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Corporate Governance in China: Progress, Predicament and Prospect

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ABSTRACT

The aim of this study is to investigate important issues in corporate governance based on review of Chinese laws and regulations and to discuss potential approach to improved quality of China's corporate governance. The writing detailed the progressive developments in corporate governance in China through examination of a series of legal and historical events, summarized and reviews chief aspects of corporate governance in China, based on currently effective laws and regulations, and addressed critical components in corporate governance in China, particularly the defects in corporate practice

identified by scholars from both China and abroad. The writing also discussed suggested solutions to these problems.

KEYWORD *Corporate governance; China; reform; international standard*

1. INTRODUCTION

A set of relationships between a company's management, its board, its shareholders and other stakeholders are formulated in corporate governance, which also provides the configuration through which the objectives of the company are positioned, and the *modus operandi* of accomplishing those objectives and assessing performance are established (Organization for Economic Co-operation and Development, hereafter "OECD", 2015, p. 9). The justiification for corporate governance is to facilitate constructing an environment of trust, transparency and accountability indispensable for cultivating long-term investment, financial stability as well as business integrity, by which upholding economic growth and social inclusiveness (OECD 2015, p. 7).

According to the OECD, "corporate governance is the system by which business corporations are directed and controlled. The corporate governance structure specifies the distribution of rights and responsibilities among different participants in the corporation, such as, the board, managers, shareholders and other stakeholders, and spells out the rules and procedures for making decisions on corporate affairs. By doing this, it also provides the structure through which the company objectives are set, and the means of attaining those objectives

and monitoring performance" (OECD 1998). Corporate governance can spread over an expansive field and outlines a scheme that demarcates the rights and responsibilities of each main group of stakeholders in a company, and sets regulations and practices for decision-makings in the areas of operation (OECD 1998). Corporate governance can assist to take full advantage of the shareholder value and efficiency of companies. From the time of its initial publication in 1999, the G20/OECD Principles of Corporate Governance have turned into an international standard for policy-makers, investors, corporations and other stakeholders (OECD 2015, p. 3).

Corporate governance in the People's Republic of China (hereafter "China") has come into view and grown as China has transferred from a plan-based economy to a market-based economy (OECD 2011, p. 13). During the early years of the past seven decades since 1949 when the Communist Party of China established the current regime that superseded the Nationalists who practiced a capitalist economic, social, and legal system, there was hardly any development in the domain of management and regulation of modern companies. Unlike their Western counterparts that have been in the legal environment where the modern corporate governance was bred, to build a connection between such a relatively fresh term as "corporate governance" and companies in China, there would have been sufficient imagination. Fortunately, when this term was well defined in the late 1990s, Chinese companies were in the right roadmap to modernizing their appearances that were solely shaped by the so-called planned economy, which were under tight control of the State. Still heavily influenced by the Party's and the State's policies, Chinese companies were released from state control in recent two decades. Regardless of many doubts about their advantages and disadvantages, efficiency and inefficiency, justice and injustice, fairness and unfairness in the process of privatization of publicly-owned enterprises, regulation and

management of Chinese companies have been changed a lot following the track of their Western counterparts.

Particularly, during the past two decades, when China got access to the World Trade Organization (hereafter "the WTO") in late 2001, the Chinese government acquired the propulsion to advance its corporate governance approach to get companies ready to compete with the overseas competitors. Commitments under the WTO append to the imperative necessity to deal with corporate governance issues in a inclusive and organized approach (Tenev and Zhang 2002, p. 2). Nevertheless, the express development still leaves several areas that requires additional enhancement.

The intention of this paper is to spot key corporate governance problems through review of laws and regulations of China and to present suggested solutions to improve the quality of China's corporate governance. The paper reviewed regulatory documents as well as some influential literature, as the basis of the presentation and discussion. Two experts from Chinese universities, Professor Mi Xinli and Professor Zhang Xing, were interviewed during the initial stage of this study. The remainder of this paper is organized as follows: Section 2 briefly describes the progressive developments in corporate governance in China based on review of a series of legal and historical events; Section 3 summarizes and reviews main aspects of corporate governance in China, based on currently effective laws and regulation; Section 4 addresses key problems in corporate governance in China, with special regards to the defects in corporate practice identified by both Chinese and abroad scholars; Section 5 discusses suggested solutions; and Section 6 concludes the paper.

2. PROGRESS OF CORPORATE GOVERNANCE IN CHINA

When talking about any issues of contemporary China, it is preferable to divide the history into periods before 1949 and after 1949; and within the 68 years since 1949, it is also preferable to divide it into sub-periods before 1978 and after 1978.

The first three decades in modern Chinese history witnessed an absolute prohibition of private ownership and thus private enterprises. Operated clandestinely, private businesses did not have any legal status and therefore not protected by any law. Only state-owned and collectively-owned enterprises were allowed, under control of the government or community (OECD 2011, p. 13). Corporate governance was characterized by integration of government administration with enterprises, without a clear line between the functions of the government and enterprises. No autonomy in operation and management existed for state-owned enterprises, because the state controlled the process of production, distribution and consumption, which were directed by premade plan and administrative command. No shareholder existed in real sense so there was not a mechanism as in any corporate law. Nor employees in real sense because workers were arranged but not employed to work in the mines and factories.

During that period, approximately 80 percent of the inhabitants engaged in agricultural production, making China a large agricultural country. Two years after the death of Mao Zedong, the former leader of the country, and downfall of the Gang of Four, the group being assumed exercising actual control over the regime, in 1976, China started its economic reform (The Third Plenary Session of the 11th Central Committee of the Communist Party of China 1978). Before 1978, peasants worked collectively in production teams; but after 1978, they became farmers working on household basis. Sudden death of great public-owned enterprises, limited agricultural output and income, surplus rural workforce, development of urbanization and demand of

migrant workers, made it possible to enlarge the private sector. Though dominated by state-owned enterprises, the Chinese economy was gradually occupied by emerging small and medium sized private enterprises as well as collectively-own enterprises. A significant part of the Chinese wealth was also transferred from public control to private hands.

State-owned enterprises had also to be reformed to cope with the new economic atmosphere with the announcement of the Decision of Economic Structural Reform made by the Communist Party of China's Central Committee in 1984. Now the ownership and management of state-owned enterprises could be separated (OECD 2011, p. 13). They acquired autonomy in operation and management for decision-making about their profits and losses, gradually putting an end to the practice of integrating government administration with enterprises. Efficiency was emphasized without change of the ownership of the enterprises. However, income gap would soon be enlarged between managers and workers, with grey income of managers attracting broad attention in the society.

In 1986, income gap would be further enlarged when the management contract system was introduced by the State Council in its "Decisions on Deepening Enterprise Reform and Invigorating Enterprises." The document established a mechanism under which negotiation between management teams and governmental organs was exploited on an incentive scheme: upon fulfillment of the fixed remittance target, the enterprise could retain extra profit; and its overall remuneration arrangement is based on the actual profit and tax. Under such an arrangement, previous Chinese officials in enterprises acquired everything from management freedom to profit incentive, and from extensive embezzlement to corruption. By deceiving whole population in general and workers in particular, and by giving bribery to officials responsible for the control of the enterprises, those managers used to

get far lower remittance targets and thus extraordinary monopolized profit from the enterprises. It was notorious that enterprises owned by all the people never had anything to do with those 80 percent of population living in the countryside before they fell in the hand of minority officials, who became the first generation tycoons in modern China. Prior to the early 1980s, individuals used to have no real ownership in state enterprises, and their compensations were not linked with companies' performance (Kang, Lu and Brown 2008, p. 2). However, when the reform began, it was well recognized by OECD that, "The basis of the contracts was often arbitrarily decided and was neither fair nor objective: the contractors shared the gains when the enterprises were profitable but were not personally liable when they incurred losses. The system failed to find a fully satisfactory solution to the challenge of separating the role of the government from enterprises." (OECD 2011, p. 14)

Reform being a painful process for Chinese society, the latter part of the 1980s witnessed further reform of shareholding system among state-owned enterprises, resulting in the commencement of the Shanghai Stock Exchange and the Shenzhen Stock Exchange in 1990, followed by foundation of the China Securities Regulatory Commission as the regulator of the stock market. At the time, the improvement of the corporate governance of listed companies became a primary issue on the agenda of the capital market development (OECD 2011, p. 15). One of the results of the reform of shareholding system was to further privatize state-owned enterprise, continuing to allocate the so-called assets owned by all the people to a small group of people, usually to those officials, managers and a few workers, who enjoyed privilege by any means in the same enterprises. Where privatization was not fully realized, state-owned enterprises suffered heavily from debt problem in early 1990s, when there was the strong demand for a modernized business law system. In December 1993, the Standing Committee of the People's Congress passed the first

Company law since 1949, classifying companies into two types, limited-liability company and limited-liability company by shares. "Corporatization of state-owned enterprises" replaced the "management contract system," meaning a larger scale of privatization, a term never publicly used and officially accepted but practiced across the country. Partly, the Company Law provided legal support to the establishment of a new corporate system and laid the foundation for corporate governance framework in China (OECD 2011, p. 15). State-owned enterprises were thus privatized and acquired the similar incentive to make profits as their Western counterparts. This was unofficially dubbed "the New Enclosure," or the process of "primitive accumulation of capital." The former was a metaphor about the transfer of the state-owned assets and enterprises to officials (managers) without any cost. The latter was a metaphor about the brutality of the officials (managers) in embezzling assets, seizing enterprises and dismissing workers, leaving large number of workers unemployed. The process could not be evaluated according to the criteria of modern corporate governance, turning the page of history lawlessly. It was not correct to say that the reform modernized the corporate governance, which did not exist in modern sense. Rather, the reform rendered the old system to an end, while introduced a new set of corporate governance. As it was put, market-oriented reforms, including corporatization and ownership diversification, have brought corporate governance issues to the forefront (Tenev and Zhang 2002, p. 1).

