COMPULSORY LICENSES FOR PHARMACEUTICAL PATENTS IN CHINA IN LIGHT OF THE TRIPS AGREEMENT

Qian YIN[*]

ABSTRACT

The recurrence of public health emergencies has made the issue of access to drugs a pertinent problem for developing countries. As a public health safeguard, the compulsory license system for patented pharmaceuticals is embodied in the international intellectual property (hereinafter "IP") norms related to public health. The Agreement on Trade-Related Aspects of Intellectual Property Rights (hereinafter "TRIPS Agreement") flexibility is a double-edged sword for the pharmaceutical patent system in developing countries. On the one hand, the exception clauses to IP protection under the TRIPS Agreement, especially the compulsory licensing system, give member states the possibility of exempting their treaty obligations in the event of a public health crisis. On the other hand, the different interpretations deriving from the ambiguity of TRIPS "flexibility" defer members from implementing compulsory licensing in response to a public health crisis. China has established a systematic set of rules, including legislation and policies on compulsory licensing and integrated the TRIPS flexibility into Free Trade Agreements (FTAs). However, it still lacks clear procedural provisions regarding the compulsory licensing of pharmaceutical patents in the context of the public health crisis, which affects China's ability to use TRIPS

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flexibility of Compulsory licenses effectively.

Furthermore, China's compulsory license law is never implemented despite the increasing need to ensure drug access and effectively respond to public health emergencies. This article aims to assess China's compulsory license system in light of the TRIPS Agreement. The article analyses how and why China's domestic compulsory license system fails to take advantage of TRIPS flexibility in substance and implementation. It suggests points for reform to enhance China's compulsory license system for pharmaceutical patents, which can effectively be utilized in public health emergencies, as well as heading towards better integration and implementation of the TRIPS flexibility, referring to the interest-balanced guiding principle.

KEYWORDS: *compulsory license, pharmaceutical patents, TRIPS flexibility, the balance of interests, China*

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I. INTRODUCTION

At the second meeting of the Emergency Committee, convened by the World Health Organization (hereinafter "WHO"), the Director-General under the International Health Regulations (hereinafter "IHR") (2005) regarding the outbreak of COVID-19 on 30 January 2020, declared that the attack now meets the criteria for a Public Health Emergency of International Concern (PHEIC).[1] India and South Africa jointly submitted a statement to the World Trade Organization (hereinafter "WTO") on 2 October 2020, seeking a waiver from certain Intellectual Property (hereinafter "IP") provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (hereinafter "TRIPS Agreement") to ensure timely access to affordable medical products, including vaccines and medicines, which was later adopted by the WTO TRIPS Council on 17 June 2022.[2] Even though many WTO Members have carried out urgent legal amendments to their national Patent Laws to expedite the issuance of compulsory licenses,[3] the Proposal for TRIPS waiver further pointed out that many countries, especially developing countries, may face institutional and legal difficulties when making use of the TRIPS flexibility, with a particular concern for the requirements of Article 31.[4] After nearly one and a half years of heated debate concerning the Proposal, the WTO Ministerial Conference issued the Decision referring to "waiver and clarification" of the existing TRIPS flexibilities, which is limited to "the exceptional circumstances of COVID-19 pandemic."[5] The Decision also posed a question or challenge to what extent the developing countries can implement the compulsory license. Therefore, the legitimacy of national implementation and practice of compulsory licenses for pharmaceutical patents are more likely to be

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[1] *Statement on the Second Meeting of the International Health Regulations (2005) Emergency Committee Regarding the OUTBREAK of Novel Coronavirus (2019-nCoV)*, WORLD HEALTH ORG. [hereinafter WHO] (Jan. 30, 2020), https://www.who.int/news/item/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-(2019-ncov).

[2] Council for Trade-Related Aspects of Intell. Prop. Rights [hereinafter Council for TRIPS], *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment, and Treatment of Covid-19: Communication from India and South Africa*, ¶ 12, WTO Doc. IP/C/W/669 (Oct. 2, 2020) [hereinafter the Proposal]; Council for TRIPS, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of Covid-19 Revised decision text*, ¶ 1, WTO Doc. IP/C/W/669/Rev.1 (May 25, 2021).

[3] The WIPO COVID-19 IP Policy Tracker provides information on measures adopted by IP offices in response to the COVID-19 pandemic, such as the extension of deadlines. In addition, the policy tracker provides information on legislative and regulatory measures for access and voluntary actions. *See COVID-19 IP Policy Tracker*, WIPO, https://www.wipo.int/covid19-policy-tracker/#/covid19-policy-tracker/ipo-operations (last visited Nov. 20, 2022).

[4] The Proposal, *supra* note 2, ¶ 10.

[5] World Trade Organization [hereinafter WTO], *Ministerial Decision on the TRIPS Agreement adopted on 17 June 2022*, ¶ 1, WTO Doc. WT/MIN(22)/30, WT/L/1141 (June 22, 2022). The Decision neither mentions the original nor amended TRIPS Waiver Proposal.

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challenged by invoking the IP protection rules under the TRIPS Agreement.[6]

The WTO TRIPS Agreement sets minimum IP protection standards and strengthens pharmaceutical patent protection.[7] For this reason, former World Bank Chief Economist Joseph Stiglitz has described the TRIPS Agreement as "a death warrant for thousands of people in the poorest countries of the world."[8] However, TRIPS Agreement also reserves the policy space for members' own IP legal systems in response to the characteristics of their legal systems and developmental needs, especially the need for public goods such as public health.[9] Therefore, to balance the public interests and the protection of patent owners' rights, as well as the prevention of abuse of patent rights, the TRIPS Agreement incorporates exceptions to pharmaceutical patent protection to protect public health. The compulsory license system is one of the flexibilities of the TRIPS agreement under the WTO system.[10] Compulsory licensing for pharmaceutical patents provides a specific mechanism to bypass a patent owner's legal monopoly by allowing alternative production or importation of a generic version of a patented medical product without the prior consent of the patent holder.[11] In a pandemic, state intervention in pharmaceuticals through compulsory licensing is regarded as essential.[12] In the view of some scholars, the justification of IP protection of pharmaceutical patents is morally questionable in the context of a global health crisis.[13]

Since its emergence, the compulsory license system has been accompanied by controversies, with developed countries deviating from TRIPS to seek more robust patent protection for their pharmaceutical

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[6] Reto Hilty et al., *Covid-19 and the Role of Intellectual Property: Position Statement of the Max Planck Institute for Innovation and Competition of 7 May 2021*, MAX PLANCK INST. FOR INNOVATION & COMPETITION RSCH. PAPER 4 (May 25, 2021), https://www.ip.mpg.de/fileadmin/ipmpg/content/stellungnahmen/2021_05_25_Position_statement_Covid_IP_waiver.pdf. IP has so far played an enabling and facilitating role rather than a hindrance.

[7] Agreement on Trade-Related Aspects of Intellectual Property Rights (¶ 6 of the Preamble), Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement].

[8] JOSEPH E. STIGLITZ, MAKING GLOBALIZATION WORK 105 (2006).

[9] Article 7 of the TRIPs Agreement allows Member countries to legitimately adopt regulations that ensure a balance between the minimum standards of IPR protection and the public good. Moreover, they can adopt measures that are conducive to social and economic welfare. Countries can also adopt measures to prevent the abuse of intellectual property rights in terms of Article 8 of the TRIPS Agreement.

[10] COMPULSORY LICENSING: PRACTICAL EXPERIENCES AND WAYS FORWARD 8 (Reto M. Hilty & Kung-Chung Liu eds., 2014).

[11] *Compulsory Licenses, the TRIPS Waiver and Access to COVID-19 Medicinal Technologies*, MEDECINS SANS FRONTIERES 2 (May, 2021), https://msfaccess.org/sites/default/files/2021-05/COVID_TechBrief_MSF_AC_IP_CompulsoryLicensesTRIPSWaiver_ENG_21May2021_0.pdf.

