



Pledging Patent Rights for Fighting Against the COVID-19: From the Ethical and Efficiency Perspective

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Abstract

In response to the great crises of the COVID-19 coronavirus, virtually all new technologies protected by patent rights have been used in practice from diagnostics, therapeutic, medical equipment, and vaccine to prevention, tracking, and containment of COVID-19. However, the moral justification of patent rights is questioned when pharmaceutical patents conflict with public health. This paper proposes a revised approach of deciding on how to address the conflicts between business ethics and patent protections and then compares the different mechanisms of clearing patent thickets. Our findings highlight that patent pledges may not only contribute to achieving the maximized substantive justice of the public but also help patent pledgors fulfill procedural justice. The advantages of patent pledges have attracted many patent holders to make public statements during the COVID-19 pandemic. In contrast, the disadvantages of a free license may make patent pledges not sustainable for a long time without the related supporting measures. Our findings will be helpful for policymakers or company managers to make an appropriate decision on rationally utilizing patent portfolios for fighting against public health crises.

Keywords Patent pledges · Distributive justice · COVID-19

Introduction

A novel disease, an "emerging coronavirus disease 2019 (COVID-19)" named by the World Health Organization (WHO), has spread abruptly across the globe since the end of 2019. The WHO declared COVID-19 as a pandemic due to the high virulence and mortality on 11 March 2020. In contrast with previous coronavirus outbreaks, such as SARS in 2002 and MERS in 2012, the COVID-19 has spread more widely and rapidly but suffered from a shortage of known available treatment and vaccines in the early days of the outbreak. On 11 April 2021, more than 135.06 million cases of COVID-19 were confirmed cumulatively, with 2.92 million deaths worldwide (WHO, 2021a). Early diagnosis is necessary for quarantine, while drug development is significant

for the treatment of COVID-19 (Nascimento et al., 2020). More importantly, the COVID-19 pandemic will not substantially recede if effective vaccines cannot be successfully developed and equitably distributed across the globe (Rabaan et al., 2020). However, some countries attempt to secure preferential access to new drugs or vaccines, called "treatment or vaccine nationalism" (McMahon, 2020), while others suffer from the inequitable distribution of such drugs or vaccines. From an individual perspective, patients who are very sensitive to the price of new medicines or vaccines will be priced out of the market (Gewertz & Amado, 2004). How to make sure the equitable global distribution of diagnosis, treatments, and vaccines is vital in fighting against the COVID-19 pandemic.

In a positive response to the great crises of the COVID-19, virtually all innovative technologies have been used in practice, from diagnostics, therapeutic, medical equipment, and vaccine to prevention, tracking, and containment of COVID-19 (Contreras et al., 2020). Meanwhile, many health-related technologies protected by patent rights, such as diagnosis, treatments, and vaccines, are called patented health technologies (McMahon, 2020). As is well-known, patent protections benefit patients by encouraging organizations to invest in new drug research and development

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(Gewertz & Amado, 2004) and drive economic growth by commercializing valuable inventions and preventing infringements (Kogler et al., 2018). It is rational that patent holders seek to maximize the profits of utilizing their patent portfolios under the efficiency theory. However, patent rights' moral justification or distribution justice is often questioned when pharmaceutical patents conflict with public health (Gewertz & Amado, 2004). It is worth further discussing the moral justification of health technology patents in the period of COVID-19 pandemic. To address the COVID-19 crisis, companies should carefully consider balancing the tension between business ethics and patent protections in the process of utilizing their patents, and then make a more rational decision.

Fortunately, increasing companies in fighting against COVID-19 tend to make patent pledges to restrict their patent enforcement. A patent pledge generally refers to a public statement and commitment made by patent holders, who are willing to out-license relevant patents to the unrestricted or restricted public under certain conditions or unconditional situations for no monetary or reasonable compensation (Ehrnsperger & Tietze, 2019). However, the term "patent pledge" is so vague that it has been labeled diversified labels in the extant literature (Contreras et al., 2020), such as non-royalty commitments of patent holders, primary access commitments (Singh, 2018). Scholars tend to adopt the patent licensing taxonomy to understand better what patent pledges are. For instance, Ehrnsperger and Tietze (2019) categorized patent pledges into eight types from three dimensions: accessibility, compensation, and conditions.

In recent, two new patent pledges, Open COVID Pledge and Open COVID-19 Declaration emerge, which have been rapidly formed in the process of fighting against the COVID-19 pandemic. To facilitate the development and deployment of health technologies in the urgent pandemic, the Open COVID Coalition developed the standard terms of the open COVID license. Moreover, GenoConcierge Kyoto, Inc. created the standardized terms of the Open COVID-19 Declaration. The standardized terms make either the Open COVID Pledge or Open COVID-19 Declaration different from previous pledges with individual provisions. Therefore, Contreras et al. (2020) called these pledges with standardized terms as coordinated pledges.

It is an open topic of how to relieve the mounting tension between patent rights and business ethics in fighting against public health crises. However, the literature on why a patent holder submits a patent pledge remains scarce. To close this gap, the paper aims at contributing to the research on how and why an increasing number of companies tend to commit patent pledges from a business ethical perspective. We endeavor to address the following questions: What is the current situation in patent pledges related to COVID-19 health technologies; What are the advantages or disadvantages of

coordinated patent pledges in the process of fighting against COVID-19; How to make a rational decision on the balance between patent protection and business ethics for companies, especially for small and medium-sized enterprises.

In doing so, we collected patent pledges submitted during the period of the COVID-19 pandemic. Oppenheimer et al. (2015) proposed a novel analysis framework for combining the efficiency theory and business ethics theory to understand intellectual property rights. To further explore why companies make patent pledges, we revise the research framework proposed by Oppenheimer et al. (2015) and focus on the combination of efficiency and ethical analysis on patent strategies from the perspective of both society and organizations.