Chinese stock markets have also been growing rapidly, especially since late 2005, when share merger reform started (Kang, Lu and Brown 2008, p. 3). Among various potential crisis that seldom breaks out, by 2010, China had become the world's second largest economy after the United States, superseding Japan, with a total GDP of US$6,066 billion. After five years, it doubled to US$11,064 billion in 2015 (World Bank 2017). China's securities market as well as corporate governance structure and emerging rules play an important

role in these economic reforms. According to World Bank WDI Database, number of listed domestic companies in China is 2,063 in 2010, increased to 2,827 in 2015. Market capitalization totaled $4,027,952 million, 66.7% of GDP in 2010, grown to $8,188,019 million, 75.4% of GDP in 2015. By the end of June 2016, there were 2,887 listed companies, 1,019 of which were state-controlled, accounting for about 47% of the total market value of all listed companies in the country (OECD Corporate Governance Factbook 2017). Part of the function of these achievements was to make it the embezzlement and appropriation of public-owned property legalized.

Of course, it cannot be negated that a progressive process of establishing the corporate governance has been on road, where rules were made step by step, little by little. First rules were mostly to liberate productivity and to improve efficiency, while the second were to refrain some of the abusive practices and to provide some remedies. For example, legal protection of shareholders' rights was not ready until 1998, when the Securities Law was promulgated, allowing company management and directors to be sued by investors due to their misbehavior in releasing false or misleading information. Further legal protection was realized with the issuance of Code of Corporate Governance for Listed Companies in China by the China Securities Regulatory Commission in 2001, which started by plainly marking right of investors (Chapter 1), and prohibited controlling shareholders from damaging the minority shareholders (Paragraph 19). Independent directors were also introduced into corporate governance, but their roles were left doubtful because they lacked stake and thus incentives in the performance of the company, and they were too weak to influence company's decision-making.

The improvement of the corporate governance was hampered by the practice of non-tradable stocks, which constituted two-thirds of the total stocks until 2005. Held by employees and umbrella companies,

non-tradable shares posed great challenge for minority investors in tradable shares, lacking legal protection in the case of floating non-tradable shares. With an initiative of the Chinese government, listed companies were required to circulate their non-tradable shares, with a compensation package approved by the holders of tradable shares. Due to the success of these companies in the stock market, circulation of their shares helped gain investors' confidence and therefore paved a way to improved corporate governance.

Independent directors were prescribed in Company Law of China in 2005 (Article 122), when the board directors were required to abstain from voting on issues that were related to their own interest. In case of misbehavior by the managers and board directors, shareholders were entitled to appeal to the supervisory board; and in case of misbehavior by members of the supervisory board, shareholders were entitled to appeal to the board of directors. The Company Law entitled shareholders to appeal to the court to start a bankruptcy process, provided that the decision was supported by at least 10 percent of shareholder votes. Shareholders were granted the right to demand a buyback of shares under certain conditions when shareholder interests might suffer. However, the actual fact was that previous officials, who became the majority shareholders at some point of time, manipulated the statistics and fabricated the false appearance of financial losses and could have transferred state property into private hands by a seemingly legitimate channel.

Threshold for public listing was loosened by the 2005 Company Law, which played a role more facilitative than prohibitive, deregulating listed companies. Approval from the State Council was no longer a necessary formality. The Company Law also reduced the sum of requirement for registered capital from RMB 100,000 Yuan to 50,000 Yuan, which can also be in the form of intellectual property and stock. It marks the successful transfer from regulated market to

freer market, from commodity-centered market to capital-centered market, where new channels would potentially be opened for accumulated wealth of general public to be involved in various investment opportunities.

The string of ideas continued in the amended Securities Law by the National People's Congress in 2006, freeing business areas that listed companies can enter, relying solely on market demand and corporate decision. The Securities Law also opened the door for methods of trading shares other than spot trading. As a preventive method, the Securities Law required that an investor protection fund be established with financing from investment banks. The amendments specified that funds derived from the settlement of transactions of investors be deposited in commercial banks, prohibiting investment banks from manipulating these investor funds or securities as part of their own funds.

3. CURRENT REGULATIONS ON CORPORATE GOVERNANCE IN CHINA

The China Securities Regulatory Commission is the subject responsible for formulating regulations on corporate governance, which is designed to cope with modern enterprise system and standardize the operating process of listed companies and security companies.

In 2001, the China Securities Regulatory Commission issued a "Code of Corporate Governance for Listed Companies in China" (hereafter "the Listed Companies Code"), applicable to all listed companies within the boundary of China, and aims at the protection of investor's interests and rights, the basic behavior rules and moral standards for

directors, supervisors, managers and other senior management members of listed companies (The Listed Companies Code, Preface). In 2004, the same Commission issued a "Provisional Code of Corporate Governance for Securities Companies" (hereafter "the Securities Companies Code"), applicable to all securities companies with the boundary of China, in order to standardize the operations of these companies in line with the modern enterprise system, ensuring the legitimate interests of the shareholders, clients and other interested parties of the securities companies, and safeguarding the independence and integrity of the securities companies' assets (The Securities Companies Code, Article 1).

These two Codes added many characteristics of corporate governance that existed in some of the major economies of the world (Li, Naughton and Hovey 2008, p. 6). They became the major measuring standard of evaluating whether a listed or a securities company has a good corporate governance structure. If major problems exist with the corporate governance structure of a listed/security company, the securities supervision and regulation authorities may instruct the company to make corrections in accordance with codes.

The legislative bases of the Code were "the basic principles of the Company Law, the Securities Law and other relevant laws and regulations, as well as the commonly accepted standards in international corporate governance" (Preface of the Listed Companies Code; Article 1 of the Securities Companies Code).

The two documents have similar structure, containing main chapters dealing with shareholder and shareholders' meetings; the listed company and its controlling shareholders; directors and the board of directors; the supervisors and the supervisory board; performance assessments and incentive and disciplinary systems; stakeholders; and information disclosure and transparency. The Security Companies Code also addresses the issues related to management personnel and

the basic principle of relationships between securities companies and clients. Based on these two Codes, referring to the Company Law, the fundamental issues dealt with in Chinese legal framework can be summarized as the following:

3.1. Legal status of shareholders

The shareholders enjoy the legal rights stipulated by laws, administrative regulations and the company's articles of association. In listed companies, a corporate governance structure shall be established to facilitate the full exercise of shareholders' rights (The Listed Companies Code, Para. 1), to ensure fair treatment toward all shareholders, especially minority shareholders (The Listed Companies Code, Para. 2). All shareholders are equal and bear the corresponding duties based on the shares they hold (The Listed Companies Code, Para. 2). A listed company shall establish efficient channels of communication with its shareholders in order to ensure shareholders to enjoy their right to know about and the right to participate in major matters of the company (The Listed Companies Code, Para. 3). Shareholders shall have the right to protect their interests and rights through civil litigation or other legal means in accordance with laws and administrative regulations. In the event the resolutions of shareholders' meetings or the resolutions of the board of directors are in breach of laws and administrative regulations or infringe on shareholders legal interests and rights, the shareholders shall have the right to initiate litigation to stop such breach or infringement. The directors, supervisors and managers of the company shall bear the liability of compensation in cases where they violate laws, administrative regulations or articles of association and cause damages to the company during the performance of their duties. Shareholders shall have the right to request the company to sue for such compensation in accordance with law (The Listed Companies Code, Para. 4).

A listed company shall set out convening and voting procedures for shareholders' meetings in its articles of association, including rules governing such matters as notification, registration, review of proposals, voting, counting of votes, announcement of voting results, formulation of resolutions, recording of minutes and signatories, public announcement, etc. (The Listed Companies Code, Para. 5). For a shareholders' meeting, the board of directors shall earnestly study and arrange the agenda, each item on which shall be given a reasonable amount of time for discussion during the meeting (The Listed Companies Code, Para. 6). A listed company shall state in its articles of association the principles for the shareholders' meeting to grant authorization to the board of directors. The content of such authorization shall be explicit and concrete (The Listed Companies Code, Para. 7). Besides ensuring that shareholders' meetings proceed legally and effectively, a listed company shall make every effort to increase the number of shareholders attending the shareholders' meetings (The Listed Companies Code, Para. 8). The shareholders can either be present in person or they may appoint a proxy to vote on their behalf, and both means of voting possess the same legal effect (The Listed Companies Code, Para. 9). The board of directors, independent directors and qualified shareholders may solicit for the shareholders' right to vote in a shareholders' meeting. No payments shall be made to the shareholders for such solicitation, and adequate information shall be provided to persons whose voting rights are being solicited (The Listed Companies Code, Para. 10). Institutional investors shall play a role in the appointment of company directors, the compensation and supervision of management and major decision-making processes (The Listed Companies Code, Para. 11).

3.2. Controlling shareholders

During the restructuring and reorganization of a company that plans to list, the controlling shareholders shall observe the principle of "first

restructuring, then listing", and shall emphasize the establishment of a reasonably balanced shareholding structure (The Listed Companies Code, Para. 15). They shall sever the company's social functions and strip out nonoperational assets. Non-operational institutions, welfare institutions and their facilities shall not be included in the listed company(The Listed Companies Code, Para. 16).

Controlling shareholders' remaining enterprises or institutions that provide services for the major business of the listed company may be restructured into specialized companies in accordance with the principles of specialization and market practice, and may enter into relevant agreements with the listed company in accordance with commercial principles.

Remaining enterprises engaged in other businesses shall increase their capability of independent development. Remaining enterprises not capable to continue operation shall exit the market, through such channels as bankruptcy, in accordance with relevant laws and regulations. Enterprises meeting certain requirements during restructuring may sever all their social functions and disperse surplus employees at one time and keep no remaining enterprises (The Listed Companies Code, Para. 17).

The controlling shareholders shall support the listed company to further reform labor, personnel and distribution systems, to transform operational and managerial mechanisms, and to establish such systems as: management selection through bidding and competition, with the chance for both promotion and demotion; employment of employees on the basis of competitive selection, with the chance for both employment and termination of employment; income distribution scheme that provides sufficient incentive, with the chance to both increase and decrease the remuneration; etc. (The Listed Companies Code, Para. 18).