[12] William Alan Reinsch et al., *Compulsory Licensing: A Cure for Distributing the Cure?*, CTR. FOR STRATEGIC & INT'L STUD. (May 8, 2020), https://www.csis.org/analysis/compulsory-licensing-cure-distributing-cure.

[13] Rivka Amado & Nevin M. Gewertz, *Intellectual Property and the Pharmaceutical Industry: A Moral Crossroads Between Health and Property*, 55(3) J. BUS. ETHICS 295, 295 (2004).

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industries and developing countries hoping to promote drug access through compulsory licensing.[14] Some WTO Members, mainly developed countries, have exercised their right to initiate WTO dispute settlement to incentive other members' policy compliance with the TRIPS Agreement, including disputes on pharmaceutical patents.[15] This debate on the scope of TRIPS flexibility ultimately found itself in the interpretation of TRIPS: developing countries interpret TRIPS flexibility as exempting the member state from its international IP protection obligations in response to a public health crisis; developed countries rejected such an interpretation and insisted that TRIPS flexibility only allows developing countries and least-developed countries a more extended implementation period.[16] Due to the complexity of interests involved, the current international legal norms and the instructions concerning WTO members' interests provided in the WTO dispute settlement system are still very limited, which gives a big challenge to legislation and policy-making. Even those advocating for greater short-term access to medicines often accept that "the policy space countries have to provide affordable medicines is sometimes bound wholesale by trade rules around IP rights."[17] Accordingly, the text of the TRIPS Agreement is the starting point of rule interpretation, from where interpreting trade-related IP rights can be linked to other considerations.[18] Nevertheless, WTO Members have attempted to improve the policy coherence, both perceived and actual, both in legal text and in judicial practice.[19] The subsequent practice of TRIPS by its membership takes a critical role when interpreting TRIPS Article 31: the Doha Declaration on the TRIPS Agreement and Public Health (hereinafter "Doha Declaration"),[20] implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (Paragraph 6

[14] Zhang Weijun (张伟君) & Zhang Taolue (张韬略), TRIPS Xieyi he Woguo Zhuanli Qiangzhi Xuke Zhidu de Wanshan (TRIPS 协议和我国专利强制许可制度的完善) [TRIPS Agreement and Perfection of Compulsory Patents License System in China], 6 SHIJIE MAOYI ZUZHI DONGTAI YU YANJIU (世界贸易组织动态与研究) [WORLD TRADE ORG. FOCUS] 24, 25 (2009).

[15] *See, e.g.*, Panel Report, *Canada — Patent Protection of Pharmaceutical Products*, WTO Doc. WT/DS114/R (adopted Apr. 7, 2000) [hereinafter *Canada — Pharmaceutical Patents* Panel Report]. The EU launched a dispute against Canada in 1997, challenging Canada's measure that facilitated the early launch of generic pharmaceuticals at the expense of patent rights. As a result, Canada modified its law to comply with the Patent protection standards under TRIPS Agreement Article 27.

[16] Olufemi Soyeju & Joshua Wabwire, *The WTO–TRIPS Flexibilities on Public Health: A Critical Appraisal of the East African Community Regional Framework*, 17(1) WORLD TRADE REV. 145, 150 (2018).

[17] Lisa Forman et al., *Assessing the UN High-Level Panel on Access to Medicines Report in Light of the Right to Health*, 5 LAWS (SPECIAL ISSUE) 43, 44 (2016).

[18] Eric M. Solovy & Pavan S. Krishnamurthy, *TRIPS Agreement Flexibilities and Their Limitations: A Response to the UN Secretary-General's High-Level Panel Report on Access to Medicines*, 50(1) GEO. WASH. INT'L L. REV. 69, 72 (2017).

[19] *Id.* at 72.

[20] WTO, *Declaration on the TRIPS Agreement and Public Health*, WTO Doc. WT/MIN(01)/DEC/2 (Nov. 20, 2001) [hereinafter Doha Declaration].

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Decision),[21] and a recently-enacted amendment to the TRIPS Agreement.[22] In addition, the Doha Declaration confirms that TRIPS flexibility is not an exception but a fundamental part of TRIPS machinery.[23]

In the case of China, even though it has been in place for many years, the compulsory license system for pharmaceutical patents has never been implemented in response to the public health crises, thus in a "zero-implementation" status.[24] The ambiguity of the TRIPS flexibility concerning compulsory license makes China adopt a prudential attitude and policy to transplant and clarify TRIPS Article 31. China defines and implements the TRIPS flexibility from three aspects: (1) the subjects of the compulsory license system; (2) the scope of diseases and drug management; (3) the grounds and coverages for granting a Compulsory License. The rules of international treaty interpretation provide a degree of consistency as a guide to the boundaries that international agreements place on formulating and interpreting WTO members' laws to predict outcomes of potential and existing disputes.[25] The paper proposes guidelines and suggestions for improving China's compulsory licensing system for pharmaceutical patents from three aspects: policy orientation, legal basis and implementation status.

II. THE INTERPRETATION OF THE COMPULSORY LICENSE FOR PHARMACEUTICAL PATENTS IN TERMS OF TRIPS FLEXIBILITY

There is certainly some flexibility in the TRIPS Agreement that readily stems from the proper application of rules of treaty interpretation.[26] If a member state exercises the TRIPS flexibility based on appropriate rules of

[21] WTO, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WTO Doc. WT/L/540/Corr.1 (July 29, 2005).

[22] WTO, *Amendment of the TRIPS Agreement,* WTO Doc. WT/L/641 (Dec. 8, 2005) [hereinafter the Amendment].

[23] *Using TRIPS flexibility to Promote Access to Medicines for PLHIV in Kenya and Uganda*, AIDSFONDS, https://aidsfonds.org/work/using-trips-flexibility-to-promote-access-to-medicines-for-plhiv-in-kenya-and-uganda (last visited Dec. 18, 2021).

[24] *See* Chen Xueyu (陈学宇), Woguo Yaopin Zhuanli Qiangzhi Xuke Zhidu Fenlei Shishi Tantao —— Jiyu Fangzhiyao Gongying Baaozhang de Shijiao (我国药品专利强制许可制度分类实施探讨——基于仿制药供应保障的视角) [On Classified Implementation of Drug Patent Compulsory License System in China —— From the Perspective of Supply Security of Generic Drug], 5 HUAQIAO DAXUE XUEBAO (ZHEXUE SHEHUI KEXUE BAN) (华侨大学学报 (哲学社会科学版)) [J. HUAQIAO UNIV. (PHILOSOPHY & SOC. SCI.)] 99, 100 (2019); Yuan Jiaojiao (袁姣姣), Woguo Yaopin Zhuanli Qiangzhi Xuke Ling Shishi Yuanyin Tanxi (我国药品专利强制许可零实施原因探析) [Analysis on the Reasons for the Zero Implementation of Pharmaceutical *Patent Compulsory License in China]*, 34 GUANGXI ZHENGFA GUANLI GANBU XUEYUAN XUEBAO (广西政法管理干部学院学报) [J. GUANGXI ADMIN. CADRE INST. OF POL. & L.] 90, 90 (2019); Weisun Rao, *China Allows Compulsory Licensing*, LEXOLOGY (Dec. 10, 2012), https://www.lexology.com/library/detail.aspx?g=2c0a5b56-b64f-4401-bd97-7d6b468cbb6b.

[25] Susy Frankel & Daniel Gervais, *Plain Packaging and the Interpretation of the TRIPS Agreement*, 46(5) VAND. J. TRANSNAT'L L. 1149, 1151-52 (2013).

[26] Solovy & Krishnamurthy, *supra* note 18, at 72.