The structure of this paper is organized as follows. After the introduction, the paper presents the literature review "Literature Review". The research framework of this paper is described in "Research Framework", and then the efficiency and ethical analysis on patent pledges are shown in "Efficiency Analysis". The discussion is in "Discussion", and the conclusions and limitations of this paper are presented in "Conclusions".

Literature Review

The literature review comprises two parts: the equitable access to patented health technologies for COVID-19 and the mechanisms of trekking through patent thickets.

Equitable Access to Patented Health Technologies

There is a hot topic of how companies take the social responsibility for providing equitable access to life-saving healthcare (Gewertz & Amado, 2004). Patented health technologies are vital for fighting against a global pandemic, especially in diagnostics, drugs, and vaccines.

First, testing and diagnosis of infections are essential during the early outbreak period. In recent years, nucleic acid testing has become a crucial clinical diagnosis tool (Soini et al., 2008), and gene patents have attracted specific concern due to ethical and social issues. Soini et al. (2008) discussed the challenges of gene tests and genome-based diagnostics in the patent field. They suggested the national healthcare system should make sure anyone needs equitable access to genetic testing. It is usually recommended to test the nucleic acid of COVID-19 coronavirus for suspected infection patients in clinical practice (Adhikari et al., 2020). However, some patent holders asserted patent rights against manufacturers even in the period of the pandemic. For instance, Labrador Diagnostics LLC, which got two patents from Therasanos company, claimed its patent rights against BioFire Diagnostics that provided diagnostic testing

for COVID-19. Great concern about patent holders who may limit the availability of diagnostic testing in the period of the health pandemic is rising (McMahon, 2020).

Second, equitable access to effective drugs as quickly as possible is required. There are no specific drugs for COVID-19 coronavirus when the pandemic started at the end of 2019. In general, developing a novel anti-viral drug is an available route to meet the current medical need. However, drug repurposing for the therapy of COVID-19 is a fast and cost-effective method that can effectively overcome the shortcoming of developing novel drugs. It has been proved to be a successful strategy in response to the current pandemic due to the decrease in mortality rate and improving patient health status (Cusinato et al.). Some patented drugs used in medical practice have been found new treatments for COVID-19. Most of the therapeutic agents are protease inhibitors or monoclonal antibodies and interferons, while some Chinese folk medicines with anti-viral properties are also used in the COVID-19 pandemic (Nascimento et al., 2020). For instance, Remdesivir, an anti-viral prodrug developed initially to treat Ebola virus disease, is detected that it has broad-spectrum activity against coronaviruses (Musa et al., 2020). Besides, Kaletra, a combination of lopinavir and ritonavir that AbbVie developed, is an effective treatment for COVID-19, though it is often used to treat HIV. On 9 March 2020, AbbVie committed that any potential barriers of patents on Kaletra would be removed from generic manufacturers (Contreras et al., 2020). Some pharmaceutical companies have made patent pledges to drop their patent rights on repurposing drugs during the COVID-19 pandemic.

Third, effective and available vaccines can recede the COVID-19, and the world will recover ultimately from the pandemic. On 13 April 2021, there are 88 vaccines in clinical development and 184 vaccines in pre-clinical development (WHO, 2021a). Moreover, the Strategic Advisory Group of Experts on Immunization (SAGE) has recommended several vaccines against COVID-19, such as Janssen Ad26.COV2.S vaccine, AZD1222 vaccine, and mRNA-1273 vaccine (WHO, 2021b). Patent right is one of the critical factors determining global access to efficacious vaccines (Clark et al., 2011). To combat the pandemic, Moderna, Inc., which developed the mRNA-1273 vaccine with the Vaccine Research Center, submitted a statement that it would not assert related patents against making vaccines.

The Mechanisms of Trekking Through Patent Thickets

Twenty years ago, Heller and Eisenberg (1998) introduced the famous hypothesis patent "tragedy of the anti-commons" in *Science*, which refers to that more fragmented and overlapping patent rights, namely patent thickets, may lead to fewer useful drugs for promoting public health in

the pharmaceutical industry. To pursue the maximized financial return, private firms that owned complementary patents tend to assert patents against potential users. In general, downstream manufacturers have to obtain a set of voluntary licenses from multiple patent holders to commercialize new technologies (Bakenov, 2017). If manufacturers also own valuable patents, cross-licensing agreements can be used, recommended by Bosetti and Vereeck (2012), to solve overlapping patents. However, if manufacturers fail to trek through patent thickets, a significant number of patents may stifle life-saving innovations in the process of research and product development. Thus, there is a growing concern about patent thickets that may hamper technology innovation (Yuan & Li, 2020). For instance, Schmidt (2007) pointed out a patent thicket would emerge in the new biotech RNA interference (RNAi), a novel approach of selectively turning genes off using short double-stranded RNA molecules, which leads to RNAi would never succeed therapeutically. In particular, whether patent rights hinder the R&D on therapies, vaccines and drugs have drawn wide attention from both scholars and policymakers during the period of the COVID-19 pandemic (Contreras et al., 2020).

Indeed, there are various mechanisms of trekking through patent thickets, which can help avoid a patent tragedy of the anti-commons. The first solution to navigating patent thickets is compulsory patent licensing. In general, a potential user should negotiate with patent holders for a voluntary license on reasonable terms within a given period. However, a voluntary patent license is hard to obtain if such negotiation fails, which may trigger a compulsory license. As a well-known mechanism, compulsory licensing is an effective legal framework for preventing patent rights abuses. According to the Paris Convention for the Protection of Industrial Property (Paris Convention), *each country has the right to take the legislative measure of granting compulsory licenses to prevent the abuse of the exclusive rights conferred by patents.*

Moreover, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) also *permits governments to authorize compulsory licensing on reasonable commercial terms in certain circumstances.* In this context, most countries have established the system of compulsory licensing in their national patent laws. For instance, either the German or French Patent Act provides five exceptional cases for compulsory licensing, in which a critical situation is for public health. It is worth noting that Israel's government issued a compulsory license for the medicinal treatment Kaletra in response to the COVID-19 pandemic, according to the Patent Law of Israel, on 18 March 2020 (Contreras et al., 2020).