The controlling shareholders owe a duty of good faith toward the listed company and other shareholders. The controlling shareholders of a listed company shall strictly comply with laws and regulations while exercising their rights as investors, and shall be prevented from damaging the listed company's or other shareholders' legal rights and interests, through means such as assets restructuring, or from taking advantage of their privileged position to gain additional benefit (The Listed Companies Code, Para. 19).

The controlling shareholders shall nominate the candidates for directors and supervisors in strict compliance with the terms and procedures provided for by laws, regulations and the company's articles of association. The resolutions made by the shareholders' meetings electing personnel or the board of directors' resolutions appointing personnel shall not be subjected to approval procedures by the controlling shareholders. The controlling shareholders are forbidden to appoint senior management personnel by circumventing the shareholders' meetings or the board of directors (The Listed Companies Code, Para. 20).

The important decisions of a listed company shall be made through a shareholders' meeting or board of directors' meeting in accordance with law. The controlling shareholder shall not directly or indirectly interfere with the company's decisions or business activities conducted in accordance with laws; nor shall they impair the listed company's of other shareholders' rights and interests (The Listed Companies Code, Para. 21).

A listed company shall be separated from its controlling shareholders in such aspects as personnel, assets and financial affairs, shall be independent in institution and business, shall practice independent business accounting, and shall independently bear risks and obligations (The Listed Companies Code, Para. 22).

3.3. Directors and board of directors

3.3.1. Election Procedures for Directors

A company shall establish a standardized and transparent procedure for director election in its articles of association, so as to ensure the openness, fairness, impartialness and independence of the election (The Listed Companies Code, Para. 28). Detailed information regarding the candidates for directorship shall be disclosed prior to the convening of the shareholders' meeting to ensure adequate understanding of the candidates by the shareholders at the time of voting (The Listed Companies Code, Para. 29). Candidates for directorship shall give written undertakings to accept their nomination to warrant the truthfulness and completeness of the candidate's information that has been publicly disclosed and to promise to earnestly perform their duties once elected (The Listed Companies Code, Para. 30) .

The election of directors shall fully reflect the opinions of minority shareholders. A cumulative voting system shall be earnestly advanced in shareholders' meetings for the election of directors. Listed companies that are more than 30% owned by controlling shareholders shall adopt a cumulative voting system, and the companies that do adopt such system shall stipulate the implementing rules for such cumulative voting system in their articles of association (The Listed Companies Code, Para. 31).

Appointment agreements shall be entered into by a listed company and its directors to clarify such matters as the rights and obligations between the company and the director, the term of the directorship, the director's liabilities in case of breach of laws, regulations or articles of association, and the compensation from the company in case of early termination of the appointment agreement for cause by the company (The Listed Companies Code, Para. 32).

3.3.2. The Duties and Responsibilities of Directors

Directors shall faithfully, honestly and diligently perform their duties for the best interests of the company and all the shareholders (The Listed Companies Code, Para. 33). Directors shall ensure adequate time and energy for the performance of their duties (The Listed Companies Code, Para. 34). Directors shall attend the board of directors meetings in a diligent and responsible manner, and shall express their clear opinion on the topics discussed. When unable to attend a board of directors meeting, a director may authorize another director in writing to vote on his behalf and the director who makes such authorization shall be responsible for the vote (The Listed Companies Code, Para. 28). The board of directors shall abide by relevant laws, regulations, rules and the company's articles of association, and shall strictly fulfill the undertakings they made publicly (The Listed Companies Code, Para. 36). Directors shall earnestly attend relevant trainings to learn about the rights, obligations and duties of a director, to familiarize themselves with relevant laws and regulations and to master relevant knowledge necessary for acting as directors (The Listed Companies Code, Para. 37).

In cases where the resolutions of board of directors violate laws or regulations or a listed company's articles of association and cause losses to the listed company, directors responsible for making such resolutions shall be liable for compensation, except those proved to have objected and the objections of whom have been recorded in the minutes (The Listed Companies Code, Para. 38). After approval by the shareholders' meeting, a listed company may purchase liability insurance for directors. Such insurance shall not cover the liabilities arising in connection with directors' violation of laws, regulations or the company's articles of association (The Listed Companies Code, Para. 39).

3.3.3. Duties and Composition of the Board of Directors

The number of directors and the structure of the board of directors shall be in compliance with laws and regulations and shall ensure the effective discussion and efficient, timely and prudent decision-making process of the board of directors (The Listed Companies Code, Para. 40).

The board of directors shall possess proper professional background. The directors shall possess adequate knowledge, skill and quality to perform their duties (The Listed Companies Code, Para. 41). The board shall be made accountable to shareholders. A listed company's corporate governance framework shall ensure that the board of directors can exercise its power in accordance with laws, administrative regulations and the company's articles of association (The Listed Companies Code, Para. 42). The board shall earnestly perform its duties as stipulated by laws, regulations and the company's articles of association, shall ensure that the company complies with laws, regulations and its articles of association, shall treat all the shareholders equally and shall be concerned with the interests of stakeholders (The Listed Companies Code, Para. 43).

3.3.4. Rules and Procedure of the Board of Directors

A listed company shall formulate rules of procedure for its board of directors in its articles of association to ensure the board of directors' efficient function and rational decisions (The Listed Companies Code, Para. 44).

The board of directors shall meet periodically and shall convene interim meetings in a timely manner when necessary. Each board of directors' meeting shall have a pre-decided agenda (The Listed Companies Code, Para. 45).

The meetings of the board of directors of a listed company shall be conducted in strict compliance with prescribed procedures. The board of directors shall send notice to all directors in advance, at the

stipulated time, and shall provide sufficient materials, including relevant background materials for the items on the agenda and other information and data that may assist the directors in their understanding of the company's business development. When two or more independent directors deem the materials inadequate or unclear, they may jointly submit a written request to postpone the meeting or to postpone the discussion of the related matter, which shall be granted by the board of directors (The Listed Companies Code, Para. 46).

The minutes of the board of directors' meetings shall be complete and accurate. The secretary of the board of directors shall carefully organize the minutes and the records of discussed matters. Directors that have attended the meetings and the person who drafted the minutes shall sign the minutes. The minutes of the board of directors' meetings shall be properly maintained and stored as important records of the company, and may be used as an important basis for clarifying responsibilities of individual directors in the future (The Listed Companies Code, Para. 47).

In the case of authorization to the chairman of the board of directors to exercise part of the board of directors' power of office when the board of directors is not in session, clear rules and principles for such authorization shall be stated in the articles of association of the listed company. The content of such authorization shall be clear and specific. All matters related to material interests of the company shall be submitted to the board of directors for collective decision (The Listed Companies Code, Para. 48).

3.3.5. Independent Directors

A listed company shall introduce independent directors to its board of directors in accordance with relevant regulations. Independent directors shall be independent from the listed company that employs them and the company's major shareholders. An independent director

may not hold any other position apart from independent director in the listed company (The Listed Companies Code, Para. 49). The independent directors shall bear the duties of good faith and due diligence toward the listed company and all the shareholders. They shall earnestly perform their duties in accordance with laws, regulations and the company's articles of association, shall protect the overall interests of the company, and shall be especially concerned with protecting the interests of minority shareholders from being infringed. Independent directors shall carry out their duties independently and shall not subject themselves to the influence of the company's major shareholders, actual controllers, or other entities or persons who are interested parties of the listed company (The Listed Companies Code, Para. 50). Relevant laws and regulations shall be complied with for matters such as the qualifications, procedure of election and replacement, and duties of independent directors (The Listed Companies Code, Para. 51).

3.3.6. Specialized Committees of the Board of Directors

The board of directors of a listed company may establish a corporate strategy committee, an audit committee, a nomination committee, a remuneration and appraisal committee and other special committees in accordance with the resolutions of the shareholders' meetings. All committees shall be composed solely of directors. The audit committee, the nomination committee and the remuneration and appraisal committee shall be chaired by an independent director, and independent directors shall constitute the majority of the committees. At least one independent director from the audit committee shall be an accounting professional (The Listed Companies Code, Para. 52).

The main duties of the corporate strategy committee shall be to conduct research and make recommendations on the long-term strategic development plans and major investment decisions of the company (The Listed Companies Code, Para. 53).

The main duties of the audit committee are (1) to recommend the engagement or replacement of the company's external auditing institutions; (2) to review the internal audit system and its execution; (3) to oversee the interaction between the company's internal and external auditing institutions; (4) to inspect the company's financial information and its disclosure; and (5) to monitor the company's internal control system (The Listed Companies Code, Para. 54).

The main duties of the nomination committee are (1) to formulate standards and procedures for the election of directors and make recommendations; (2) to extensively seek qualified candidates for directorship and management; and (3) to review the candidates for directorship and management and make recommendations (The Listed Companies Code, Para. 55).

The main duties of the remuneration and appraisal committee are (1) to study the appraisal standard for directors and management personnel, to conduct appraisal and to make recommendations; and (2) to study and review the remuneration policies and schemes for directors and senior management personnel (The Listed Companies Code, Para. 56).

Each specialized committee may engage intermediary institutions to provide professional opinions, the relevant expenses to be borne by the company (The Listed Companies Code, Para. 57), and shall be accountable to the board of directors. All proposals by specialized committees shall be submitted to the board of directors for review and approval (The Listed Companies Code, Para. 58).

3.4. Supervisors and supervisory board

3.4.1. Duties and Responsibilities of the Supervisory Board

The supervisory board of a listed company shall be accountable to all shareholders. The supervisory board shall supervise the corporate finance, the legitimacy of directors, managers and other senior

management personnel's performance of duties, and shall protect the company's and the shareholders' legal rights and interests (The Listed Companies Code, Para. 59).

Supervisors shall have the right to learn about the operating status of the listed company and shall have the corresponding obligation of confidentiality. The supervisory board may independently hire intermediary institutions to provide professional opinions (The Listed Companies Code, Para. 60).