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international treaty interpretation, then such measures will withstand scrutiny by a WTO panel or the Appellate Body.[27] In addition, interpreting rules can promote an understanding of the boundary of international agreements, ensuring the members make policy decisions regarding public health based on compliance with international obligations.[28] The rules of treaty interpretation are thus essential for the integrity of the international IP regime.[29] The report of the United Nations Secretary-General's High-Level Panel on Access to Medicines (The HLP Report) proposes that countries can take advantage of TRIPS flexibility to increase short-term access to medicines.[30] Vienna Convention on the Law of Treaties (hereinafter "the VCLT" or "the Vienna Convention") defines the TRIPS flexibility as "a set of norms, rules and standards that allow variations in the implementation of the TRIPS obligations, including limits on the exercise of IPRs," [31] providing WTO member states significant latitude to make a good faith and proper interpretation of the ordinary meaning of the terms in TRIPS Agreement.[32]

A. Principles of Treaty Interpretation

Article 3.2 of the Understanding On Rules and Procedures Governing the Settlement of Disputes (Dispute Settlement Understanding) and WTO Appellate Body have affirmed the status of Article 31 of the VCLT as customary rules of interpretation of public international law when clarifying the controversial treaty text.[33] The Appellate Body has further explained that "the only rules which may be applied in interpreting the meaning of a concession are the general rules of treaty interpretation set out in the Vienna Convention."[34]

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[27] *Id.* at 80.
[28] Frankel & Gervais, *supra* note 25, at 1151-52.
[29] *Id.* at 1152.
[30] U.N. SECRETARY-GENERAL & CO-CHAIRS OF THE HIGH-LEVEL PANEL, REPORT OF THE UNITED NATIONS SECRETARY-GENERAL'S HIGH-LEVEL PANEL ON ACCESS TO MEDICINES: PROMOTING INNOVATION AND ACCESS TO HEALTH TECHNOLOGIES 7-11 (Sept., 2016), https://www.politico.eu/wp-content/uploads/2016/09/HLP-Report-FINAL-Sept-2016.pdf [hereinafter HLP Report or Report].
[31] Vienna Convention on the Law of Treaties art. 31(1), May 23, 1969, 1155 U.N.T.S. 331 [hereinafter VCLT or Vienna Convention].
[32] Frankel & Gervais, *supra* note 25, at 1167.
[33] Article 3.2 of the Dispute Settlement Understanding provides that the dispute settlement system clarifies the agreements "in accordance with customary rules of interpretation of public international law".
[34] Appellate Body Report, *European Communities — Customs Classification of Certain Computer Equipment*, ¶84, WTO Doc. WT/DS62/AB/R, WT/DS67/AB/R, WT/DS68/AB/R (adopted June 22, 1998); *See* Appellate Body Report, *India — Patents Protection for Pharmaceutical and Agricultural Chemical Products*, ¶ 46, WTO Doc. WT/DS50/AB/R (adopted Jan. 16, 1998):

> These rules must be respected and applied in interpreting the *TRIPS Agreement* or any

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Article 31(1) of the VCLT confirms the text's ordinary meaning as the starting point of treaty interpretation, following that text must be given ordinary meaning in context and in light of the object and purpose of the treaty. Article 31(2) of the VCLT further elaborates that the contextual material includes text, preamble, and annexes. Next, Article 31(3) of the VCLT allows for the consideration of non-contextual materials along with the context, specifically, a subsequent agreement, subsequent practice, and relevant rules of international law.[35] Accordingly, there are four primary sources of treaty interpretation: textual meaning, context, non-contextual material, and object and purpose.

B. Textual Meaning of TRIPS Article 31

According to the interpreting rules of the VCLT, the title and text of the TRIPS Article 31 are the starting points of interpretation.[36] However, it is argued here that Articles 27 and 28 are general provisions subject to the specific exceptions in Articles 30 and 31 of the TRIPS Agreement. According to well-established principles of legal construction, where a general legal provision conflicts with a specific legal provision, the specific legal provision takes precedence.[37]

Compulsory licensing is dealt with under Article 31 of the TRIPS Agreement, referred to as ''other use without authorization of the right holder.'' Article 31 does not specify the grounds on which compulsory licenses can be issued, but rather sets forth conditions and procedures for granting compulsory licenses to prevent member states from abusing the system. These include a case-by-case determination of compulsory license

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> other covered agreements . . . Both panels and the Appellate Body must be guided by the rules of treaty interpretation set out in the *Vienna Convention* and must not add to or diminish rights and obligations provided in the WTO Agreement.

; Solovy & Krishnamurthy, *supra* note 18, at 83. The International Court of Justice has recently treated Article 31 of the Vienna Convention as customary international law. *See* Kasikili/Sedudu Island (Bots. v. Namib.), Judgment, 1999 I.C.J. ¶ 18 (Dec. 13). Neither Botswana nor Namibia were parties to the Vienna Convention but both of them considered Article 31 applicable ''inasmuch as it reflects customary international law''.

[35] *See* VCLT, *supra* note 31, art. 31(3):

> There shall be taken into account, together with the context: (a) Any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions; (b) Any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation; (c) Any relevant rules of international law applicable in the relations between the parties.

[36] Frankel & Gervais, *supra* note 25, at 1166-67.

[37] Silvia Borelli, *The (Mis)-Use of General Principles of Law:* Lex Specialis *and the Relationship Between International Human Rights Law and the Laws of Armed Conflict*, *in* 46 GENERAL PRINCIPLES OF LAW: THE ROLE OF THE JUDICIARY 265, 265 (Laura Pineschi ed., 2015).

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applications: demonstration of a prior negotiation with the patent owner for a voluntary license, limited scope and duration of such use, non-exclusive and non-assignable use, use predominantly for the supply of the domestic market, the adequate remuneration, and so on. However, where compulsory licenses are granted to address a national emergency or other circumstances of extreme urgency, certain requirements are waived to obtain a voluntary license from the patent holder. It also leaves members full freedom to stipulate other grounds, such as those related to non-working or failure to work of patents, public health,[38] or the public interest, for issuance of compulsory license. In practice, members implement compulsory licensing systems by allowing the manufacture of generic drugs or by declaring a national health crisis. In addition to national discretion on determining the grounds, Article 31 of the TRIPS also gave members the right to decide the circumstances that constitute a national emergency.

Besides implementing and transforming Article 31 into domestic laws, members may incorporate the TRIPS flexibility on compulsory license into TRIPS-plus agreements.[39] Many countries have entered into agreements to refine these conditions of granting a compulsory license, although in most cases, the effect of these agreements is to limit its issuance. On this basis, member states can further translate the provisions of the TRIPS-plus agreements into domestic laws. For example, based on Article 20 of the US–Jordan Free Trade Agreement, which limits the grounds for granting a compulsory license, Article 22 of the Jordanian Patent Law was amended in 2001 to add language explicitly restricting the grounds on which a compulsory license may be granted.[40]

C. Interpretation Based on the Object and Principle of TRIPS Agreement

The object and purpose of the TRIPS Agreement are set out in Articles 7 and 8, and their interpretative role needs to be considered when giving the ordinary meaning of the TRIPS Article 31.[41] TRIPS Article 7 clarifies the intent of interest balance—the balance of rights and obligations, the ‘‘mutual advantage’’ of producers and users. Consequently, the ‘‘balance of interests’’

[38] Santosh Kumar Verma, *TRIPS Agreement and Access to Medicines* 75-77 (Dec. 1, 2006), https://www.kansai-u.ac.jp/ILS/publication/asset/nomos/29/nomos29-06.pdf.

[39] Bilateral or multilateral economic and trade agreements, establishing more protective standards for IP in comparison with the TRIPS Agreement, are termed TRIPS-Plus agreements. Whether by means of higher protection or lower or more difficult adoption of limitations and exceptions provided by the same TRIPS Agreement.

[40] Saad Abughanm, The Protection of Pharmaceutical Patents and Data Under TRIPS and US–Jordan FTA: Exploring the Limits of Obligations and Flexibilities: A Study of the Impacts on the Pharmaceutical Sector in Jordan 1 (2012) (SJD thesis, Univ. of Toronto).

[41] Frankel & Gervais, *supra* note 25, at 1167-68.