The second mechanism of clearing patent thickets is to construct a patent pool, which refers to a set of agreements between two or more patent holders to license a package of essential patents to one another and any third party that

is willing to pay the associated royalties (Verbeure et al., 2006). In general, cross-licensing agreements are recommended to solve overlapping patents in a given industry (Bosetti & Vereeck, 2012). However, patent pools have an essential advantage. Many complementary patents are consolidated into a single source, which may be an effective way of overcoming patent thickets (Contreras, 2018). The U.S. Patent and Trademark Office (USPTO) has suggested that patent pools can be used to clear patent thickets (Clark et al., 2001). As a result, many organizations make great efforts to set up various patent pools, which leads to patent pools have been widely utilized to clear patent thickets in industries ranging from telecommunications to aircraft throughout the last 150 years (Clarkson & DeKorte, 2006). In particular, the WHO proposed setting up a patent pool to address the potential problem of patent fragmentation in combating coronavirus (Verbeure et al., 2006). On 29 May 2020, the WHO officially launched a COVID-19 Technology Access Pool (C-TAP) to make health technologies. The purpose of setting C-TAP is to contribute the patents related to developing effective therapeutics to the Medicines Patent Pool (MPP) and then sublicense these patents to manufacturers.

The third approach of trekking through patent thickets is patent pledges. In the era of open innovation, many organizations start to rethink their patent strategies, often labeled open patent strategies. For instance, IBM had announced not to assert 500 patents against the development and distribution of open-source software in the early 2000s. At the same time, Tesla also committed not claiming patent rights if any party used its patents in good faith in 2014. Such a public statement of not asserting patent rights made by patent holders has triggered a hot debate in the academic and practical world. Despite the variations of "patent pledges", one of the essential characteristics is that the potential uses can utilize pledged patents without litigation threat over at least a period. More importantly, patent pledges are irrevocable and legally enforceable once committed (Allen, 1983).

Moreover, ultimately giving up patent rights and outright contributing inventions to the public domain may be another option for patent holders. Creations without patent protections will become common resources. In this sense, the famous "tragedy of the commons" proposed by Hardin (1968) will emerge, which refers to a shared resource that would be overused and depleted if it is unrestrainedly used. Assigning appropriate ownership rights to resources is an effective approach to clearing the tragedy of the commons, which leads to owners maximize their returns by restricting excessive usages. Patent rights improve the practical uses of relevant inventions and avoid the tragedy of the commons by privatizing inventions.

Fragmented and overlapping patent rights may result in an under-utilization of inventions, while ultimately giving up patent rights will lead to the overuse of creations. Therefore,

neither giving up patents nor excessively asserting patent rights will benefit public health and social well-being. This dilemma is likely to occupy a middle ground between exclusive patent rights and the public domain. However, little literature discusses how increasing firms tend to commit patent pledges from a business ethical perspective. How a company selects a suitable patent strategy is very important for clearing patent thickets. Notably, a company should decide to better balance private profit and social well-being during a disease pandemic.

Research Framework

The purpose of this paper is to explore how to make a rational decision on utilizing patent rights for fighting against COVID-19. In doing so, we adopt the research framework proposed by Oppenheimer et al. (2015), which is helpful for managers in making decisions on how to address ethical conflicts systematically. However, we modify the research framework proposed by Oppenheimer et al. (2015) in two aspects. First, we analyze enterprise business ethics at a societal level and organization level, which leads to our ethical framework is composed of four elements: common good, utilitarianism, distributive justice, rights, and duties. The original ethical framework proposed by Oppenheimer et al. (2015) consists of six elements in which both virtue and caring are included from an individual perspective. As the paper focuses on studying how an organization makes a rational decision for fighting the COVID-19 crisis, it is more suitable to research enterprise business ethics at the social and organizational levels instead of an individual dimension.

Second, we disassemble distributive justice into substantive justice and procedural justice. Notably, the paper highlights the importance of procedural justice in the ethical analysis framework. According to the justice theory proposed by Rawls (Resnik, 2003), a just society should follow two fundamental principles of justice: the liberty and difference principle. The first principle, liberty, emphasizes that everyone has an equal right to equal fundamental liberties. In contrast, the difference principle is the second principle in which inequalities can be justified when the most significant benefit is the least advantaged society. Moreover, the liberty principle takes precedence over the difference principle. Patent right is not the essential liberty of the people, which leads to it will not be protected by the liberty principle but is subject to redistribution by following the difference principle (Gewertz & Amado, 2004). In this context, procedural justice is vital for any adjustments in both patent rights and the wealth accumulated from patent royalties. Besides emphasizing a set of exclusive rights, patent rights also focus on procedural fairness based on individual equality (Paul & Mukhopadhyay, 2010). The result of redistribution can be

called substantive justice in a society, while redistribution is named procedural justice. As a result, Simms (2004) proposed an essential framework that studying business ethics should be substantive and process levels.

Table 1 depicts the modified research framework of combining efficiency and business ethical analysis. Either efficiency or ethics study can be conducted from the view of both society and organization.

Efficiency for Society

From a societal perspective, efficiency analysis consists of two essential factors: the legal system and societal well-being. Making decisions by a company usually depends on the efficiency of the legal system. The justification of patent rights has been hotly discussed in the extant literature. A patent is a right to exclude others from practicing an invention during a given period, which the government grants to the patent holder. Patent rights are to reward patent holders for their intellectual labor, and thereby the incentive mechanism may encourage innovators to carry on their creative works. Otherwise, the human community may suffer from no new inventions (Yung, 2009). Thus, a patent institution is entailed in balancing patent holders' interests and public interests in health care (Gewertz & Amado, 2004).

The second factor in the process of efficiency analysis is the societal well-being of a given society. The critical criteria are Pareto optimality and welfare maximization for evaluating societal well-being (Oppenheimer et al., 2015). Pareto optimality prefers an ideal situation in which the well-being of one person could not be improved without harming others. The economy is at a Pareto optimum if there is no way to enhance society's well-being further. Therefore, a business decision made by a company should not harm any entity or individual in the process of Pareto improvements.

