standardization-related legal norms.

Objectively speaking, the exclusivity of a COVID-19 vaccine patent conflicts with the attributes of the vaccine as a public product. Unlike other products, the degree of IP protection in the pharmaceutical industry is one of the most extensive and stringent in the world, with rights and interests in intellectual achievements covering all aspects from raw materials to production, storage, and transportation. This is attributed to the relatively high R&D and marketing costs of pharmaceutical products. As an important component of pharmaceutical industry products, the development and promotion costs of vaccines are directly influenced by the level of economic development of a country or region. Countries with insufficient R&D and production capacity face accessibility problems in terms of both production and price of newly developed vaccines, but this should not hinder the case for vaccines to become global public goods. The ultimate goal of developing a COVID-19 vaccine is to make a significant contribution to the equitable protection

and promotion of the well-being of all human beings worldwide.^[67] The COVID-19 pandemic is having a devastating impact on many important aspects of both society and individual lives, not just on public health and economics, and decisions about distribution and prioritization cannot be made based on public health science or economics alone.^[68]

There are two key points for the effective control of the COVID-19 pandemic: a strong commitment to the development of technologies that prevent and treat the disease, and the need for such technologies to be equitably distributed. Costa Rica's proposal to create a "Technology Access Pool for the Fight Against the 2019 Coronavirus Epidemic" deserves serious consideration. The main body of the Costa Rican initiative, which would go some way in alleviating conflicts over the distribution of knowledge on COVID-19 vaccines, addresses a key issue for vaccines to become public goods; namely, the broad access to technology. A fast-track and equitably licensed clearinghouse has the potential to accelerate scientific discovery. This technology access pool mechanism also has the potential to facilitate equitable and affordable access to potential health technologies by mobilizing the largest global manufacturing capacity, as it will enable interested and qualified development subjects, producers, and service subjects to either license or become licensed IP on an equitable basis in a non-exclusive manner.^[69] Constructing a system of standards for vaccine R&D and distribution by multiple players and letting these standards direct the distribution of benefits, like a social contract, will ultimately land on the point of considering global public interest without discouraging innovation by R&D players. This, then, requires the application of a holistic way of thinking to propose systematic solutions.

5. Preliminary Proposals for Solving the Legal Dilemma of Patenting Covid-19 Vaccines by a Collaboration between Patents and Standards

5.1. International Legal and Public Policy Support is Needed to Alleviate the Legal Dilemma

From the perspective of a macro strategy, international cooperation is indispensable for the development of COVID-19 vaccines to combat the pandemic. It is necessary to establish a new model of long-term cooperation to facilitate a continuous and non-separated process from basic research to applied research and industrial development.^[70] The ability to grant IPR to innovations is not the main obstacle to the diffusion of anti-epidemic products; it is factors such as inefficient medical and procurement systems and inadequate funding that are the focus of global efforts to strengthen global health systems. Existing multilateral platforms in the vaccine field typically include vaccine development and production mechanisms, such as GAVI, DCVM, and CEPI, and vaccine distribution policy mechanisms, such as the WHO and UNICEF. It is particularly important to highlight the Global Influenza Surveillance and Response System, which serves as a network of laboratories across 110 countries, and is almost entirely funded by governments or foundations for the production of influenza vaccines. Medical experts from around the world meet annually to analyze and discuss the latest data on emerging influenza strains to determine which strains should be included in each year's vaccine. In the context of the outbreak of COVID-19 and the intensification of vaccine development in countries around the world, in order to prevent commercial pharmaceutical companies from using patent protection to privatize and lock-in knowledge sharing, the model for influenza vaccine development can be referred to by establishing international foundations or co-funding vaccine development by individual national governments to reduce the R&D costs of pharmaceutical companies, thus reducing the reliance of vaccines on patent protection to generate economic benefits. In April 2020, the WHO released the "Target Product Profiles for COVID-19 Vaccine" and several other regulatory documents. These standards provide direction for the WHO to further guide the development of COVID-19 vaccine candidates. The target audience for the WHO's internal standards include vaccine developers, manufacturers, distributors, and national (regional) regulators. The WHO will also provide scoring guidelines to promote consistency and predictability in evaluations.^[71] This process will require international collaboration, and as the demand for global infectious disease control grows with globalization, a few countries alone will not be able to solve the entire problem. It will require the participation of

other sovereign countries to work together to finance global infectious disease control by promoting collaboration. The gap between what many developing countries need and what they can provide in terms of funding and public management has remained wide for decades, and the COVID-19 pandemic will only make this situation worse.^[72]