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is currently reflected in the TRIPS Agreement, with its combination of compulsory obligations and exception clauses. TRIPS Article 8.1 provides: "Members may, in formulating or amending their laws and regulations, adopt measures 'necessary' to protect public health and nutrition, and to promote the public interest . . . provided that such measures are consistent with the provisions of this Agreement." This article, therefore, allows members to enjoy legislative flexibility to protect public health to the extent consistent with the TRIPS Agreement. Article 8 is considered a policy-declarative provision of principles that balances the interests between right holders and the public health interests and illustrates the rationale for the exceptions to substantive rights. For example, Section 27(2) excludes the patentability of inventions "which is necessary to protect public orders or morality, including to protect human, animal or plant life or health."

While Article 8.1 provides relevant context for interpreting other provisions of the TRIPS Agreement, by its explicit terms, measures taken to protect public health must be "consistent with the provisions of this Agreement." Specifically, TRIPS Article 8.1 states that members "may", but not "shall", take measures violating the IP protection obligations to protect the public health interests. The term "necessary" indicates that it is imperative to consider whether an alternative measure achieves the same legitimate objective of protecting public health, but with less IP-restrictive effect.[42] Given the status of the specific exceptions, TRIPS Article 7 and Article 8 provide relevant context for interpreting Article 31: to protect public health, if an alternative measure could not be expected to employ, members can deviate from the Intellectual Property Rights (hereinafter "IPRs") protection obligations and grant a compulsory license, which could not be considered inconsistent with the provisions of this Agreement.

D. Referring to Subsequent Agreements of the TRIPS

The Doha Declaration and Paragraph 6 Decision further articulate the relationship between the TRIPS Agreement and public health. Some scholars also suggested that the Doha Declaration should be considered a subsequent practice in applying the treaty under Article 31(3) of the Vienna Convention, as paragraph 5(a) of the Declaration gives guidance on the interpretation of the TRIPS Agreement.[43] Therefore, the TRIPS Agreement and subsequent

[42] Panel Report, *United States — Section 337 of the Tariff Act of 1930*, ¶ 5.26, L/6439 (Nov. 7, 1989), GATT BISD (36th Supp.), at 345, 390; *see* General Agreement on Tariffs and Trade art. XX, Oct. 30, 1947, 61 Stat. A-11, 55 U.N.T.S. 194 [hereinafter GATT]. The term "necessary" has most frequently been interpreted in the context of disputes involving defenses under the exception in Article XX of the GATT 1994, including Article XX(b), which provides an exception for certain measures "necessary to protect human, animal or plant life or health."

[43] Sandra Bartelt, *Compulsory Licences Pursuant to TRIPS Article 31 in the Light of the Doha Declaration on the TRIPS Agreement and Public Health*, 6 J. WORLD INTELL. PROP. 283, 302 (2003).

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provisions should be interpreted following the objectives and principles of the Agreement. Naigen took a case study on the *Australian Plain Packaging Tobacco* and further demonstrated that WTO Panel took the Doha Declaration's emphasis on protecting public health as a standard to identify whether the special requirements for trademark use constitute "unreasonable obstruction", is in line with the principles of treaty interpretation.[44]

1. The Doha Declaration. The Doha Declaration was adopted by the WTO Ministerial Conference of 2001 in Doha, which "affirms that the TRIPS Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health, and in particular, to promote access to medicines for all."[45] The fifth paragraph of the Doha Declaration further clarifies the patent-related flexibility mechanism under the TRIPS Agreement: (1) its provisions should be interpreted in the light of the objectives and principles of the TRIPS Agreement; (2) each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted; (3) each Member has the right to decide what constitutes a national emergency or other circumstances of extreme urgency and to expand interpretations of the "public health"; (4) allow each Member to freely establish its own regime of exhaustion of IP rights in compliance with most-favored-nation treatment and national treatment provisions. It is recognized that the Doha Declaration goes beyond merely confirming the relevance of Articles 7 and 8 for the interpretation of the TRIPS Agreement; it also guides future rulings by panels and the Appellate Body dealing with public health issues.[46] This "flexibility" principle also guided the EU's handling of public health-related IP disputes arising from the transit of generic drugs in India and Brazil in 2010. Because Article 31(f) of TRIPS restricts compulsory licenses to "primarily" domestic manufacture of goods, this Declaration proposes that the compulsory licensing of pharmaceutical patents under the subsequent agreements should break through the restrictions.
2. The Paragraph 6 Decision. To find an expeditious solution to the problem of WTO Members that are unable to make effective use of compulsory licensing due to insufficient or lack of manufacturing capacities in the pharmaceutical sector, the WTO's General Council adopted the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, as a waiver

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[44] Zhang Naigen (张乃根), Gonggong Jiankang Xiangguan Zhishi Chanquan de Guojifa Wenti (公共健康相关知识产权的国际法问题) [On International Law Concerning Public Health-Related IP Issues], 11 ZHISHI CHANQUAN (知识产权) [INTELL. PROP.] 3, 8-9 (2020).

[45] Doha Declaration, *supra* note 20, ¶ 4.

[46] *See* Frederick M. Abbott, *The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO*, 5(2) J. INT'L ECON. L. 469, 492-96 (2002).

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from TRIPS 31(f). This waiver removed the limitation on exports with respect to the grant of a compulsory license to the extent necessary for the production of a patented pharmaceutical product. However, the Paragraph 6 Decision contains several limitations on this waiver. On the one hand, the grounds for exporting Members to grant a compulsory license are limited to the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. On the other hand, Paragraph 2 of the Decision lists a series of criteria for qualifying as an eligible importing country and requires them to fulfil corresponding obligations. Consequently, Canada was the first and only country so far to have taken advantage of the Decision, which issued a compulsory license for HIV/AIDS medicines for export to Rwanda.[47]

3. Protocol Amending the TRIPS Agreement. By 6 December 2005, the General Council adopted the Decision on an ''Amendment of the TRIPS Agreement'' to which the ''Protocol Amending the TRIPS Agreement'' was attached, incorporating the 2003 waiver into the TRIPS Agreement.[48] The Amendment Protocol entered into force on 23 January 2017, following acceptance by two-thirds of WTO Members.[49] The TRIPS Protocol eliminated the restriction on exporting members granting a compulsory license in the pharmaceutical sector and removed legal barriers to international trade in generic medicines granted and produced under the compulsory license system. Therefore, this amendment allows developing and least developed member countries to obtain cheaper essential medicines. Members who have not yet accepted the amendment must do so by 31 December 2023. Before that, the waiver will continue to apply until members accept the amendment and it takes effect.[50]

While Doha Declaration and other subsequent agreements have some contextual value for interpreting the TRIPS Agreement, they do not represent an authoritative interpretation within the meaning of Article IX:2 of the

[47] *Canada Is First to Notify Compulsory License to Export Generic Drug*, WTO (Oct. 4, 2007), https://www.wto.org/english/news_e/news07_e/trips_health_notif_oct07_e.htm; *TRIPS: Special Compulsory Licenses for Export of Medicines*, WTO, https://www.wto.org/english/tratop_e/trips_e/guidenotifications_e.pdf (last visited Feb. 20, 2022). Through a dedicated webpage on notifications, see *TRIPS and Public Health: Notifications*, WTO, https://www.wto.org/english/tratop_e/trips_e/public_health_e.htm (last visited Nov. 20, 2022). Countries have to notify the WTO when they export pharmaceutical products manufactured under compulsory licenses under the ''paragraph 6'' system; clicking on ''view notifications'', the result list shows Canada is the one country made notification. *See Notifications by Exporting WTO Members*, WTO, https://www.wto.org/english/tratop_e/trips_e/public_health_notif_export_e.htm (last visited Nov. 20, 2022).

[48] The Amendment, *supra* note 22.

[49] WTO, *Protocol Amending the TRIPS Agreement Done at Geneva on 6 December 2005*, WTO Doc. WLI/100 (Jan. 30, 2017).