Moreover, the welfare maximization of a given society is often used to evaluate societal well-being, which is to calculate the maximizing outcome of the net gain to all parties. A business decision made by an organization should be efficient if its revenue is more significant than any loss to others. In theory, such efficiency can be called a potential Pareto improvement or Kaldor–Hicks efficiency (Oppenheimer et al., 2015).

Table 1 Framework of combining the efficiency and ethical analysis

	Efficiency analysis	Ethical analysis
The perspective of society	1. Legal system 2. Societal well-being	4. Common good 5. Utilitarianism
The perspective of an organization	3. Costs and revenues	6. Procedural justice 7. Substantive justice 8. Rights and duties

Efficiency for Organizations

The most common approach of measuring companies' efficiency is to calculate the costs and revenues of an individual company. A rich literature studies the efficiency for firms: how a firm can minimize the cost at a given output level or maximize the output at a given cost level (Oppenheimer et al., 2015). A decision to pursue efficiency made by a company relates to its business strategy of maximizing profits.

Ethical Analysis From a Societal Perspective

A justicial society should consider the common good and ensure the welfare of everyone. From a societal perspective, the ethical analysis consists of studying the common good and utilitarianism. The similarity between the common good and utilitarianism is to emphasize the benefit of a community or society. However, there is also a difference between the common good and utilitarianism. The common good analysis highlights all members of society should be considered from a holistic point of view, while the utilitarianism approach gives priority to the majority's interests. According to the opinion of Lowry and Peterson (2012), utilitarianism can be defined as a decision that should be made if and only if "the good surplus consequences over bad ones is at least as great as that of alternative actions". As a result, utilitarianism is often understood as "the greatest good for the greatest number" (Oppenheimer et al., 2015).

Ethical Analysis From an Organizational Perspective

Oppenheimer et al. (2015) proposed that organizational business ethics analysis should consider distributive justice, rights, and duties. In general, distributive justice analysis evaluates whether a distribution in society is fair by measuring the distribution of costs and benefits. Most literature on business ethics focuses on the results of distribution, namely substantive justice. However, procedural justice in the process of distribution is often ignored. To close this gap, we analyze distributive justice from two dimensions: substantive justice and procedural justice for a company.

On the other hand, rights and duties are the critical factors of ethical analysis for a company. Notably, the concept of "right" refers to the moral right of a company making a decision, which may include legal right or natural right. The duty analysis emphasizes how to protect the moral rights of others when a company makes a business decision. There is a dilemma about balancing legal rights with other rights for pharmaceutical firms (Oppenheimer et al., 2015). The success of developing medicine depends upon patent rights protection (Bosetti & Vereeck, 2012). Pharmaceutical firms

can fully utilize patents to achieve maximized profits. However, it may be more beneficial to the common good if firms give up some rights from a moral perspective.

Patent Pledge Analysis

To explore the mechanism of patent pledges for the COVID-19, we collect all types of patent pledges, including coordinated pledges and unilateral pledges. We collected 29 patent pledges at the official website of open COVID pledges (<https://opencovidpledge.org>) and obtained 101 samples of Open COVID-19 Declaration (<https://www.gckyoto.com/covid19>). Moreover, we logged the IPR Pledge Database at <http://www.pijip.org/non-sdo-patent-commitments> and retrieved five unilateral patent pledges for fighting against COVID-19. To avoid sample duplication, we checked these samples manually and found Fujitsu Limited submitted both open COVID pledges and open COVID-19 declaration at the same time. In total, 135 organizations had made patent pledges by 31 December 2020, in which there are 29 open COVID pledges, 101 open COVID-19 declarations, and six unilateral patent pledges.

Patent holders actively submitted patent pledges but strictly limited the purpose of using pledged patents in preventing, diagnosing, treating, and containing COVID-19. There are more than one million pledged patents. However, most pledged patents can be merely applied in the field of preventive measure. For instance, SAP, a software company that focuses on machine learning and advanced analytics technologies, created the Corona-Warn App in cooperation with Deutsche Telekom to trace the infection chains of COVID-19 in Germany. The number of patent pledges concerned with diagnostics, drugs, and vaccines is minimal. Table 2 depicts patent pledges on diagnostics, treatments, and vaccines in response to COVID-19.

Table 3 shows that there are various types of patent pledges for the COVID-19. For instance, the Open COVID Coalition provides three categories of licenses for taking patent pledges. The most common form is standard Open COVID Licenses (OCL-Licenses), in which OCL-P v1.1 is especially applicable to patent pledges. The second category of licenses is OCL-Compatible Licenses (OCL-Compatible), which can be compatible with custom licenses and the existing licenses, such as MIT license and Apache 2.0 license. The third category is OCL-Alternative Licenses (OCL-Alternative), which may contain some special terms differentiated from OCL-P v1.1 and OCL-Compatible. To simplify patent pledge analysis, we compare the similarities and differences among unilateral patent pledges, Open COVID Pledge, and Open COVID-19 Declaration. Table 4 presents the results of the comparison.

There are many commons among unilateral patent pledges, the Open COVID Pledge and Open COVID-19 Declaration, such as goals, purposes, and behavior choice. To improve patent development and utilization, patent holders will not seek injunctive against any production activities of stopping the spread of COVID-19.

On the other hand, there are some differences among unilateral patent pledges, the Open COVID Pledge and Open COVID-19 Declaration. For instance, the applicable periods are different across patent pledges. The period of implementing the Open COVID Pledge is from 1 December 2019 to 1 year after the WHO declares the COVID-19 pandemic to have ended, but not beyond 1 January 2023. By contrast, the Open COVID-19 Declaration is available from the declaration date to the ending date on which the WHO declares the COVID-19 no longer constitutes a public health emergency. In unilateral patent pledges, however, the ending date is determined by pledgors, though patent pledges are valid during the period of the COVID-19 pandemic.