A listed company shall adopt measures to ensure supervisors' right to learn about company's matters and shall provide necessary assistance to supervisors for their normal performance of duties. No one shall interfere with or obstruct supervisors' work. A supervisor's reasonable expenses necessary to perform their duties shall be borne by the listed company (The Listed Companies Code, Para. 61).

The record of the supervisory committee's supervision as well as the results of financial or other specific investigations shall be used as an important basis for performance assessment of directors, managers and other senior management personnel (The Listed Companies Code, Para. 62).

The supervisory board may report directly to securities regulatory authorities and other related authorities as well as reporting to the board of directors and the shareholders' meetings when the supervisory board learns of any violation of laws, regulations or the company's articles of association by directors, managers or other senior management personnel (The Listed Companies Code, Para. 63).

3.4.2. The Composition and Steering of the Supervisory Board

Supervisors shall have professional knowledge or work experience in such areas as law and accounting. The members and the structure of the supervisory board shall ensure its capability to independently and

efficiently conduct its supervision of directors, managers and other senior management personnel and to supervise and examine the company's financial matters (The Listed Companies Code, Para. 64).

A listed company shall formulate in its articles of association standardized rules and procedures governing the steering of the supervisory board. The supervisory board's meetings shall be convened in strict compliance with the rules and procedures (The Listed Companies Code, Para. 65).

The supervisory board shall meet periodically and shall convene interim meetings in a timely manner when necessary. If for any reason a supervisory board meeting cannot be convened as scheduled, an explanation shall be publicly announced (The Listed Companies Code, Para. 66).

The supervisory board may ask directors, managers and other senior management personnel, internal auditing personnel and external auditing personnel to attend the meetings of supervisory board and to answer the questions that the supervisory board is concerned with (The Listed Companies Code, Para. 67).

Minutes shall be drafted for the meetings of the supervisory board, which shall be signed by the supervisors that attended the meetings and the person who drafted the minutes. The supervisors shall have the right to request to record in the minutes explanatory notes to their statements in the meetings. Minutes of the meetings of the supervisory board shall be properly maintained and stored as important records of the company (The Listed Companies Code, Para. 68).

3.5. Performance assessments and incentive and disciplinary systems

3.5.1. Performance Assessment for Directors, Supervisors and Management Personnel

A listed company shall establish fair and transparent standards and procedures for the assessment of the performance of directors, supervisors and management personnel (The Listed Companies Code, Para. 69).

The evaluation of the directors and management personnel shall be conducted by the board of directors or by the remuneration and appraisal committee of the board of directors. The evaluation of the performance of independent directors and supervisors shall be conducted through a combination of self-review and peer review (The Listed Companies Code, Para. 70).

The board of directors shall propose a scheme for the amount and method of compensation for directors to the shareholders' meeting for approval. When the board of directors or the remuneration and appraisal committee reviews the performance of or discusses the compensation for a certain director, such director shall withdraw (The Listed Companies Code, Para. 71).

The board of directors and the supervisory board shall report to the shareholder meetings the performance of the directors and the supervisors, the results of the assessment of their work and their compensation, and shall disclose such information (The Listed Companies Code, Para. 72).

3.5.2. Selection of Management Personnel

The recruiting of management personnel of a listed company shall be conducted in strict observation with relevant laws and regulations and the company's articles of association. No institution or individual shall interfere with a listed company's normal recruiting procedure for management personnel (The Listed Companies Code, Para. 73). The recruiting shall be carried out in a fair and transparent manner, through domestic and international markets for professional management, making full use of intermediary agencies (The Listed Companies Code,

Para. 74). Employment agreements shall be entered into by a listed company and its management personnel to clarify each party's rights and obligations (The Listed Companies Code, Para. 75). The appointment and removal of managers shall be in compliance with legal procedure an shall be publicly announced (The Listed Companies Code, Para. 76).

3.5.3. Incentive and Disciplinary Systems for Management

To attract qualified personnel and to maintain the stability of management, a listed company shall establish rewarding systems that link the compensation for management personnel to the company's performance and to the individual's work performance (The Listed Companies Code, Para. 77). The performance assessment for management personnel shall become a basis for determining the compensation and other rewarding arrangements for the person reviewed (The Listed Companies Code, Para. 78). The results of the performance assessment shall be approved by the board of directors, explained at the shareholders' meetings and disclosed (The Listed Companies Code, Para. 79).

A listed company shall specify management personnel's duties and responsibilities in its articles of association. If management personnel violate laws, regulations or the company's articles of association and cause damages to the company, the board of directors of the company shall actively investigate and pursue such personnel's legal liabilities (The Listed Companies Code, Para. 80).

3.6. Stakeholders and clients relationship

A listed company shall respect the legal rights of banks and other creditors, employees, consumers, suppliers, the community and other stakeholders (The Listed Companies Code, Para. 81); and shall actively cooperate with its stakeholders and jointly advance the

company's sustained and healthy development (The Listed Companies Code, Para. 82).

A company shall provide the necessary means to ensure the legal rights of stakeholders. Stakeholders shall have opportunities and channels for redress for infringement of rights (The Listed Companies Code, Para. 83). Necessary information shall also be provided to banks and other creditors to enable them to make judgments and decisions about the company's operating and financial situation (The Listed Companies Code, Para. 84).

A company shall encourage employees' feedback regarding the company's operating and financial situations and important decisions affecting employee's benefits through direct communications with the board of directors, the supervisory board and the management personnel (The Listed Companies Code, Para. 85).

While maintaining the listed company's development and maximizing the benefits of shareholders, the company shall be concerned with the welfare, environmental protection an public interests of the community in which it resides, and shall pay attention to the company's social responsibilities (The Listed Companies Code, Para. 86).

3.7. Information and disclosure and transparency

Information disclosure is an ongoing responsibility of listed companies. A listed company shall truthfully, accurately, completely and timely disclose information as required by laws, regulations and the company's articles of association (The Listed Companies Code, Para. 87). In addition to disclosing mandatory information, a company shall also voluntarily and timely disclose all other information that may have a material effect on the decisions of shareholders and stakeholders, and shall ensure equal access to information for all shareholders (The Listed Companies Code, Para. 88). Disclosed information by a listed company shall be easily comprehensible.

Companies shall ensure economical, convenient and speedy access to information through various means (such as the Internet) (The Listed Companies Code, Para. 89). The secretary of the board of directors shall be in charge of information disclosure, including formulating rules for information disclosure, receiving visits, providing consultation, contacting shareholders and providing publicly disclosed information about the company to investors. The board of directors and the management shall actively support the secretary's work. No institutions or individuals shall interfere with the secretary's work (The Listed Companies Code, Para. 90).

A listed company shall disclose information regarding its corporate governance in accordance with laws, regulations and other relevant rules, including but not limited to: (1) the members and structure of the board of directors and the supervisory board; (2) the performance and evaluation of the board of directors and the supervisory board; (3) the performance and evaluation of the independent directors, including their attendance at board of directors' meetings, their issuance of independent opinions and their opinions regarding related party transactions and appointment and removal of directors and senior management personnel; (4) the composition and work of the specialized committees of the board of directors; (5) the actual state of corporate governance of the company, the gap between the company's corporate governance and the Code, and the reasons for the gap; and (6) specific plans and measures to improve corporate governance (The Listed Companies Code, Para. 91).

A company shall timely disclose detailed information about each shareholder who owns a comparatively large percentage of shares of the company, the shareholders who actually control the company when acting in concert and the company's actual controllers in accordance with relevant regulations (The Listed Companies Code, Para. 92).

A listed company shall learn about and disclose in a timely manner, changes in the shareholding of the company and other important matters that may cause changes in the shareholding of the company (The Listed Companies Code, Para. 93).

When controlling shareholders increase or decrease their shareholding or pledge the company's shares, or when the actual control of the company transfers, the company and its controlling shareholders shall timely and accurately disclose relevant information to all shareholders (The Listed Companies Code, Para. 94).

3.8. Insider Information and Related Party Transactions

Concerning the scope of insiders, Article 74 of the Securities Law of China stipulates that persons possessing inside information relating to securities trading include: (1) the directors, supervisors and senior managers of an issuer; (2) the shareholders holding 5% or more of the shares of a company and the directors, supervisors and senior managers of such shareholders, as well as the persons in practical control of a company and the directors, supervisors and senior managers of such persons; (3) a company held by an issuer and the directors, supervisors and senior officers of such company; (4) the persons with access to the relevant inside information by virtue of their positions in a company; (5) the staff members of the securities regulatory authorities and other persons who perform their statutory administrative duties in respect of the issuance and trading of securities; (6) the relevant staff members of the sponsors, securities companies engaged for underwriting, stock exchanges, securities registrar and clearance institutions and securities service institutions; and (7) such other persons as may be so prescribed by the securities regulatory authority under the State Council.

Concerning insider information, Article 75 In the course of securities trading, any unpublished information relating to the business or

financial position of a company, or carrying significant effect on the market price of the securities of a company, shall constitute inside information.

All of the following information falls into the category of inside information: (1) the major events specified in the second paragraph of Article 67 of this Law; (2) a company's plan for profit distribution or capital increase; (3) a major change in the share capital structure of a company; (4) a major change in the surety for debts of a company; (5) any pledge, disposition or retirement of a principal business asset of a company, the value of a single transaction of which exceeds 30 percent of the total value of such asset; (6) potential liability for major losses to be assumed in accordance with law as a result of the activities of a director, supervisor or senior manager of a company; (7) the plans relating to the acquisition of a listed company; and (8) such other important information having an obvious effect on the trading price of securities as may be so defined by the securities regulatory authority under the State Council.

According to the Securities Law, Article 73 Persons possessing inside information relating to securities trading and persons obtaining such information unlawfully are prohibited from making use of such inside information in securities trading activities.

When a person with insider information deals with the related securities, leaks the information, or encourages another person to purchase or sell the securities prior to the publication of the information, any illegal income generated will be confiscated, and a fine equal to five times the illegal income obtained may be levied. The relevant conduct may also constitute a criminal offense. When transactions are conducted between related parties, their nature, type, and other pertinent information (such as the amounts involved and the basis for determining the transfer/disposal price) must be disclosed in the financial statements. the China Securities Regulatory Commission

will require listed companies to publish supplementary public notices to make up for any under-reporting.