[50] *Id.*

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Marrakesh Agreement Establishing the WTO.[51]

E. Case Study on the Compulsory License for Pharmaceutical Patents

To a certain extent, Articles 7, 8, 30 and 31 of the TRIPS Agreement, although envisaged to address the public health crisis, pose a substantial legal risk of resorting to the WTO dispute settlement mechanism because member states have not agreed on the rules of interpretation. The Doha Declaration affirms the TRIPS flexibility that members can adopt to protect public health, promoting international IP norms related to public health and heading to balanced development.[52] Three WTO IP disputes related to public health provide a window of how to resolve a conflict between public health and IP protection among WTO members, following Article 8 of the TRIPS Agreement and related specific provisions and the principle of ''flexibility'' stated in the Doha Declaration.

Regarding the relationship between patent rights and compulsory license, especially, Articles 27.1 and 31 of TRIPS, *Canada — Patents Protection of Pharmaceutical Products*[53] and *Brazil — measures Affecting Patents Protection* cases reflect different interpretations. In 1999, the European Communities (EC) initiated a WTO dispute challenging the consistency of Canada's Patents Act with the TRIPS Agreement.[54] The EC accused Articles 55.2(1) and 55.2(2) of the Canadian Patents Act of violating TRIPS Article 27.1 and the non-discrimination principle in Article 28.1.[55] The EC complained that exception clauses of the TRIPS Agreement deprived of the patentees' exclusive right to the patented product during the term of

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[51] Carlos M. Correa, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health*, WHO 44 (June, 2002), https://apps.who.int/iris/bitstream/handle/10665/67345/WHO_EDM_PAR_2002.3.pdf.

> A "declaration" has no specific legal status in the framework of WTO law; it is not strictly an authoritative interpretation in terms of Article IX.2 of the Marrakesh Agreement Establishing the WTO. However, given the content and mode of approval of the Doha Declaration, it can be argued that it has the same effects as an authoritative interpretation.

[52] Solovy & Krishnamurthy, *supra* note 18, at 92.

[53] The United Nations Conference on Trade and Development pointed out that *Canada — Patents Protection of Pharmaceutical Products* case is an IP dispute involving public health under Articles 7 and 8 of TRIPS. However, the ruling came before the Doha Declaration. If guided by paragraph 5 of the Doha Declaration, its ruling is likely to differ in some important respects. *See supra* note 15, at 14..

[54] *Canada — Pharmaceutical Patents* Panel Report, *supra* note 15.

[55] *See* Patent Act, R.S.C. 1985, c P-4, § 55.2(1)-(2). Section 55.2(1) of the Patents Act—so-called "regulatory review exception" that permits competitors to use a patented invention, without the authorization of the patents holder, for the purposes of obtaining marketing approval; Section 55.2(2) of the Patent Act—so-called "stockpiling exception" that allows competitors to manufacture and stockpile patented pharmaceuticals for sale upon expiration of the patent.

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protection. However, Canada argued that these provisions are ''limited exceptions'' to a patent granted within the meaning of Article 30 of TRIPS, thus not subject to Articles 27 and 28. There is a deeper disagreement between Canada and the EC over the role of TRIPS Article 30 and how to interpret and approach it under the general IP protection provisions. Canada asked for a broad interpretation of the three elements of Article 30 of TRIPS in according with the objective of protecting public health under the TRIPS Agreement, while the EC proposed to adopt a strict interpretation, restricting the three elements strictly to the textual meaning of Article 30.[56] The Panel devoted a considerable portion of its decision to interpret the textual meaning of the three elements of Article 30, only referring to Articles 7 and 8. The Panel began by holding that Article 30 exceptions are subject to Article 27, even though there is no dispute settlement language in Article 30 suggesting that granted exceptions may be restricted to a certain type or class.[57]

Brazil promulgated a new Patent Law—the Industrial Property Law to implement the TRIPS Agreement on 14 May 1996. Article 68(1) allows the invocation of the ''local working'' requirement to initiate compulsory licenses: the government can authorize a compulsory license if the patentee does not manufacture the patented product or process in the territory of Brazil within three years of the patent being granted.[58] The US alleged that the ''local working'' requirement and definition of ''non-exploitation'' are inconsistent with Brazil's obligations under Articles 27 and 28 of the TRIPS Agreement and Article III of the GATT 1994.[59] The US contended that local working requirement detracts from the anti-discrimination rule enshrined in TRIPS Article 27, since the requirement could only be satisfied by the local production, but not the importation of the patented subject matter, discriminating against all imported products in favor of locally produced products.[60]

In contrast with the decision in the Canada case, the Panel has adopted

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[56] Christopher Garrison, *Exceptions to Patent Rights in Developing Countries* 21-23 (UNCTAD & ICTSD, Issue Paper No.17, 2006).

[57] *Dispute Settlement: World Trade Organization 3.14 TRIPS*, UNCTAD 21-22 (2003), https://unctad.org/system/files/official-document/edmmisc232add18en. pdf.

[58] *See* Ministry of Econ. Indus. Prop. Protection Off., *Law on Industrial Property*, WTO 22 (art. 68(1)) (June, 2002), https://www.wto.org/english/thewtoe/acce/mkde/wtaccmkd24a2leg1.pdf. The following also occasion a compulsory license:

1. Non-exploitation of the object of the patent within the Brazilian territory for failure to manufacture or incomplete manufacture of the product, or also failure to make full use of the patented process;

2. The compulsory license that is the subject of Paragraph 1 shall only be required when 3 (three)years have elapsed since the patent was granted.

[59] *See* Request for the Establishment of a Panel by the United States, *Brazil — Measures Affecting Patent Protection*, WTO Doc. WT/DS199/3, at 1 (Jan. 9, 2001).

[60] Gov't Braz. Ministry of Econ., Nat'l Inst. Indus. Prop., *Directorate for Patents, Computer Programs, and Topographies of Integrated Circuits*, WIPO 9 (Feb. 14, 2019), https://www.wipo.int/export/sites/www/scp/en/meetings/session_30/comments_received/brazil_1.pdf.

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a different interpretation rule in the Brazil case: the specific exception in TRIPS Article 31 applies to the rights under Articles 27 and 28 and does not violate the principle of "non-discrimination". When the TRIPS framework provides for exceptions that permit WTO Members to deviate from the exclusive patent rights, Brazil was most likely to cite Article 31 to justify its policy. Only by reading these provisions, including Articles 7, 8, 30 and 31, can the meaning of Article 27(1) be determined. This more inclusive approach accords with the well-established principles of treaty interpretation. However, in the Canada case, the Panel says that it is an "acknowledged fact" that Article 27 is not subject to exceptions under Articles 30 and 31 because it is simply "understood . . . without the need for any textual provision so providing."[61] Therefore, WTO Panel took the interpretation as a "fact" that is simply "understood" that: Article 27(1) was absolute and not derogatory from Article 31 and Article 30.[62] In terms of the interpretation rules, the Panel haven't given enough consideration to the objective and purpose of the TRIPS agreement. Indeed, one eminent scholar cautions that "the text of a treaty must be read as a whole: 'one cannot simply concentrate on a paragraph, an article, a section, a chapter or a part.'"[63](emphasis added) According to the titles of Articles 30 and 31 of TRIPS, the interpretation principles of the VCLT, and the objective and principle of the TRIPS Agreement, TRIPS does not oppose the "differentiated" treatment of member states to protect public interests. Therefore, some scholars pointed out that measures of anti-public health crisis may deviate from IP protection rules, but cannot be accused of being against the "anti-discrimination" principle.[64] This interpretation method and principle have been further applied in a recent case, the *European Union and a Member State — Seizure of Generic Drugs in Transit*.