Moreover, there are various options for patent right limitation in unilateral patent pledges. Some patent holders offer

Table 2 Patent pledges on diagnostics, treatments, and vaccines

Patent holders	Types of pledges	Pledge date	Technology fields
AbbVie	Unilateral pledge	9 March 2020	Drugs
University of California Berkeley Innovative Genomics Institute	Unilateral pledge	29 March 2020	Diagnosis and treatments
Fortress and Labrador Diagnostics	Unilateral pledge	17 March 2020	Diagnostics
SMITHs Group	Unilateral pledge	21 March 2020	Medical equipment
Medtronic	Unilateral pledge	30 March 2020	Medical equipment
Oxford University	Unilateral pledge	8 April 2020	Vaccines, diagnostics, and remote monitoring
RADVAC	OCL-P v1.1	21 August 2020	Vaccine
New Jersey Institute of Technology	OCL-Compatible	22 August 2020	Diagnosis
OVSI	OCL-Alternative	23 August 2020	Medical equipment
Moderna, Inc	Unilateral pledge	8 October 2020	mRAN vaccine

Table 3 Comparison across unilateral patent pledges, Open COVID Pledge, and Open COVID-19 declaration

	Unilateral patent pledges		Open COVID pledge-patent (OCL-P) 1.1	Open COVID-19 declaration
Goals	To combat the COVID-19 pandemic and to bring it to an end as quickly as possible	Make a statement not enforcing related patents against manufactory	To speed the development and dissemination of the technologies needed to end the COVID-19 pandemic	To establish an environment of preventing the spread of COVID-19
Behavior choice	Make a statement not enforcing related patents against manufactory	Related patents owned by pledgors	Pledge granting a non-exclusive, royalty-free, worldwide, fully paid-up patent license, but not including sublicense right	Make a declaration without seeking any compensation
Objects	Related patents owned by pledgors	Related patents owned by pledgors	Related patents owned by pledgors	Intellectual Property Rights, including patents, owned by declarers
Purposes	To develop preventive measures, diagnostics, treatments, and vaccines for the COVID-19	Related patents owned by pledgors	Solely to diagnose, prevent, contain, and treat COVID-19	Any activities of stopping the spread of COVID-19, such as diagnosis, prevention, containment, and treatment of COVID-19
Term limitation	The term of patent pledges generally covers the period of the COVID-19 pandemic, but pledgors will determine the precise date	Related patents owned by pledgors	1 December 2019—one year after the WHO declares the COVID-19 pandemic to have ended, but not beyond 1 January 2023	Declaration date—the ending date on which the WHO declares the COVID-19 no longer constitutes a public health emergency of international concern
Right limitation	Not seek injunctive relief. However, the license rate takes many forms: free, or reasonable, and non-discriminatory	Related patents owned by pledgors	Not assert any regulatory exclusivity, Not seek injunctive or regulatory relief	Not seek any compensation, Not enforce intellectual property rights in any manner

Open COVID Pledge-Patent (OCL-P) 1.1 at <https://opencovidpledge.org/v1-1-ocl-p/>

Open COVID-19 Declaration at <https://www.gkyoto.com/covid19-1>

Unilateral patent pledges from the IPR Pledge Database at <http://www.pjip.org/non-sdo-patent-commitmen>

Table 4 Comparing the distributive justice among three mechanisms

		Compulsory licensing	Patent pools	Patent pledges
Substantive justice	Temporary injunction	No	Maybe	No
	Permanent injunction	No	Maybe	No
	Free license	–	–	Maybe
	Rational license	Yes	Maybe	Maybe
	Excessive compensation	–	Maybe	–
Procedural justice	Character	Government-authorized	Collective agreement	Commitment
	Procedure	Very complicated	Very complicated	Smooth

free licenses or do not seek any compensation, while others assert reasonable and non-discriminatory patent licenses. A reasonable royalty is different from the policy of "not seek any compensation" in the Open COVID Pledge and Open COVID-19 Declaration. Therefore, there are more alternative options to set the valid term or patent right limitation regarding unilateral patent pledges.

Efficiency Analysis

As a new phenomenon, making patent pledges has not been supported by national law or international treaties. Most countries have provided patent legal frameworks for protecting inventions to incent technology innovation. In most cases, firms actively assert patent rights and seek to implement high-priced patent licensing strategies. However, patent pledgors have initiatively given up some patent rights to achieve the opportunity of technology markets. Notably, both the Open COVID Pledge and Open COVID-19 Declaration do not assert patent rights against anyone who uses the pledged patents for fighting against the COVID-19. To some extent, patent pledges can help improve societal well-being from a societal perspective. The rationality of a patent pledge is that patent holders shift their strategies from traditional licenses to a more open strategy. The majority of patent pledgors do not seek a temporary or permanent injunction against patent usages over some time. Moreover, some patent holders even promise not to assert patent royalty under a specific condition for a certain period.

Especially, patent holders in Open COVID Pledge or Open COVID-19 promise not to seek any compensation and not enforce patent rights. Patent holders make an important business decision of giving up some patent rights, which can lead to societal well-being is improved without harming any entity or individual.

In the short run, patent holders will suffer from certain losses because some patent rights are given up in patent pledges. However, patent pledgors who pursue long-term development strategy or improving public health may achieve competitive advantages and cooperation opportunities in the long run.

Business Ethical

In general, the majority's interests in a community will be profoundly improved from a utilitarian perspective. For instance, either Open COVID Pledge or Open COVID-19 will benefit the common interests of all members in the period of the COVID-19 pandemic because any firm in the world can freely use the pledged patents without any restriction (Ehrnsperger & Tietze, 2019). However, patent pledgors cannot guarantee the common interests of all members are protected due to the diversity and complexity of patent pledges. The majority of patent pledges emphasize the applicable conditions in practice, which may be a restriction to a given technology field, or a particular territory, or a time limitation for a pledged patent. As a result, most patent pledges will be suitable for patent usages in the related condition, rather than all the cases. Making a patent pledge can be regarded as a kind of open patent strategy adopted by companies to relieve the tension between exclusive patent rights and societal well-being. Once an open patent strategy is selected, companies may make a patent pledge to open their patent license immediately. Thus, the process of making a patent pledge is entirely controlled by patentees instead of others from a procedural justice perspective.