At the international level, a mechanism should be built for the mutual integration and coordination of standards and patents based on a knowledge exchange platform. Countries should work together to ensure that important technologies, IP data, and expertise on vaccines are widely shared. Both timely and public news on the development trend of IPR and standardization in the industry should be published to accelerate the formation of regional standardization and coordination mechanisms, encourage companies to indirectly or implicitly incorporate their own IPR into technical standards in key technology areas, and guide domestic companies to proactively use IPR and anti-unfair competition/anti-trust legal tools to prevent IPR holders from abusing their market dominant power developed during the process of drafting standards. The TRIPS Agreement sets out the basic principles and measures to prevent IPR abuse in Articles 8.2 and 40.2. In Article 8.2, members are encouraged to take measures to prevent IPR holders from abusing their rights or from taking actions that unreasonably restrict trade or adversely affect international technology transfer. Although the TRIPS Agreement does not adopt more stringent measures to regulate the abuse of rights by IPR owners, it gives each member the right to legislate on their own. Therefore, this provision can be actively used to adjust the anti-trust law enforcement policy in a timely manner, according to the situation of industrial development, so as to provide room for the development of standards to survive while curbing anti-competitive behaviors of the pioneering standard-controlling companies.^[73] The COVID-19 vaccine market is valued at around \$100 billion, yet the value of the corresponding vaccines will exceed trillions of dollars in the future when human beings face various new and unknown infectious diseases. Therefore, COVID-19 vaccines are likely only the beginning, and it is difficult to paint a full picture of the more serious challenges and opportunities that lie ahead. In response, countries, organizations, and companies must be prepared to create new systems and apply them efficiently to combat public health threats.

5.2. Building A Chartered Innovation Community Based on Contractual Industrial Alliance

With the development of world economic integration and the intensification of international competition, companies' patent pooling is a successful industrial competition paradigm in high-tech industries such as electronics, information technology, communication technology, and biopharmaceuticals.^[74] Converting patented technologies into standards is an effective means to cope with knowledge spillover that leads to disputes over rights and interests, and is also beneficial in solving the problem of IPR for collaborative innovation. In a sense, the incorporation of patents into standards is a way to expand the patent alliance, which has a lower and more convenient access thresholds for market participants outside of the alliance, and minimizes the risk of infringement on the IPR of all parties in the alliance. In the process of R&D, collaborative innovation organizations have better internal division of labor and innovation coordination than the R&D of individual projects. It is also easier for the relevant collaborative organization's subjects to disclose patent technology when they participate in the formulation of standards. Technology alliances can take various forms, ranging from the looser forms of memoranda of understanding, strategic consensus, and R&D collaboration to the tightest forms of joint ventures, bona fide equity participation, and mutual shareholding.^[75]

In the first half of the 21st century, the rapid changing of the times has required us to take a hard look at the social contract that exists between science and society. This contract is a form of responsibility that is chosen, authorized, and owned by society. In collaborative innovation organizations, the synergistic relationship between members is based on a contract, both formal and informal.^[76] In general, the vocation of science also requires the vaccine industry to determine whether such a contract can be a reasonable and acceptable norm for its social responsibility to be effectively fulfilled.^[77] In forming such a contract between society and science, science is asked to provide reliable knowledge and to communicate its findings to the public.^[78] From both the

theoretical and practical perspectives, Boilerplate Agreements (BoAs) for licensing proprietary technologies facilitate the development of biotechnology industries.^[79] The organization and mode of operation of new vaccine developments and industrialization should be further opened up from contractual "industry alliances" to chartered "innovation communities." The GAVI, WHO, and CEPI are leading a multilateral mechanism, known as the COVAX program, to improve the efficiency of vaccine development, and several international organizations are playing a key role in this effort to provide the foundation for rapid vaccine production. The COVAX program could improve the efficiency of vaccine development, and is a powerful initiative. The COVAX program could improve the efficiency of vaccine development, and is a powerful initiative. Subsequent extensions of this collaborative mechanism to the front-end vaccine development phase could be explored.