Chapter 1 of the Listed Companies Code states the following three major points for related-party transactions (the China Securities Regulatory Commission, 2001): 12. Written agreements shall be entered into for related party transactions among a listed company and its connected parties. Such agreements shall observe principles of equality, voluntarity, and making compensation for equal value. The contents of such agreements shall be specific and concrete. Matters such as the signing, amendment, termination and execution of such agreements shall be disclosed by the listed company in accordance with relevant regulations (Para. 12, the Listed Companies Code).

Efficient measures shall be adopted by a listed company to prevent its connected parties from interfering with the operation of the company and damaging the company's interests by monopolizing purchase or sales channels. Related party transactions shall observe commercial principles. In principle, the prices for related party transactions shall not deviate from an independent third party's market price or charging standard. The company shall fully disclose the basis for pricing for related party transactions (Para. 13, the Listed Companies Code).

The assets of a listed company belong to the company. The company shall adopt efficient measures to prevent its shareholders and their affiliates from misappropriating or transferring the capital, assets or other resources of the company through various means. Listed company shall not provide financial guarantees for its shareholders or their affiliates (Para. 13, the Listed Companies Code).

3.9. Fiduciary Duties

According to the Company Law, directors, supervisors and the manager of a company shall comply with the articles of association of the company, faithfully perform their duties and maintain the interests

of the company and shall not take advantage of their position, functions and powers in the company to seek personal gains. They shall not take advantage of their functions and powers, and accept bribes or other unlawful incomes, nor may they misappropriate the property of the company (Article 59, The Company Law).

Directors and the manager of a company shall not misappropriate company funds or lend company funds to others, nor may they deposit company assets in their own personal accounts or in personal accounts of other individuals; use company assets as security for the personal debts of shareholders of the company or of other individuals (Article 60, The Company Law).

Directors and the manager shall not operate for themselves, or for others, the same category of business as is operated by the company they are serving or, engage in activities which impair the interests of the company. If doing so, the incomes derived there from shall belong to the company. Nor may they enter into contracts or conduct transactions with the company except as provided for in the articles of association or approved by the shareholders' meeting (Article 61, The Company Law).

Directors, supervisors and the manager take the responsibility not disclosing any company secrets except as provided for by law or approved by the shareholders' meeting (Article 62, The Company Law). If violating laws, administrative regulations or the articles of association in performance of their duties and thus cause damage to the company they shall be held liable for compensation (Article 63, The Company Law).

4. PREDICAMENT IN IMPROVING CORPORATE GOVERNANCE IN CHINA

4.1. Insider control of corporate affairs

A high level corporate governance is an impossible task due to lack of separation between ownership and management, which are played by only insider-managers, who are in turn controlled by their CPC and ministerial associates, who have no incentives to select the best managers or to ensure companies are efficiently and profitably operated. Documented abuses by controlling shareholders are very common practice in these companies (Lin 2004, pp. 7-8).

4.2. Weak Protection of Shareholders Rights

In Chinese, minority shareholders, commonly called private investors, are usually considered only speculators who wish to benefit from the increased price of securities, but not benefit from the company's performance, and thus their rights as investors are seldom protected (Jiang 2004, pp. 4-5). Criminal Law, Company Law, and Securities Law of China have not provided a procedure and specific clauses for enforceable civil actions (Lin 2004, pp. 8).

4.3. Insider trading, self dealings, collusion and market manipulation

A general lack of supervision leads to extensive insider trading, self dealings, collusion and market manipulation (Li, Naughton and Hovey 2004, p. 24; RAND 2008, p. 2; Kang, Lu and Brown 2008, p. 30-31; Lin 2004, pp. 8-9). However, it is wrong to say that this is due to the fact that the state is the ultimate owner of the state-owned enterprises and most listed firms. On the contrary, it is due to the fact that these companies are seldom monitored and the personnel in these companies benefit privately from these inappropriate practice.

4.4. Dysfunction of the board of directors

The Code for Corporate Governance of Listed Companies requires recognition of minority interests in appointment of directors. However, large shareholders have more power on such an issue based on their greater voting power. Politicians and state-controlling owners play a controlling role in most boards and committees due to the highly concentrated ownership structure. Therefore, no independent board can be expected and no director would like to represent minority shareholders (Li, Naughton and Hovey 2004, p. 25; RAND 2008, p. 2; Lin 2004, pp. 9-10).

4.5. Weak Supervisory Board

A two-tier board is practiced in corporate governance in China. However, in most cases, the supervisory board is only a nominal organization, which does not play any role in monitoring the board of directors. The selection of directors and managers are not supervised by supervisory board (RAND 2008, p. 2; Kang, Lu and Brown 2008, p. 29-30; Lin 2004, p. 10).

4.6. Weak Auditing Profession

Due to a general lack of skills and supervision mechanism, there are many problems in the operation of most Chinese accounting firms, which are lagging behind international criteria. Their defective practice causes many cases of fraud in Chinese securities market. Clearly defined liability of the Certified public accountants in China can only be found in one piece of legislative document, i.e. in the decision of the People's Congress on the implementation of the Company Law, which prescribed that, criminal charges could be imposed if auditors intentionally provide false documents concerning asset valuation, capital verification, and examination that resulted in serious consequences. The punishment could be imprisonment for up to five years and fines for up to RMB 200,000 Yuan (Lin 2004, pp. 10-11). Besides this, there is no legal basis for holding them liable.

4.7. Weak External Governance Structure

Lin identified four areas of weakness in the external governance structure. The first is that the market for corporate control is weak due to the lack of professional management, obstacles in regulations, and lack of transparency. The second is the missing of an independent judiciary in China and thus a weak enforcement system. The third is the missing of monitor by players such as banks, professional organizations, and the mass media. And finally, small and insignificant number of institutional investors do not play a major role to improve corporate governance (Lin 2004, p. 11). These critics are sometimes controversial, and in most times not recognized in official discourse, let alone any action to be taken in dealing with them.

4.8. Falsification and Fabrication of Financial Data

In the area of corporate governance, an obstacle between ideal and reality has been that the expectation for following international criteria always loses to the fact that there is a lack of motivation for transparency on the corporate side. Therefore, mandatory disclosure cannot be guaranteed and investors cannot trust the accuracy of the corporate reports. General investors cannot acquire the reports timely, neither can they understand them clearly. Thus the company can be operated beyond the control of both the government and the investors, whose efforts should have played an important role in improving corporate governance but only been left in vain (RAND 2008, p. 2; Kang, Lu and Brown 2008, pp. 31-32; Lin 2004, p. 9).

5. POSSIBLE SOLUTIONS TO KEY PROBLEMS IN CORPORATE GOVERNANCE IN CHINA

To solve these problems, a number of suggestions can be valuable in improving corporate governance in China.

First of all, emphasis on shareholder's rights should always be implemented in laws, regulations and practice (Lin 2014). Considering the maintenance of healthy operation of the Chinese securities market, the role of all shareholders, particularly that of those minority shareholders, should be respected and protected in the decision-making and supervision mechanism.

In addition, the obligation of controlling shareholders should be put under supervision (Lin 2014). In China, in frequent cases, such controlling shareholders in state-owned enterprises are theoretically those representatives of the state, but in reality insider-managers authorized by the state. They have the power beyond any law and regulations to benefit solely from the monopolized management and operation of the businesses, sometimes at the expense of other shareholders. This situation should be ameliorated as long as the reform of state-owned companies is preferred.

Furthermore, clearly defined, empowered and independent boards of directors and supervisors should be installed so as to improve the quality of their operations. Specialized committees, including corporate strategy committee, nomination committee, remuneration committee, and auditing committee should also be strengthened. Concerning the remuneration, a performance-related compensation mechanism should be introduced (Li, Naughton and Hovey 2004, p. 26).

From a long-run, general legal atmosphere should also be improved in China to enforce provisions on investor protection. Irregularities should be diminished to a minimum so as to breed investors' confidence with the investment environment (Li, Naughton and Hovey 2004, p. 27).

6. CONCLUSIONS

It is noteworthy that the reform in China in the past four decades constituted of two strings of ideas: one string was to liberate productivity and improve efficiency, while the other was to establish legitimacy for a minority of the emerging rich class to take control of property that was originally designed to belong to, in theory, a majority or even all people. As such, in conclusion, development of Chinese law is both a legal topic and a political mechanism, without which social stability is feared unable to be maintained.

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Legal Foundation of Bolar Exemption

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The legal foundation of the Bolar exemption, which allows generic drug manufacturers to obtain marketing permission for pharmaceutical products before the expiration of patents, is based on international agreements such as the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). TRIPS aims to strike a balance between long-term social objectives and short-term goals by providing patent protection while allowing certain provisions to ensure accessibility to medicines.

Under TRIPS, member states are obligated to provide patent protection for inventions that meet certain criteria, including novelty, inventive step, and industrial applicability. However, there are exceptions to patenting in the context of public health, such as inventions that could exploit human, animal, or plant life or health. Article 30 of TRIPS allows countries to limit patent rights through exceptions if it does not unreasonably exploit the patent.

TRIPS also includes flexibilities that support public health, including the Bolar provision. The Bolar exemption allows generic manufacturers to conduct research and seek marketing authorization for pharmaceutical products before the patent expires. This provision is particularly important during health crises, as it facilitates timely access to medications. However, practical obstacles and variations in the implementation of Bolar exemptions exist among countries.

Challenges in implementing Bolar provisions during health crises include the need for a case-by-case approach, limitations in national legislation, and the complexity of the intellectual property system. Intellectual property (IP) tools, such as secondary patents and patent thickets, can also act as barriers to the entry of generic and biosimilar medicines into the market.

Overall, the legal foundation of the Bolar exemption and other TRIPS flexibilities plays a crucial role in promoting access to medicines, especially during health crises. However, addressing challenges and ensuring efficient implementation of these provisions remains an ongoing concern.