More importantly, either Open COVID Pledge or Open COVID-19 has disclosed the standard terms at its official website can attract more small and medium-sized enterprises to participate in patent pledges fighting against the COVID-19. Patent holders should keep their promises that do not assert any compensation and enforce related patent rights against any activities of stopping the spread of COVID-19 once they submit pledge commitments. Thus, common interests will be preserved, and societal well-being in a community will be improved by making patent pledges because patent holders give up related patent rights to some extent from the perspective of substantive justice.

Discussion

In the period of the COVID-19 pandemic, how to balance the tension between patent protections and business ethics for companies is an open issue worth discussed. Our study highlights increasing companies tend to commit patent pledges that may take various forms for battling against the COVID-19. Companies making patent pledges will achieve distributive justice, including procedural justice and substantive justice, from a business ethical perspective.

Biomedical Ethics

Most health-related technologies, such as diagnosis, treatments, and vaccines, are concerned with biomedical ethics, making health technologies differentiated from other innovative technologies. Four principles of biomedical ethics, namely autonomy, beneficence, non-maleficence, and justice, are generally regarded as a universal guideline for biomedical ethics, which Beauchamp and Childress developed in the 1970s (Tsai, 1999). Notably, non-maleficence is recommended as a fundamental principle of the common morality by Beauchamp and Childress because any moral person could not reject this principle (Herissone-Kelly, 2011). The principle of non-maleficence emphasizes that anyone ought not to inflict harm or the risk of damage on others, namely "first, do no harm" (Clark et al., 2018). Hence, the principle of non-maleficence has become a norm of identifying the morally committed (Herissone-Kelly, 2011). The potential risks or harms may arise from using some technologies, which leads to the principle of non-maleficence has been hotly discussed in the extant literature, such as negative emotion, discrimination, and infringing on the independence or privacy of patients (Robillard et al., 2019). Interestingly, non-maleficence is also regarded as the core value of perceived morality in the business domain due to its unique moral value (Christen et al., 2014).

How to fairly and non-discriminatively allocate scarce medical resources is one of the critical ethical issues in the essential times of the COVID-19 pandemic. It will violate the bioethical principle of non-maleficence if the allocation of treatments or vaccines is in terms of wealth and power in a society. For instance, elites can receive COVID-19 treatment in hospitals sponsored by the government, while many patients in the poor and middle-class were turned away from hospitals without treatment in Bangladesh (Siraj et al., 2020). Moreover, some developed countries attempt to take precedence over acquiring drugs and vaccines for the COVID-19, which leads to the global

distribution of such treatments or vaccines is unequitable (McMahon, 2020). It violates the ethical principle of non-maleficence to give priority to one group of countries or people by depriving others. Hence, from a bioethical perspective, the healthcare system for the benefit of special people should not be reserved if it could be harmful to others in society (Siraj et al., 2020).

Patent holders can facilitate the supply of medical resources by commercializing health patented technologies, though states have played essential roles in allocating scarce medical resources. So far, many repurposing drugs for the COVID-19 have been successfully developed, and WHO has recommended several vaccines against the COVID-19. Patent pledges committed by patent holders, such as AbbVie, and Moderna, Inc., can help generic drug manufacturers reach free patent licenses, which will substantially increase the supply of drugs and vaccines for developing countries or the poverty population. The bioethical principle of non-maleficence can assist patent holders worldwide to make rational decisions on who should receive health patented technologies. Hence, companies making patent pledges can help eliminate discrimination against developing countries or the poor and address the issue of the unfair allocation of treatments or vaccines under the principle of non-maleficence.

The Advantages of Patent Pledges

Several alternative mechanisms can be used to clear patent thickets. From the perspective of efficiency analysis, patent holders who establish patent pools or are granted compulsory licensing may get more benefits than patent pledgors who give up the enforcement of patent rights in the period of the COVID-19 pandemic. Surprisingly, many patent holders tend to commit patent pledges instead of adopting compulsory licensing or establishing patent pools to fight against COVID-19. To explore the advantages of patent pledges, we compare three mechanisms of trekking through patent thickets from a business ethical perspective.

TRIPS provides the minimum levels of protecting intellectual property, including compulsory licensing besides general rules, for 164 member states in the World Trade Organization (WTO). Compulsory licensing systems across member states ought to be consistent with the provisions of Article 31 TRIPS, though they are diversified. Thus, the paper takes Article 31 TRIPS as an example to analyze compulsory licensing from the perspectives of efficiency and business ethic.

The rationale of compulsory licensing systems is to maintain a delicate balance between the pharmaceuticals accessibility at an affordable price and the incentives for technology innovation, under the necessary limitation on patent protections (Bartelt, 2003). If a government authorizes compulsory

licensing, the welfare of the given society will be maximized due to the sharp reduction of medication prices. Hence, according to the national Patent Act, compulsory licensing authorized by a given government will enhance societal well-being and benefit people from a societal perspective.

From an organizational perspective, compulsory licensing will sharply reduce companies' profits on medications, though "adequate remuneration" should be paid to patent holders for patent economic value. As a result, patent holders prefer negotiating with a given government to reduce the price of medications to a compulsory licensing authorized by a particular government. For instance, the large pharmaceutical companies dealt with the Brazilian government to reduce the price of HIV medication to avert issuing a compulsory licensing during the period of an explosive HIV/AIDS epidemic in the late 1990s (Flanagan & Whiteman, 2007).