Shipments of generic drugs, produced in India and destined for non-European markets through European customs, have been intercepted and seized by the EU at least twenty times.[65] Tensions over the eventual seizure of generic drugs reached a tipping point in May 2010. The EU intercepted the in-transit generic drugs produced in India and destined for Brazil, which prompted India and Brazil to initiate requests for consultations against the EU at the WTO.[66] India has accused the EU measures of being unreasonable

[61] *Canada — Pharmaceutical Patents* Panel Report, *supra* note 15, ¶ 7.91.
[62] *Id.* ¶ 7.93. *See also* Althaf Marsoof, *Local Working of Patents: The Perspective of Developing Countries*, *in* MULTI-DIMENSIONAL APPROACHES TOWARDS NEW TECHNOLOGY: INSIGHTS ON INNOVATION, PATENTS AND COMPETITION 315, 326 (Ashish Bharadwaj et al. eds., 2018).
[63] *WTO Analytical Index: DSU — Article 3*, WTO 15 (Aug., 2022) https://www.wto.org/english/res_e/publications_e/ai17_e/dsu_art3_jur.pdf.
[64] Paul Champ & Amir Attaran, *Patent Rights and Local Working Under WTO TRIPS Agreement: An Analysis of the US-Brazil Patent Dispute*, 27 YALE J. INT'L L. 365, 390 (2002).
[65] John W. Miller & Geeta Anand, *India Prepares EU Trade Complaint*, WALL ST. J. (Aug. 6, 2009 12:01 AM), https://www.wsj.com/articles/SB124949598103308449.
[66] *See* Request for Consultations by India, *European Union and a Member State — Seizure of*

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because they enforce strict patent control procedures and fail to take into account the patent immunity afforded to generic drug manufacturers by the TRIPS flexibility.[67] However, the EU has not argued that the manufacture of generic drugs violates the TRIPS agreement; instead, the EU only looked at the legality of the interception of medicines.[68]

In terms of the agreements cited in consultations, India and Brazil raised certain legal issues concerning the EU's seizure of in-transit drugs that violated obligations[69] by imposing unnecessary restrictions on the freedom of transit of generic medicines lawfully manufactured or exported from India.[70] India further believed that the EU measures might also hold the developing and least-developed countries with insufficient or no capacity in the pharmaceutical sector, back from importing pharmaceuticals to protect public health. Therefore, these detentions were inconsistent with certain fundamental obligations under Article 31 of the TRIPS Agreement, reading together with the provisions of Paragraph 6 Decision.[71] Ultimately, India and the EU reached a settlement agreement in July 2011. The EU agreed to substantially reform the customs and patent enforcement procedures, and India suspended its WTO complaint accordingly.[72] The Panel further stressed that relevant provisions must be interpreted in accordance with the objective and principle set out in Articles 7 and 8 of the TRIPS Agreement and the Doha Declaration towards the realization of what is emphasized in Article 12 of the International Covenant on Economic, Social and Cultural Rights: "[that all people have the right] to the enjoyment of the highest standard of physical and mental health."[73]

Generic Drugs in Transit, WTO Doc. WT/DS408/1, G/L/921, IP/D/28 (May 11, 2010) [hereinafter Request for Consultations by India, *European Union — Generic Drugs*]. *See also* Request for Consultations by Brazil, *European Union and a Member State — Seizure of Generic Drugs in Transit*, WTO Doc. WT/DS409/1, IP/D/29, G/L/922 (May 19, 2010) [hereinafter Request for Consultations Brazil, *European Union — Generic Drugs*].

[67] *See* Request for Consultations by India, *European Union — Generic Drugs*, *supra* note 66, at 3-4.

[68] TG Team, *India and EU Reach an Understanding on Issue of Seizure of Indian Generic Drugs in Transit*, TAXGURU (July 28, 2011), https://taxguru.in/finance/india-eu-reach-understanding-issue-seizure-indian-generic-drugs-transit.html. The news discusses India's claims and the path to fulfilment but does not mention any European claims on the legality of Indian production of generic drugs.

[69] The detentions were inconsistent with Article V of GATT 1994, which enshrines the freedom of transit of goods through the territory of each contracting party of GATT via the routes most convenient for international transit; were also inconsistent with Articles 41 and 42 of the TRIPS Agreement as these detentions created barriers to legitimate trade, led to abuse of the rights conferred on the owner of a patent. *See* John Zarocostas, *Brazil and India File Complaint Against EU over Seizure of Generic Drugs*, THEBMJ (May 18, 2010), https://www.bmj.com/content/340/bmj.c2672.

[70] *See* Request for Consultations Brazil, *European Union — Generic Drugs*, *supra* note 66, at 1-2.

[71] TG Team, *supr*a note 68.

[72] *Id.*

[73] *See* Request for Consultations by India, *European Union — Generic Drugs*, *supra* note 66, at 3.

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III. CHINA'S COMPULSORY LICENSE SYSTEM FOR PHARMACEUTICAL PATENTS

A. Heading Towards a Consistency with TRIPS Agreement

1. The Pre-TRIPS Stage — The first Patent Law in 1984 (Patent Law 1984)[74] deployed compulsory licensing under failure to work or insufficient working, failing to incorporate the public health emergency as a reason for granting a compulsory license. Consequently, the Patent Law 1984 kept silent on compulsory licensing for pharmaceutical patents but adopted an alternative measure—excluding pharmaceuticals from patentability. Article 5 stipulated that: ''no patent shall be granted for any invention that violates the laws of the State, goes against social morals, or impair public interest.'' Article 25.5 stipulates explicitly that: ''the patents were not granted to drugs and substances obtained by chemical methods.'' To actively respond to the IP protection standard stipulated in the ''US Tax Reform Act of 1986'', China amended the Patent Law in 1992 according to the Memorandum of Understanding on the Protection of Intellectual Property Rights between China and the United States.[75] Noticeably, the Patent Law 1992[76] expanded patentable subject matter to include chemical inventions, including pharmaceuticals, and extended the patent terms for invention patents from fifteen to twenty years. The amendment expanded the application grounds of compulsory license to the event of "public interest so requires", ensuring the availability of medicines under the high IP protection standards.[77]

2. The Post-TRIPS Stage — China amended the Patent Law in 2000 (hereinafter "Patent Law 2000")[78] to adopt higher IP protection standards, applying for accession to WTO. The Patent Law 2000 did not make effective use of the flexible provisions of the TRIPS Agreement and restricted the scope, duration and termination of implementing the compulsory licenses.[79]

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[74] Zhonghua Renmin Gongheguo Zhuanli Fa (中华人民共和国专利法) [Patent Law of the People's Republic of China] (promulgated by the Standing Comm. Nat'l People's Cong., Mar. 12, 1984, effective Apr. 1, 1985), CLI.1.1943(EN) (Lawinfochina).

[75] *See* U.S. Gen. Acct. Off., *U.S.-China Trade: Implementation of Agreements on Market Access and Intellectual Property*, REP. TO THE HONORABLE HANK BROWN, U.S. SENATE 7 (Jan., 1995), https://www.gao.gov/assets/ggd-95-61.pdf.

[76] Zhonghua Renmin Gongheguo Zhuanli Fa (中华人民共和国专利法(1992 修正)) [Patent Law of the People's Republic of China (1992 Amendment)] (promulgated by the Standing Comm. Nat'l People's Cong., Aug. 25, 2000, effective July 1, 2001), CLI.1.5926(EN) (Lawinfochina).

[77] *See id.* art. 52: "Where a national emergency or any extraordinary state of affairs occurs, or where the public interest so requires, the Patent Office may grant a compulsory licence to exploit the patent for invention or utility model".

[78] Zhonghua Renmin Gongheguo Zhuanli Fa (中华人民共和国专利法(2000 年修正)) [Patent Law of the People's Republic of China (2000 Amendment)] (promulgated by the Standing Comm. Nat'l People's Cong., Dec. 27, 2008, effective Jan. 1, 2009), CLI.1.31016(EN) (Lawinfochina).

[79] Zhang Cao et al., *The Legislative Approach and System Improvement of China's Compulsory Licensing for Drug Patents*, 15 DRUG DESIGN, DEV. & THERAPY 3717, 3719 (2021).