1. The Relation of TRIPS on Pharmaceutical Patents to the Good of Public Health

The implementation of intellectual property pragmatism, particularly patents on drugs, can hinder heavily accessibility of medicines. For example, it is probably that the price of medicines rises suddenly, the motivation of local producers is reduced, or the motivation of research and development is increased. As a result, accessibility to medicines would become difficult. Therefore, realisation of intellectual property rights strictly could directly lead to difficult accessibility to the human right to health.[1] The WTO Doha

[1] Cullet Philippe. Patents and Medicines: The Relationship between TRIPS and the Human Right to Health. International Affairs (Royal Institute of International Affairs 1944-) Vol. 79, No. 1 (Jan., 2003), pp. 139-160.

Declaration on TRIPS and Public Health was agreed by WTO members in 2001, from a structured public health policy regarding intellectual property systems.[2] However, it has been struggling for international law to account for human rights and economic development.[3]

The philosophy of TRIPS is to balance both the long term social objectives by providing incentives for future inventions and creations, and short term goals in allowing the use of existing inventions and creations.[4] WTO members are obliged to provide patent protection for any invention belonging to a product or process, while allowing certain provisions stated in Article 27.1.[5] In Article 33, terms of protection shall end on the expiration date of the period of twenty years from the date of filing. [6] Implying context of non-discrimination, Member State cannot discriminate against different fields of technology in their patent regimes.[7] Nor can Member States discriminate against the place of the invention or if the product is imported or produced locally. [8]

Despite the facts listed above, there are three criteria to be fulfilled in order to qualify for a patent, such that an invention should have a sense of

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[2] WTO. TRIPS and publish health <https://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm> accessed 19 May 2021

[3] WTO. Agreement on Trade-Related Aspects of Intellectual Property Rights (as amended on 23 January 2017) <https://www.wto.org/english/docs_e/legal_e/31bis_trips_01_e.htm>accessed 19 May 2021

[4] WTO. TRIPS and Pharmaceutical patents fact sheet (WTO OMC, September 2006) p.1<https://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf> accessed 23 July 2021.

[5]The TRIPS Agreement Article 27 section 1. Subject to the provisions of paragraphs 2 and 3

[6] The TRIPS Agreement Article 33.

[7] The TRIPS Agreement Article 27.1

[8] ibid.

"novelty", and it is compulsory to have an "inventive step" and not "obvious", also " industrial applicability". [9] Last but not least, details of the invention shall be described in the application while made public.[10] Member States are able to require the applicant to disclose the details of the invention as well as the best practices of carrying out the product or process. [11]

In the context of public health, Member State can refuse to grant patents, where the inventions could possibly commercially exploit human, animal or plant life or health according to Article 27.2 [12] Certain circumstances that enable methods that are diagnostically, therapeutically and surgically, able to treat humans or animals listed in Article 27.3a. [13] Also, stated in Article 27.3b, particular plants and animal inventions are excepted from patenting. [14] Further, under the TRIPS Agreement Article 30, Members are able to limit exceptions to patent rights, if certain conditions do not exceed "unreasonable" exploitation of the patent.[15]

Article 30 indicates that countries may allow generic drug manufacturers to obtain marketing permission from the public health authorities without the approval of the patent owner and even before the expiration of the patent. [16] The TRIPS Agreement Articles 8 and 40 give Members the power to act preventively towards patent owners and other holders of IP rights from abusing IP rights, such as unreasonably restraining trade, or hampering the international transfer of technology.[17]

Relevantly, Article 30 of TRIPS Agreement provides its Members who can "provide limited provisions to the exclusive rights conferred by a patent,

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[9] ibid.
[10] ibid.
[11] The TRIPS Agreement Article 20.1 Article 29.1
[12] The TRIPS Agreement Article 27.2
[13] The TRIPS Agreement Article 27.3a
[14] The TRIPS Agreement Article 27.3b
[15] The TRIPS Agreement Article 30.
[16] ibid.
[17] ibid.

provided that such provisions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties. " Additionally, Article 31 indicates a set of the "other uses without authorisation of the right holder", which includes the eligible use by the government or third parties authorised by the government, and which are not outlined in Article 30. [18]

There are certain obligations under the TRIPS Agreement for Member States on patenting pharmaceuticals.[19] According to TRIPS Article 27.1 Member States are required to obtain patenting for any inventory objects which includes products such as medicine or a process that can be a method to produce chemical ingredients for a medicine. Article 27.1 further rules that Member States should not discriminate between "different fields of technology" in their patent regimes, or "place of invention" or if the products are "imported or locally produced".

In addition, Article 27.1 outlines that there are three criteria for qualifying a patent: such a patent shall be "novel" and including the "inventive step" and "industrial applicability" meaning that it must be useful as an invention. Article 29.1 demands that the invention should file the application with the invention of detailed description which will be made public. Moreover, the applicant may be required to disclose the best method to carry out the invention. Article 33 indicates that patent protection lasts at least 20 years from the date of the filing of the patent application.

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[18] WTO, Part II- Standards concerning the availability, scope and use of intellectual property rights section 5 and 6. https://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm > accessed 23 July 2021.

[19] ibid.

2. TRIPS Flexibilities

Most of the flexibilities were settled at the Doha Ministerial Conference in November 2001 and member governments came to the conclusion that the TRIPS Agreement shall be interpreted in such a way supporting public health, to ease up access to existing medicines as well as create new medicines.[20] The term "flexibilities" became popular especially after the Doha Declaration on TRIPS and Public Health expressing TRIPS "flexibilities" used by trade negotiators within the IP community. [21]

Furthermore, the phrase "flexibility" appears in several provisions, including paragraphs 6 of the TRIPS Agreement's preamble: "[...] the special needs of the least-developed country Members in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base." Article 66.1 explains the definition of the word "flexibility" as it appears in the Preamble: "In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of[...]"

In 2011, the UNAIDS/WHO/UNDP policy brief for economies to use the TRIPS flexibilities reported an increased access to HIV/AIDS treatments.[22] However, practical obstacles exist in using Bolar exemptions.[23] In the long struggle for bridging disagreements and balancing the benefits of different players, only limited but useful achievements have been made.

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[20] ibid.

[21] ibid.

[22] WIPO. SCP/31/5 Annex I, page 7 (23) <https://www.wipo.int/edocs/mdocs/scp/en/scp_31/scp_31_5.pdf> accessed 17 April 2021

[23] ibid.

The Bolar provision, in conjunction with research provisions, is used to advance science and technology.[24] It is supplemented by a more general research exemption, which is an exemption from infringement of specific research activities. In addition, Bolar exemption does have a basis in EU law whereas research exemption has its scope varying significantly from a country to another.[25] Because researchers may use a patented invention for research and to better understand the invention.[26]

The Bolar exemption to the TRIPS Agreements serves as a mechanism to expedite governments' access to medications during a health crisis.[27] A corporation may perform actions to seek marketing authorisation for a pharmaceutical product before the patent expires for the protection of the active substance of the original medicinal product under the Bolar exemption.[28] Furthermore, the grey area of marketing and selling under the Bolar exemption is when a company freely markets and sells a generic version of a patented drug for the express purpose of testing. [29]

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[24] ibid.

[25] Pinsent Masons, 'Broadening safe harbours and patent exemptions for pharmaceuticals in Europe' (Outlaw, 26 February 2020) ,<https://www.pinsentmasons.com/out-law/analysis/safe-harbours-patent-exemptions-pharmaceuticals-europe> accessed 27 July 2021

[26] WTO. ' TRIPS and Pharmaceutical patents fact sheet' (WTO OMC, September 2006) p1<https://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf> accessed 23 July 2021

[27] ibid.

[28] European Commission (EC), ' Commission staff working document of the Regulation' (Brusself, 25.11.2020) No 469/2009 SWD 292 Final <https://ec.europa.eu/docsroom/documents/43847/attachments/2/translations/en/renditions/native> accessed 15 August 2021

[29] ibid.

It has been revealed that despite the significant decrease of price, it has been still a critical factor obstructing obtaining HIV treatment in Low- and middle-income countries (LMICs).[30] Previous findings proved that the application of TRIPS flexibilities, have a positive impact on accessing treatments.[31] Thailand invoked compulsory licensing due to failure to negotiate a suitable price for the HIV/AIDS drug Kaletra (lopinavir/ritonavir) with Abobott in 2007.[32]

According to UNAIDS and WIPO research, among 142 countries, 95 of them have available data indicating that 56% actually implemented the TRIPS flexibilities including Bolar provision into their national patent legislation.[33] The study also found that the percentage of countries implementing the flexibilities varies from 0% for the least developed countries to 93% for high-income countries.[34] The inequality of economic development and unbalanced quality of living make the gap unfortunately unignorable. While the LMICs have had little access to innovative achievements in technological developments, there is also a lack of response to such issues in their legal systems. Even worse, there has long been an idea that taking intellectual property protection as negatively affecting the affordability and availability of access to pharmaceuticals.[35]

On the other side of the coin, there is the issue of patent infringement which is the commission to prohibit any acts without respect to a patented

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[30] WIPO. SCP/31/5 Annex I, page 7 (23)<https://www.wipo.int/edocs/mdocs/scp/en/scp_31/scp_31_5.pdf> accessed 17 April 2021

[31] ibid.

[32] ibid.

[33] UNAIDS Box 3: WIPO study on patent-related flexibilities in 142 countries <https://www.unaids.org/sites/default/files/media_asset/JC2049_PolicyBrief_TRIPS_en_1.pdf> accessed 17 May 2021

[34] ibid.