From the perspective of substantive justice, the common interests of all members of a community will be protected by compulsory licensing due to the price reduction in medications. However, the process of authorizing compulsory licensing may be very complex and uncertain from the perspective of procedural justice. Some disadvantages may prevent the effective use of compulsory licensing for COVID-19. The major countries in the world, such as the U.S. and China, are decline to adopt compulsory licensing in practice. Moreover, some high-income countries with a strong research-based pharmaceutical industry vigorously oppose developing countries to issues compulsory licensing (Flanagan & Whiteman, 2007). More importantly, a given government will grant compulsory licensing at a national state level instead of a global patent license. In nature, compulsory licenses are territorial (McMahon, 2020), limiting global access to efficacious treatments and vaccines. As a result, compulsory licensing has minimal effectiveness for fighting against the COVID-19 pandemic globally.

Like a double-edged sword, a patent pool may create anticompetitive effects besides procompetitive benefits. In general, patent pools bring procompetitive benefits in two ways. A patent pool can reduce transaction costs by reducing the number of patent licenses and effectively address complement problems by allowing patent holders to coordinate their behaviors on patent licenses (Delcamp, 2015). However, patent pools may be anticompetitive due to the increase in patent royalty if the share of integrated firms is large sufficiently (Reisinger & Tarantino, 2019). Under certain circumstances, a patent pool in which patent holders collectively possess strong market power will harm competition in relevant markets.

Indeed, participating in patent pools can be regarded as a cooperative patent strategy adopted by patent holders (Han, 2015). As a patent pool has dual properties, patent holders can freely choose how to implement collaborative patent

strategies but have to comply with the constraints of anti-trust law to reduce the anticompetitive effects. The primary incentive for patent holders participating in patent pools is an economic benefit (Verbeure et al., 2006). Patent holders usually assert royalty for essential patents in patent pools under the principle of "fair, reasonable and no discrimination" to undertake the cost of creating a patent pool and achieve the prospect of adequate revenue. However, the rule of profit distribution adopted by patent pools cannot offer enough incentive for patent holders who own a few essential patents, leading to them being outside of patent pools (Tesoriere, 2019). Hence, only patent holders who have many essential patents are willing to participate in a patent pool.

From the perspective of procedural justice, setting up a patent pool is a complex and lengthy process with a high cost of negotiating an agreement. There are multiple steps, but all steps involve many expenses in establishing a patent pool (Verbeure et al., 2006). Moreover, many patent holders with a few patents prefer remaining outside of patent pools to participating in a patent pool (Tesoriere, 2019), which results in the procompetitive benefit of patent pools will be significantly reduced.

From the perspective of substantive justice, not all patent pools guarantee that common interests are preserved. A patent pool with procompetitive benefits can assist in improving societal well-being and the common good. By contrast with separate negotiations, a patent pool will promote negotiation efficiency by reducing transaction costs and integrating complementary patents (Gallini, 2017). However, a patent pool may harm societal well-being if the royalty rate set collectively is too high or coordinated restrictions are unreasonable. Patent pools with anticompetitive effects are deemed to be unlawful if they cannot contribute to the efficiency-enhancing of integrating complementary patents.

In general, patent holders will assert legal relief against patent infringers, seeking injunctions and claiming compensations. However, patent holders may give up some rights in particular cases rather than completely abandon patent rights. Patent pledges have some substantial advantages that have attracted increasing patent holders to make a public statement or commitment without asserting injunction comparing with compulsory licensing and patent pools. Table 3 presents the results of comparing distributive justice among the three mechanisms.

Table 3 shows that patent pledges have significant advantages for fighting against the COVID-19 pandemic. First, the procedure of making a patent pledge is smoother and more straightforward than establishing a patent pool or granted a compulsory license from the perspective of procedural justice. A compulsory licensing can be regarded as a special license that needs to be authorized by a given government, while establishing a patent pool may be considered a collective behavior in which many patent holders are willing to

reach patent licenses. The procedure regarding either authorized a compulsory license or establishing a patent pool is cumbersome and time-consuming. However, a patent pledge is a unilateral statement or commitment to granting patent licenses, leading to patent pledges being more straightforward and efficient. In particular, standardized patent pledges, such as Open COVID Pledge-Patent (OCL-P) 1.1, make patent pledges are more convenient for patent holders. As a result, increasing medium and small-sized enterprises prefer to commit patent pledges for fighting against COVID-19 due to the smooth procedure.

Second, patent pledges will help the public achieve the maximized substantive justice by patent holders dropping some rights. Patent pledges may take various forms and can be categorized into unilateral and coordinated patent pledges for COVID-19. There are multiple options for patent holders with personalized terms in a unilateral patent pledge, such as offering a free license or asserting a reasonable and non-discriminatory royalty fee. However, patent holders are bound to promise not to claim temporary or permanent injunction against the users of patented technologies no matter what kind of patent pledges. More importantly, patent pledges can cross national borders and limitations, which will assist patent users in acquiring global licenses. Hence, patent pledges make generic drug manufacturers produce drugs or vaccines for COVID-19 with an open license. Increasing the supply of medicines and vaccines will substantially improve the accessibility of life-saving healthcare in the period of the COVID-19 pandemic. The more rights the patent holders in patent pledges give up, the more the public will benefit from patent pledges.

Third, patent pledges can relieve the tension between public health and patent protections to a great extent by keeping a subtle balance between short-term losses and long-term gains. Patent holders voluntarily commit patent pledges that not asserting some rights to fight against COVID-19 in the period of the COVID-19 pandemic. The pledged patent rights merely give up by patent holders for some time. However, patent rights would be recovered when the COVID-19 pandemic ends. Despite suffering from less revenue for a time, patent holders would achieve a good reputation for social responsibility and get the potential opportunities for patent licenses in the long term.