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On 13 June, 2003, China State Intellectual Property Office (hereinafter "SIPO")[80] promulgated the Measures on Compulsory Licensing of Patents (hereinafter "Licensing Measures 2003"), which stipulated in detail the procedures for granting a compulsory license, exploitation fee and terminating procedures. In 2002, the outbreak of the SARS virus posed a great threat to China's public health, and the Doha Declaration gave the enlightenment to further China's amendment to improve the accessibility of drugs in response to such health emergencies. The Measures for Compulsory License on Patent Implementation concerning Public Health Problems in 2005 (hereinafter "Health Measures 2005")[81] made a statutory interpretation of the compulsory license of drugs, which clarified the scopes of "infectious diseases" and "drugs", as well as provided detailed explanations for the two situations of "public interest" and "national emergency". Specifically, the Law on the Prevention and Treatment of Infectious Diseases[82] stipulated that "infectious diseases" include AIDS, tuberculosis, malaria, and other infectious diseases, while "drugs" refer to the patented products treating the above-mentioned infectious diseases.[83] Obviously, it can be seen that the Health Measures 2005 only permitted granting compulsory licenses for drugs for infectious diseases.[84]

3. Active Response Phase — In 2008, the Patent Law (hereinafter "Patent Law 2008")[85] was revised for the third time. The Patent Law 2008 has a special chapter providing compulsory licenses based on Patent Law 2000 with the following modifications. To protect public health, the China National Intellectual Property Administration (hereinafter "CNIPA") may grant compulsory licenses for patented drugs manufactured and exported to countries or regions that comply with the provisions of the relevant

[80] Since 28 August, 2018, "State Intellectual Property Office [hereinafter SIPO]" has changed its name to "China National Intellectual Property Administration [hereinafter CNIPA]". What's more, the "Patent Administration Department of the State Council", also known as the SIPO or the CNIPA, has been stipulated in the Patent Law. Therefore, in this Article, SIPO, CNIPA, and the "Patents Administration Department of the State Council" are referred to the same department, an administrative agency directly under the State Council. The name "CNIPA" is used uniformly in this paper to avoid misunderstanding.

[81] Sheji Gonggong Jiankang Wenti de Zhuanli Shishi Qiangzhi Xuke Banfa (涉及公共健康问题的专利实施强制许可办法) [Measures for Compulsory License on Patent Implementation concerning Public Health Problems] (promulgated by the Instrumentalities of the State Intell. Prop. Off., Nov. 29, 2005, effective Jan. 1, 2006), CLI.4.66212(EN) (Lawinfochina) [hereinafter Health Measures].

[82] Zhonghua Renmin Gongheguo Chuanranbing Fangzhi Fa (中华人民共和国传染病防治法) [Law of the People's Republic of China on Prevention and Treatment of Infectious Diseases] (promulgated by the Standing Comm. Nat'l People's Cong., Feb. 21, 1989; rev'd and effective Aug. 28, 2004), CLI.1.54998(EN) (Lawinfochina).

[83] *Id.* arts. 3, 4.

[84] *See* Cao et al., *supra* note 79, at 3720.

[85] Zhonghua Renmin Gongheguo Zhuanli Fa (2008 Xiuzheng) (中华人民共和国专利法(2008 年修正)) [Patent Law of the People's Republic of China (2008 Amendment)] (promulgated by the Standing Comm. Nat'l People's Cong., Dec. 27, 2008, effective Oct. 1, 2009), CLI.1.111782(EN) (Lawinfochina).

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international treaty in which China participates.[86] The amendment reflects that China actively exempted drug exporters from the obligations under Article 31(f) of the TRIPS prior to the final amendment of TRIPS. However, other than to fight against the abuse of patent rights and protect public health, the scope of compulsory licensing is limited to supply to the domestic market.[87]

In line with the revision of the Patent Law in 2008, the State Council of China approved the Implementing Regulations of the Patent Law in 2010 (hereinafter "Implementation Regulations 2010"), which expanded the scope of patented pharmaceuticals. The "pharmaceutical product to which patent right has been granted" refers to any patented product and technology in the pharmaceutical sector needed to address public health problems, including the patented active ingredients necessary for the product's manufacture and the diagnostic kits required for its use.[88] To enhance the operability of China's compulsory license system, the Implementation Regulations 2010 improved the application procedure and further clarified the qualifications of subjects participating in the compulsory licensing process.[89]

By 2012, the CNIPA formulated the Measures on Compulsory Licensing of Patents (hereinafter "Licensing Measures 2012"), simultaneously repealing the Licensing Measures 2003 and the Health Measures 2005. The Licensing Measures 2012 has more detailed provisions on compulsory licensing, involving procedural matters.[90] Article 6 granted the competent departments under the State Council to recommend the CNIPA adopt a compulsory license for implementing the invention patent or utility model patent in an emergency or for public interest purposes. However, it was not until 2018 that the Opinions Concerning Reforms of Policies to Improve the Supply and Utilization of Generics (hereinafter "Opinions 2018") made a non-exclusive list of the competent departments, The Opinions 2018 clarified the departmental responsibilities of compulsory patent licensing and established a priority review and approval system based on pharmaceutical patent compulsory license.[91] To promote the balance of interests, on the one hand, Opinions 2018 will promote the development and the innovation of generics, ensuring the availability of some patented pharmaceuticals; on the other hand, the government will establish an early-warning patent system in the pharmaceutical industry to mitigate the risk of patents infringement for

[86] *See id.* art. 50.
[87] *See id.* arts. 48, 49.
[88] *See* Zhonghua Renmin Gongheguo Zhuanli Fa Shishi Xize (2010 Xiuding) (中华人民共和国专利法实施细则(2010 修订)) [Implementing Regulations of the Patent Law of the People's Republic of China] (promulgated by the State Council People's Republic China, June 15, 2001; rev'd by the State Council Jan. 9, 2010), art. 73, CLI.2.126175(EN) (Lawinfochina).
[89] *See id.* art. 74.
[90] See Cao et al., *supra* note 79, at 3720.
[91] *See generally id.*

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generic drug makers.[92]

On 17 October, 2020, the Standing Committee of the National People's Congress in China promulgated the fourth amended Patent Law, which came into effect on 1 June, 2021. The newly revised Patent Law 2020 changed Article 14 of Patent Law 2008 to Article 49, because the original Article 14 should have been part of the compulsory license system, making the Patent Law more standardized and systemized. The amendment, for the first time, introduced a patent linkage system for pharmaceutical-related patents in China to align with international practices. At the same time, due to Articles 50 to 52 of the amended Patent Law introducing a "patent open license system", Chapter VI "Compulsory License for Exploitation of a Patent" was changed to "Special License for Patent Exploitation", in which the original Articles 48 to 50, dealing with the compulsory license of patents, has been postponed to Article 53 to Article 55.

B. China's Implementation of TRIPS Flexibility of the Compulsory License for Pharmaceutical Patents

The non-specific language employed in the TRIPS provisions put the national implementation at risk of being challenged for legitimacy. For example, member states can adopt varied interpretations of the meaning and scope of "public non-commercial use", "national emergency", "extreme urgency" and so on. Meanwhile, TRIPS provides no clear standards for implementing relevant provisions, for example, the calculating method of "reasonable remuneration". TRIPS does not specify at what level a compulsory licence can or should be authorized.[93] According to Mercurio, four primary areas are not satisfactorily resolved by TRIPS and its subsequent agreements: (i) the scope of diseases and products covered under the exception; (ii) countries that would be eligible to use the system; (iii) ensuring adequate remuneration; and (iv) safeguarding the system against diversion of drugs into other markets.[94]

China's legislation on the compulsory license system for pharmaceutical patents has gradually developed from a single legislative model to composite legislation composed of legal norms with various levels of effectiveness.[95] What's more, China has formed a system of rules from legislation to policy

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[92] Katherine Wang, *China Announces New Initiatives to Level the Playing Field for Innovative and Generic Drugs*, ROPES & GRAY (Apr. 17, 2018), https://www.ropesgray.com/en/newsroom/alerts/2018/04/china-announces-new-initiatives-to-level-the-playing-field-for-innovative-and-generic-drugs.

[93] Mathur Harshita, *Compulsory Licensing Under Section 92A: Issues and Concerns*, 13 J. INTELL. PROP. 464, 468-69 (2008).