[35] Sell Susan K, '*Private Power, Public Law: the Globalization of Intellectual Property Rights*' (Cambridge University Press 2003)

invention from the patent holder.[36] Licenses are therefore granted to such a permission.[37] Patent infringement varies in jurisdictions, and it generally includes the use or sale of the patented invention. [38]

According to the WIPO, the objective and goals of the Bolar exemption of the **regulatory review provision** in countries are to avoid a de facto extension of the patent term.[39] Bolar exemption is to aid in the marketing of generic medicines immediately after the patent term expires,[40] to boost market competition.[41] Furthermore, competition lowers product prices, which promotes the affordability of patent-expired medicines, reducing access to and the cost of treatment.[42]

The regulatory review provision is a mechanism to increase competition and, as such, should be recommended in developing countries to apply to their patent laws, among other provisions outlined in the WHO Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property, which calls everyone to action to implement TRIPS flexibilities by allowing them to be incorporated into national laws. [43]

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[36] WIPO<https://www.wipo.int/export/sites/www/sme/en/documents/pdf/ip_panorama_3_learning_points.pdf> 31 May 2021

[37] ibid.

[38] ibid.

[39] WIPO, SCP/27/3 Standing Committee on the Law of Patents. Twenty - Seventh Session Geneva, (11 -15 December 2017) <https://www.wipo.int/edocs/mdocs/scp/en/scp_27/scp_27_3.pdf > accessed 14 May 2021

[40] WIPO, SCP/27/3 Standing Committee on the Law of Patents. p 4, objectives and goals 4.

[41] ibid.

[42] WIPO, SCP/27/3 Standing Committee on the Law of Patents. pa 17 and 18.<https://www.wipo.int/edocs/mdocs/scp/en/scp_27/scp_27_3.pdf >accessed 14 May 2021

[43] WIPO, 'The Global Strategy and Plan of action on public health, innovation and Intellectual Property'

Member States of WIPO administered treaties have a certain degree of manoeuvre to implement their obligations.[44]

Moreover, a separate declaration on TRIPS and Public health is made.[45] Member governments were granted that TRIPS Agreement will not prevent them from taking measures on protection of public health.[46] The Least Developed Countries until 2016 are granted the extension on pharmaceuticals for patent protection in regard to the TRIPS agreement.[47] Countries rather use TRIPS flexibilities than going under the Doha Declaration Paragraph 6 Waiver mechanism because it is too lengthy and trivial a procedure.[48] TRIPS flexibilities have provisions that are "public health sensitive" including Article 6 exhaustion parallel imports, Article 31 experimental use of early working/''Bolar provision'' and Article 31 in the TRIPS Agreement compulsory licensing. [49]

The advantageous utilisation of TRIPS flexibilities, especially Bolar exemption, would positively impact access to the COVID-19 vaccines during health crises.[50] [51] During the COVID-19 pandemic, discussions about patent

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<https://www.who.int/phi/implementation/phi_globstat_action/en/>accessed 14 May 2021

[44] WIPO, 'Meaning of flexibilities' <https://www.wipo.int/ip-development/en/agenda/flexibilities/meaning_of_flexibilities.html> accessed 8 June 2021

[45] ibid.

[46] ibid.

[47] ibid.

[48] ibid.

[49] WHO, 'Access to affordable medicines for HIV/AIDS and hepatitis: the intellectual property rights context.' Chapter 3 <https://apps.who.int/iris/bitstream/handle/10665/204741/B5144.pdf?sequence=1> accessed 14 May 2021

[50] WTO. TRIPS 31bis. <https://www.wto.org/english/docs_e/legal_e/31bis_trips_01_e.htm> accessed 19 May 2021

protection, reasonable access to technological knowledge, and balancing the innovator and the end-user were a focus in both the private and public sectors in regards to the creation of new vaccines and medications to combat the disease. TRIPS flexibilities have been credited as allowing economies to address the pressing public health crisis.

3. Bolar Exemption under Health Crises

Patent owners are granted exclusive rights under the TRIPS agreement to prevent anyone from making, using, offering for sale, selling, or importing patented products, which are exempted by Articles 30 and 31.[52] Furthermore, Article 30 allows Member States to make provisions for exclusive patent rights, and such provisions must meet three cumulative conditions, referred to as the three-step test: the provisions must be limited; they must not be unreasonably conflicted with the normal exploitation of the patent; and they must not unreasonably prejudice the patent owner's legitimate interest, taking into account of the legitimate interests of third parties.[53]

The "regulatory provision" refers to the situation in which generic manufacturers can continue to offer their copies of medications after the patent expires.[54] Bolar Provision' is used by Member States to advance

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[51] Doha WTO Ministerial 2001: TRIPS WT/MIN(01)/DEC/2 Declaration on the TRIPS agreement and public health adopted on 14 November 2001.< :https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm> accessed from 9 April 2021

[52] The TRIPS Agreement Article 30, 31

[53] The TRIPS Agreement Article 30

[54] WTO, 'FACT SHEET: TRIPS AND PHARMACEUTICAL PATENTS Obligations and exceptions' (World Trade Organisation, 2021) <https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm#Bolar> accessed 19 May 2021

science and technology, by allowing researchers to use patented inventions for research to understand the invention.[55] It allows generic firms to exploit patent-protected inventions to acquire marketing authorisation without the agreement of the patent owners, allowing them to market the items after the patent expires. [56] It further permits the use of patented knowledge for the development of information required for regulatory and market-entry approval during the patent term.[57]

The importance of bolar exemption amid global health crises is demonstrated. Some nations, according to Article 30, enable generic medication producers to exploit a protected invention to get marketing authorisation from public health authorities without the patent owner's approval or knowledge, and before the patent protection expires. [58]

To launch a pharmaceutical product, the company must first seek regulatory approval while undertaking clinical studies and trials to ensure that the medication is both safe and effective.[59] In the case of generic or biosimilar drugs, the producer relies on some of the data supplied by the original application for marketing authorisation with the original

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[55] ibid.

[56] WHO, Access to affordable medicines for HIV/AIDS and hepatitis: the intellectual property rights context. 3. TRIPS flexibilities and compulsory licensing. <https://apps.who.int/iris/bitstream/handle/10665/204741/B5144.pdf?sequence=1>accessed 14 May 2021

[57] ibid.

[58] WTO, 'FACT SHEET: TRIPS AND PHARMACEUTICAL PATENTS Obligations and exceptions' (World Trade Organisation, 2021) <https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm#Bolar> accessed 19 May 2021

[59] EC, Volume 2 A procedures for marketing authorisation Chapter 1 Marketing authorisation July 2019 <https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-2/vol2a_chap1_en.pdf> accessed 19 May 2021

pharmaceutical product, to avoid doing comprehensive clinical trials.[60] The provisions to patent rights are considered such as private use or experimental purposes and use, before a patent is granted.[61]

4. Challenges to Implementation of Bolar Provisions under Health Crisis

Difficulties in practical use

Using TRIPS flexibilities, such as Bolar clauses, can be challenging in practice.[62] TRIPS flexibilities are used to protect public health, however the "case by case" or "product by product" approach required at the national level when employing flexibilities to overcome IP obstacles conflicts with national legislation.[63] There are expectations from trading partners, as well as a lack of practical and institutional capacity to employ TRIPS flexibilities swiftly and efficiently when health crises develop, in addition to restrictions

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[60] ibid.

[61] WIPO, 'Certain aspects of National/Regional Patent Laws:Exceptions and Limitations of the Rights Status as of April 2020' , <https://www.wipo.int/export/sites/www/scp/en/national_laws/exceptions.pdf> accessed 18 May 2021

[62] WTO TRIPS provisions on remuneration for non-voluntary use of a patent, Section 2 , page 13, <https://www.who.int/hiv/amds/WHOTCM2005.1_OMember State.pdf> accessed 28 July 2021

[63] IP/C/672 Waiver from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of COVID-19-responses to questions, paragraph 51, <https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?language=E&CatalogueIdList=270209,270165,270173,270168,269875,269476,269346,269188,268935,268754&CurrentCatalogueIdIndex=1&FullTextHash=&HasEnglishRecord=True&HasFrenchRecord=False&HasSpanishRecord> accessed 28 July 2021

in the national legal system.[64] As a result, suitable TRIPS-compliant safeguards must be implemented into national laws.[65] Furthermore, the measures must be practical and easy to apply.[66]

The TRIPS flexibilities in the IP system, as outlined by WIPO IPO, demonstrate the practical steps that Member States committed to at the sixth session of the Committee on Development and Intellectual Property (CDIP) to assist in understanding the flexibilities.[67] There seemed to be a sufficient number of reliable sources of guidelines to aid with various applications, such as The Medicines Law & Policy, which gives a flowchart to guide the user through the process of filing the best alternative application.[68] It provides the TRIPS Flexibilities Database with instances on implementation of the flexibilities in the national IP laws in jurisdictions such as Finland, the US and China.[69] However, with a list of extensive regulations and provisions, the best practices are left to the national authorities to comprehend and adjust.

IP as barriers

IP tools, which many innovators used to govern the life cycle of medicinal products are, in fact, acting as barriers and affecting the timely entry to the

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[64] ibid.

[65] ibid.

[66] ibid.

[67] WIPO IPO. Flexibilities in the Intellectual Property System. <https://www.wipo.int/ip-development/en/agenda/flexibilities/> accessed 27 July 2021

[68] Medicines Law & policy, Tools, https://medicineslawandpolicy.org/wp-content/uploads/2017/05/Flowchart-Tools-MLP.pdf> accessed 30 July 2021

[69] Medicines Law &Policy, The Trips Flexibilities Database, <http://tripsflexibilities.medicineslawandpolicy.org/> accessed 30 July 2020

market of generic and biosimilar medicines.[70] Secondary patents are used widely to create so-called "evergreening" strategies and Patent thickets, where multiple "follow-up" overlapping patents stating different aspects of the same product that can be filed in different jurisdictions.[71]

Further, the White Paper by Pinsent Masons, Medicines for Europe and Accord mentioned that patent thickets may contain "protection of polymorph or hydrated forms of the active substance (API) , its salts or isomeric forms, a substantially pure form of the API or an impurity formed in the manufacturing process, formulations, different concentrations of dosage forms, the manufacturing and analytical methods, the use in specific patients groups or for diagnosis, or a second medical use." [72] In short, patent thickets around a device means that biosimilar companies are unable to switch between devices.