Some scholars have studied the cumulative innovation effect model of competitive patent pools based on different technical standards, and found that a company's R&D investment can be viewed as game behavior. Further, in the case of competitive patent pools in an industry, the amount of a company's R&D investment is influenced by competitors' R&D investment, which will affect whether companies participate in patent pool construction, patent pool rule-making, the relationship between new patents and old ones in the patent pool, and so on. To govern the IPR of collaborative innovation organizations and improve the collaborative innovation IP rules, we should realize the evolution from episodic agreements to continuous rules and charters. The members who join an alliance, such as universities, research institutes, companies, and so on, must abide by such intra-alliance rules, which rise to be the charter of a collaborative innovation organization, which is similar to a country's "constitution." The poor adaptability of the COVID-19 vaccine market and the collaboration of patents and standards for the vaccines to achieve synergistic development requires, in addition to the provision of financial support, the delineation and establishment of a standard-system architecture for vaccine R&D, promotion, and application; the formation of a basic platform for innovation communities; and the realization of a stable supply and deployment of public products for COVID-19 vaccines.

5.3. Upgrade the SEP System in the Open Innovation Pattern

Facing the severe situation of public health and safety around the world, discussion of the standard and patent coordination mechanism is complex as it includes not only prior coordination in the process of standard-making, revision, and implementation, but also post-event coordination through judicial means after conflicts and disputes arise. Further, it includes not only the coordination of IP conflicts in national/local standards but also the coordination of conflicts arising from IPR in group standards, enterprise standards, and de facto standards. Objectively, the rules related to public goods must be infiltrated into the rules of SEPs—at least in the face of a big event that involves the fate of mankind—and the system that deals with the crisis needs to be upgraded to an SEP "version 2.0" for the benefit of all mankind rather than just from the optimization of the FRAND principle of safeguarding the interests of industrial development. The public good attributes of the COVID-19 vaccine need to be clearly reflected in the rules of patent-standard collaboration, and the FRAND principle should be adopted for the licensing system of essential medical patents to alleviate the confusion caused to patients by medical patent owners' refusal to issue licenses to voluntary licensees on FRAND terms, or as an effective alternative to issuing compulsory licenses.^[80] We need to break the confinement of SEP formalism and upgrade openness to form a synergistic development system of patents and standards that actively intervene without fear of generating illegal monopolies. As long as the scope of the agreement is truly limited to standards development and keeps R&D, distribution, and marketing separate from each other, the anti-trust risks faced by companies that develop compatible standards are relatively small. The Global Influenza Research Network, which has successfully provided information needed to produce seasonal influenza vaccines for decades, is a strong example of high-cost, high-risk open science.

Open innovation does not provide additional market rewards but rather changes the way science

is practiced and knowledge is generated. It is critical to ensure equitable and affordable access to existing and new health technologies. In accordance with past practice, the ISO does not intervene in substantive patent-related matters and is not responsible for identifying or confirming the status, attribution, or distribution of benefits of any patent rights contained in a standard. All details of patent rights involved in the preparation of a standardized document are set out in the introduction and/or in the ISO filing list. In the face of the current COVID-19 pandemic, it would be appropriate to show more proactive action on the specific matter of how the core patents arising from vaccine development should be harmonized and aligned with the relevant rights and interests.

6. Conclusions

With the unprecedented pace of COVID-19 vaccine development, the global fight against the pandemic is at its dawn. Perhaps we need an international consensus stating that, for the sake of public health for all, vaccine development needs a new and innovative rule structure that can balance the economic benefits with the basic human rights of vulnerable communities.

Global collective R&D initiatives for new vaccines beyond the efficiency of chip R&D can be seen as a reboot of the collective consciousness of all humanity in the new century. During the COVID-19 pandemic, countries have worked to address the IPR dilemmas and paradoxes that face COVID-19 vaccines by promoting the creation of alternative incentives. Entities such as the CEPI and COVAX, and the C-TAP and non-entities were established as a result of these efforts. Despite the conflicting purposes and nature of the IPR and standards system design, IPR and standards can be synergistic when viewed in the context of jointly advancing knowledge and innovation. The consensus on Internet applications and carbon emissions cannot be reached without the massive amounts of cutting-edge technologies and standards embedded in them as the basic supporting elements without much consideration of political factors and traditional biases. Specifically, in the field of vaccine R&D and usage, the institutional guarantee for the synergistic development of patents and standards should be followed up and improved.

We believe that the tension between innovators and implementers should be resolved in a free market environment, with voluntary negotiation and efficient interoperability in the face of the distribution of benefits from the R&D results of COVID-19 vaccines. In other words, in the long term, we should use patents as a “ring” and standards as a “chain,” and multiple actors should build an “innovation community” for human public health safety in future.

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