The Disadvantages of Patent Pledges

There are obvious disadvantages of patent pledges in response to the COVID-19 pandemic. Adopting a strategy of free patent license for a long time will be detrimental to the sustainable development of enterprises. Adequate protection of patent rights is necessary for the medical industry to develop innovative drugs (Zhang & Liu, 2020) and achieve success (Bosetti & Vereeck, 2012). The development of

therapeutic solutions and vaccines requires vast investment and lots of work but has to bear high risk. Patent protection can effectively enhance company performance in the pharmaceutical industries than the other industries by protecting therapeutic inventions from imitation (Yuan et al., 2020). Hence, an appropriate patent strategy is crucial for companies allocating resources and enhancing competitive advantages (Yuan & Li, 2019), which will help companies gain profit on developing therapeutic or vaccine inventions (Soini et al., 2008). Human society will cope with crises if enterprises have the strong ability to develop therapeutic solutions or vaccines sustainably.

On the other hand, merely depending on patent pledges could not comprehensively solve global equitable access to the medical resources for COVID-19. The supply of drugs and vaccines could not be enhanced dramatically in the context of patent pledges if there are no generics manufacturers making drugs or vaccines for COVID-19. A patent can be regarded as an intermediate between research & development and products, leading to patents usually considered crucial outputs of innovation activities and vital technical resources for new product development (Yuan et al., 2020). In this case, the capacity of making drugs and vaccines will profoundly affect the supply and distribution of the medical resources for COVID-19. Suppose few generics manufacturers can make drugs and vaccines. The global equitable accessibility of the medical resources for COVID-19 cannot be guaranteed even in the context of patent pledges, especially in developing countries.

Management Implications

To battle COVID-19, several types of coordinated pledges have been developed, such as Open COVID Pledge and Open COVID-19, which leads to increasing companies prefer committing patent pledges. The paper reveals the advantages and disadvantages of patent pledges using the analysis framework of combining efficiency and business ethics. Our findings have some management implications.

First, either WHO or World Intellectual Property Organization (WIPO) should advocate patent holders actively commit patent pledges for fighting against COVID-19. In patent pledges, patent holders promise to give up some rights, at least not asserting injunctive relief against patent users, which will facilitate manufacturers' access to the patented health technologies. There are several vaccines against COVID-19 recommended by SAGE, 88 vaccines in clinical development, and 184 vaccines in pre-clinical development up to April 2021. However, only a few patent holders have committed patent pledges for COVID-19, such as Moderna, Inc. that made the patent pledge for the mRNA-1273 vaccine. If increasing patent holders who own therapeutic or vaccine patents commit patent pledges, patent

pools proposed by the WHO, either C-TAC or MPP, would be set up as quickly as possible.

Second, national governments should play more critical roles in developing and allocating treatments or vaccines for COVID-19. Free patent pledges are not sustainable for companies that have invested in the development of health technologies. The government in a given country has the statutory obligation of providing medical necessities and healthcare services to its people. To overcome the disadvantages of patent pledges, national governments should offer various policy measures to promote COVID-19 health technologies. For instance, national governments may provide public money for national companies to develop health technologies (McMahon, 2020) or use their healthcare budgets to purchase healthcare services for the public (Siraj et al., 2020). Hence, patent pledges will be sustainable for patent holders in the context of government support.

Third, making a patent pledge, either a unilateral pledge or a coordinated pledge, is a rational decision for companies during the global COVID-19 pandemic. A fact that cannot be ignored is patent thickets will prevent useful drugs from promoting public health. It is almost impossible to trek through patent thickets during the COVID-19 pandemic adopting the traditional mechanisms, such as obtaining voluntary licenses or establishing patent pools. However, committing patent pledges make manufacturers can use patented health technologies for COVID-19. With the increasing supply of diagnostics, therapeutic, and vaccines, equitable access to life-saving healthcare may be solved gradually in the future. Therefore, the COVID-19 pandemic epidemic will be contained and eliminated eventually if international organizations, national governments, patent holders, and manufacturers can work together.

Conclusion

It is an interesting issue why many patent holders prefer committing patent pledges to establish patent pools or granted compulsory licensing for fighting against COVID-19. This paper adopts the research framework of combining efficiency and ethical analysis to compare different mechanisms of clearing patent thickets. Our findings highlight that the advantages of patent pledges have attracted many patent holders to make public statements during the COVID-19 pandemic. In contrast, the disadvantages of a free license may make patent pledges not be sustainable without the related supporting measures. The contribution of this paper is twofold.

On the one hand, the paper revised the approach of how to make a rational decision on addressing the conflicts between business ethics and patent protections proposed by Oppenheimer et al. (2015). Distributive justice is only one aspect

of ethical analysis in the analysis framework proposed by Oppenheimer et al. (2015), but the procedure of distribution is ignored. The revised method highlights procedural fairness in the process of making a business decision. The paper disassembles distributive justice into substantive justice and procedural justice and then studies business ethics from two dimensions: substantive justice and procedural justice. The ethical analysis framework of combining substantive justice and procedural justice is helpful for further comprehensively evaluating various options, and then a company will make a rational decision. The method proposed by this paper can help policymakers or company managers in deciding on how to relieve the increasing tension between business ethics and patent rights during the period of public health crises.

On the other hand, our research enriches the literature on the moral justification of patent rights and gains an insight into why increasing patent holders tend to make patent pledges to fight against COVID-19 from a business ethical perspective. We find out that patent pledges contribute to achieving the maximized substantive justice for the public and help patent pledgers fulfill procedural justice if the disadvantages of patent pledges can be overcome effectively. Notably, standardized patent pledges, such as Open COVID Pledge-Patent (OCL-P) 1.1, are beneficial to the welfare of everyone and achieving distributive justice for anyone. Our findings can help company managers make an appropriate decision on utilizing patent portfolios to fight against public health crises for management practice.

Like many previous studies in this area, our research has limitations too, and further investigation is necessary for the future. Our findings primarily build on the cases of patent pledges for COVID-19. The samples analyzed are small, especially the patent pledges on diagnostics, treatments, and vaccines are minimal. With the development of health patented technologies, patent pledges, including unilateral pledges and coordinated pledges, will increase. Thus, further research will collect more samples of patent pledges used to tackle public health crises.

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