Medecins sans frontieres(MSF) has produced a report on the impact of patents on the introduction of inexpensive vaccines in developing countries.[73] While the report focuses on pneumococcal conjugate vaccines (PCV) and the human papillomavirus (HPV) vaccine, it reveals the broad patent claims that have been applied for or granted across the entire spectrum of vaccine development, production, and use, including vaccine-production

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[70] EIPG, 'Barriers to generic and biosimilar entry on the market', <https://www.pharmaworldmagazine.com/barriers-to-generic-and-biosimilar-entry-on-the-market/> accessed 20 July 2021

[71] ibid.

[72] Robert Vida, Catherine Drew, Belinda Lavin, Becky Ellis, Ewan Bruce. White paper: Anatomy of a failure to launch: a review of barriers to generic and biosimilar market entry and use of competition law as a remedy, (Medicines of Europe, 4 November 2020), <https://www.medicinesforeurope.com/docs/2020.11.04-Medicines-for-Europe-Whitepaper.pdf > accessed 30 July 2021

[73] MSF, 'MSF analysis of EU communications to TRIPS Council on COVID-19 IP waiver proposal, Technical Report (29 June 2021) <https://msfaccess.org/msf-analysis-eu-communications-trips-council-covid-19-ip-waiver-proposal> accessed 16 August 2021

materials such as chemical reagents, host cells, vectors, and DNA/RNA sequences; vaccine compositions; process technologies; and vaccine delivery systems.[74]

Patents generated uncertainty, increased costs, and delayed competition, resulting in high pricing and access obstacles in developing countries. In 2016-2017, MSF filed a patent objection and later a writ petition to challenge Pfizer's vaccine composition patent, which blocked the development of alternative versions of Pfizer's PCV13 vaccine. When an identical patent was granted, a South Korean vaccine researcher was ordered to stop making PCV13. MSF's patent invalidation action against Pfizer for PCV13 remains pending in India.[75]

Unless meaningful actions are done to resolve intellectual property restrictions, a similar situation will arise with COVID-19 vaccines. Many patent filings and grants have already been discovered, including more than 100 patents on mRNA platform technologies that are employed in COVID-19 vaccines. [76]

TRIPS Plus provisions

TRIPS Plus is an official term for protecting IPRs that are not included in the requirements of TRIPS Agreements.[77] These North-South trade arrangements embrace IPR chapters that oblige signing parties with higher

[74] ibid. 47
[75] ibid. 48
[76] ibid. 49
[77] WHO, Impact Assessment of TRIPS Plus Provisions on Health Expenditure and Access to Medicines, (WHO, 22-24 November 2006) https://apps.who.int/iris/bitstream/handle/10665/205326/B2072.pdf> accessed 25 July 2021

IPR standards, which are the TRIPS-plus provisions. [78] In fact, FTAs are technologically asymmetric meaning that they are on the sole profit of countries that are net-exporters of IP related goods, whereas, net-importer countries are put to extreme burden with heavily protected goods by IPR. [79]

Further, FTAs suggest higher IP protection than TRIPS-plus provisions established, thus depriving the parties to use TRIPS flexibilities to protect public health. [80] Provisions included in FTAs compose potential challenges for the Bolar provisions. [81] Commission on Intellectual property rights, innovation and public health (CIPIH) study back in 2005 already found that FTAs between developed countries (essentially the US) and developing countries, have risk on effective use of TRIPS flexibilities in developing countries for public health purposes. [82]

One of the requirements of TRIPS plus is data exclusivity, which established a ground for governments to provide an exclusivity period for the test data developed by the originator company.[83] TRIPS-plus provides data exclusivity as it prevents registration of generic medicines for 5 years, which

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[78] Wael Armouti. Evolution of data exclusivity for pharmaceuticals in Free Trade Agreements, (south centre policy brief 76, April 2020), < https://www.southcentre.int/policy-brief-76-april-2020/> accessed 30 July 2021

[79] ibid.

[80] ibid.

[81] Sisule F. Musungu (South Centre) and Cecilia Oh(World Health Organization) The use of Flexibilities in TRIPS by developing countries: can they promote access to medicines? page 3, (Commission on Intellectual property rights, innovation and public health (CIPIH) study 4C , August 2005), < https://www.who.int/intellectualproperty/studies/TRIPSFLEXI.pdf> accessed 30 July 2021

[82] ibid.

[83] Wael Armouti. Evolution of data exclusivity for pharmaceuticals in Free Trade Agreements, (south centre policy brief 76, April 2020), < https://www.southcentre.int/policy-brief-76-april-2020/> accessed 30 July 2021.

is not required by TRIPS.[84] Further, the cheaper generic products entering into developing countries will be delayed because of data exclusivity protection.[85] However, countries who signed FTAs are able to mitigate its effects on public health by adjusting its national legislation such as to limit the scope and to provide exceptions to data exclusivity. [86]

Data exclusivity

Another type of IP provision that should be addressed is data exclusivity, which can have a significant negative impact on generic competition by delaying the entry of generic drugs into national and international markets.[87] Data exclusivity prohibits generic competitors from using clinical test data submitted by original pharmaceutical companies, affecting generic companies, which are typically located in developing countries and are unlikely to have the necessary funds and capabilities to replicate the time-consuming clinical trials required, for example, by the Food and Drug Administration (FDA) to prove the safety and efficacy of a certain drug. [88]

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[84] WTO. Public Health protection in patent laws: selected provisions pdf., page 7, box 5.

[85] Wael Armouti. Evolution of data exclusivity for pharmaceuticals in Free Trade Agreements, (south centre policy brief 76, April 2020), < https://www.southcentre.int/policy-brief-76-april-2020/> accessed 30 July 2021.

[86] Sisule F. Musungu (South Centre) and Cecilia Oh(World Health Organization) The use of Flexibilities in TRIPS by developing countries: can they promote access to medicines? page 3, (Commission on Intellectual property rights, innovation and public health (CIPIH) study 4C , August 2005), < https://www.who.int/intellectualproperty/studies/TRIPSFLEXI.pdf> accessed 30 July 2021

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[88] Alessandro Pigoni, 'TRIPS-Plus Provisions and the Access to HIV Treatments in Developing Countries' (E-IR, 19 April 2020) <

Competition policy

Competition is the antonym of monopoly, businesses should be a competitive game in a free market, with the consumers as beneficiaries.[89] During COVID-19, there are countries desperate for respirators and chemicals that are needed to test the disease, further they need their production facilities in China to produce the goods, which are being confined.[90]

All this is due to globalisation, which enhances economic growth, however it makes countries dependent on the countries with which trade happens.[91] Thus, globalisation is in its nature interdependent with each country,[92] however there are aspects that should be mitigated especially for the health crisis.

Fred Jenny from UN further discusses that under a health crisis, there is absolutely no time to run a full program of scientific experiments on medical clinical trials to test the most appropriate medicines against the virus, therefore the government is better to act on the intuition to reach decisions faster.[93] Both the public and private policy should act in accordance with the

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https://www.e-ir.info/2020/04/19/trips-plus-provisions-and-the-access-to-hiv-treatments-in-developing-countries/ > accessed 14 August 2021

[89] EC, 'What is competition policy?' <https://ec.europa.eu/competition-policy/consumers/what-competition-policy_en> accessed 17 August 2021

[90] OECD Competition Division, 'COVID-19: Fred Jenny on economic resilience and the role of competition policy in times of crisis' (22 April 2020) <https://www.youtube.com/watch?v=UR7x_ZxteUg&t=55s> accessed 14 August 2021

[91] ibid.

[92] Martin Wolf, 'Globalisation and interdependence ' (31 August 2004) <https://www.un.org/esa/documents/un.oct.2004.globalisation.and.interdependence.pdf> accessed 16 August 2021

[93] ibid.

common goal, that the industrial policy should repatriate their allocations domestically to prevent health crises.

Positive competition policies should be adopted for a long-run, such as inter-state cooperation, across continents collaborations. To eliminate price gouging is to distribute the resources to those who really need them. Sometimes, government interventions should apply to the industry prices. For example, in Finland and the US, state aid is also provided during the health crisis so that industry is able to quickly restart to the domestic economic re-boost.[94] [95] On the other hand, China provided the highest ever amount of humanitarian assistance, already in over 150 countries, during COVID-19.[96]

Another aspect is that the resources should be distributed equally, meaning that people should be separated from the infected people. At the beginning of the COVID-19 pandemic, due to the fact that many countries were not prepared for such a crisis, many people were left unprotected with personal protective equipment. For example, this is impossible when Finland did not have the resources to provide FFP-class protective equipment in Finland, not because it is unnecessary but because there is a shortage of such equipment.[97] In addition, for the Finnish elderly care, many caregivers had

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[94] Ministry of Economic Affairs and Employment, 'Temporary amendments to business development aid to continue until the end of 2021', (23 June 2021) <https://valtioneuvosto.fi/en/-/1410877/temporary-amendments-to-business-development-aid-to-continue-until-the-end-of-2021> accessed 16 August 2021

[95]Tax foundation, 'The COVID-19 Relief Bill Contains over 100 Billion USD in state Aid After All, (23 December 2020) <https://taxfoundation.org/coronavirus-relief-state-aid/> accessed 16 August 2021

[96] CSIS, ' China's Humanitarian Aid: Cooperation amidst Competition' (17 November 2020)<https://www.csis.org/analysis/chinas-humanitarian-aid-cooperation-amidst-competition> accessed 16 August 2021

[97] HS, 'Finnish Institute of Occupational Health: There is no reason for the widespread use of FFP-class protective equipment in Finland - They are not enough for everyone, says the expert: " A surgical mask is enough for

no face-masks for all visits.[98] Such a situation occurred also in many other countries at the time, only relieved in the following months.

everyday use"' (3 Feberuary 2020) <https://www.hs.fi/hyvinvointi/art-2000007779039.html> accessed 16 August 2021

[98] Yle, 'Many relatives have been frightened by faceless caregivers at the elderly - there are not enough masks for all visits, even if the instructions require it.' (15 April 2020<https://yle.fi/uutiset/3-11306112> accessed 16 August 2021