[94] Bryan C. Mercurio, *TRIPS, Patents, and Access to Life-Saving Drugs in the Developing World*, 8(2) MARQUETTE INTELL. PROP. L. REV. 211, 237 (2004).

[95] *See generally* Cao et al., *supra* note 79.

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in the compulsory licensing for pharmaceutical patents.[96] Issuing a compulsory license for patented pharmaceuticals is not only guaranteed by China's Patent Law and general regulations of the compulsory patent license, but also escorted by a supporting drug-management system. China's current compulsory licensing legal system for pharmaceutical patents involves five legal documents: Patent Law 2021, Implementing Regulations 2010; Licensing Measures 2012; Opinions 2018; the Measures for the Administration of Drug Registration.

Therefore, referring to Mercurio's statement and the status quo of China's compulsory license system, three primary areas which are needed to be clarified under China's compulsory license legal system:(1) the subjects of the compulsory license system; (2) the scope of diseases and drug management; (3) grounds and coverages for granting a Compulsory License.

1. The Subjects of the Compulsory License System for Pharmaceutical Patents — Since the TRIPS gives parties full leeway to regulate the subject qualifications for initiating the compulsory license of pharmaceutical patents, as well as the specific government departments to issue a compulsory license. However, referring to previous comparative studies,[97] China has limited the scope and imposed severe restrictions on the subject's qualifications for initiating compulsory licenses.

First, China's compulsory license system subjects for pharmaceutical patents include initiating subjects, issuing subjects, and proposing subjects. Initiating a compulsory license includes two ways: an *ex-officio* license or a third-party application, based on different granting grounds. In the event of a national emergency or for public health purposes, the relevant competent departments of the State Council can initiate a compulsory license for pharmaceutical patents. In other cases, entities or individuals are qualified to initiate a compulsory license when meeting the implementation requirements. For example, Article 53 of the Patent Law 2021 stipulates that in the event of anti-competition and non-sufficiently exploitation, the CNIPA may grant a compulsory license upon the application of the entity or individual. Article 54 further states: "where a national emergency or any extraordinary state of affairs occurs, or where the public interest so requires, the CNIPA may grant a compulsory license to exploit the patents for invention or utility model."

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[96] Ma Le, *Dilemmas and Countermeasures on Implementing Compulsory Licensing of Pharmaceutical Patents to Cope with Public Health Crisis*, 2(2) SCI. TECH. & L. 141, 146 (2021).

[97] These articles explore the implementations of the TRIPS compulsory license, especially Article 31, typically by India and Brazil. For example, see Viren Konde, *Recent Developments in Compulsory Licensing of Pharmaceutical Patents in India*, 22(1) J. COMM. BIOTECHNOLOGY 64, 64 (2016); Chen Yongfa (陈永法) et al., Yindu Yaopin Zhuanli Qiangzhi Xuke Zhidu Yanjiu (印度药品专利强制许可制度研究) [The Drug Patent Compulsory Licensing System in India and Its Empirical Study], 8(1) JIAGE LILUN YU SHIJIAN (价格理论与实践) [PRICE: THEORY & PRACTICE] 90 (2018).

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According to Article 49 of the Patent Law 2021, the issuing subjects can only be the CNIPA. At the same time, Articles 2 and 6 of the Licensing Measures 2012 clarify that CNIPA is responsible for accepting and investigating the petitions and making decisions on the issuance and the termination of compulsory licensing, and the adjudication of the royalties of compulsory licensing.[98]

At the same time, Licensing Measures 2012 stipulates that the relevant competent departments of the State Council have the right to recommend the CNIPA to initiate compulsory licensing, but fail to specify which departments have such a right to advise. It was not until 2018 the Opinions 2018 specified that in the interests of public health, the National Health Commission, the Ministry of Industry and Information Technology and the National Medical Products Administration might carry out joint Evaluations and make recommendations, then the CNIPA makes the final Decision on the implementation of compulsory licenses. Even though Opinions 2018 also indicates that any entity or individual qualified to initiate a compulsory license may request CNIPA for issuing a license. However, it evades the problem of under which occasion the non-official one can be the initiating subject.[99]

2. The Scope of Diseases and Drug Management — Even at the stage of negotiations on Paragraph 6 Decision, developed countries and developing countries had a crash on the scope of diseases and products covered by the exception of patent rights.[100] Developing countries asserted that any agreement could not include a defined list of eligible diseases or exclude any pharmaceutical products used to address public health concerns.[101] Developed countries countered this by revising the text and spirit of the Doha Declaration itself. Paragraph 1 states that the Doha Declaration addresses "public health problems afflicting many developing and least developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria, and other epidemics."[102] In addition, Paragraph 6 Decision defines "pharmaceutical products" as "any patented products or relevant process needed to address the public health problems as recognized in Paragraph 1 of the Declaration". However, after carefully reading paragraph 1, we know it makes a non-exhaustive list of diseases or public health crises.

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[98] *See generally* Ma, *supra* note 96; Cao et al., *supra* note 79.

[99] Chaoyi Jiang, *Who Is the God of Medicine—Deciphering China's Stance on Pharmaceutical Compulsory Licensing*, 14(4) ASIAN J. WTO & INT'L HEALTH L. & POL'Y 471, 488 (2019).

[100] The debate on the scope of diseases was the major stumbling block towards reaching a consensus and resolving the issue. While developed countries proposed that the scope of diseases and corresponding products are limited to a true "public health crisis", developing countries argued that Paragraph 1 of the Declaration did not qualify "public health" in Paragraph 4 or limit the scope of diseases that may be addressed when finding a solution to the Paragraph 6 problem. *See* Mercurio, *supra* note 94, at 237.

[101] *Id.* at 235.

[102] *See* Doha Declaration, *supra* note 20, ¶ 1.

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Accordingly, the issue of product coverage is also ill-defined.

The Opinions 2018, for the first time, introduced the "extraordinary situation such as a serious threat to public health" into "where a national emergency or any extraordinary state of affairs occurs, or where the public interest so requires."[103] Furthermore, except for infectious diseases, a national emergency happens in the event of the "shortage of drugs for serious and critical diseases," a situation where public health is seriously threatened. And "serious and critical diseases" here should include diseases other than infectious diseases.[104] In addition, on 28 October, 2021, the General Office of the State Council issued Opinions of the General Office of the State Council on the Improvement of the Medical Insurance and Relief System for Serious and Critical Diseases pointed out that "assistance fees shall cover the medication fees for chronic diseases or outpatient treatment costs for serious and critical diseases." Therefore, the patented pharmaceuticals subject to compulsory licensing are not limited to those for infectious diseases, but also include chronic diseases, such as cancer and cardiovascular diseases. In addition, according to Article 2 of the Public Health Emergency Response Law,[105] public health emergencies refer to the epidemics of infectious diseases that occur suddenly and cause or may cause severe damage to public health and other threats to public health security.

China has established a supporting drug-management system for pharmaceutical-patent compulsory licensing. The General Office of the Central Committee of the Communist Party of China and the General Office of the State Council issued the Opinions on Deepening the Reform of the Evaluation and Approval Systems and Encouraging Innovation on Drugs and Medical Devices on 1 October, 2017 (hereinafter "Opinions 2017"). The Opinions 2017 emphasized that the priority review and approval system for pharmaceutical under compulsory licensing should be established, that is, in the event of serious threats to public health, accelerating the evaluation and approval of the application for registration of drugs that compulsory licenses have granted.[106] And Opinions 2017 calls for insisting on encouraging

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[103] Cao et al., *supra* note 79, at 3720.

[104] "Infectious diseases" include AIDS, tuberculosis, malaria, and other infectious diseases stipulated in the Health Measures, which only recognize drugs for infectious diseases as the object of compulsory licensing.

[105] Tufa Gonggong Weisheng Shijian Yingji Tiaoli (2011 Xiuding) (突发公共卫生事件应急条例 (2011 修订)) [Regulation on Responses to Public Health Emergencies (2011 Revision)] (promulgated by the State Council People's Republic China, Jan. 8, 2011, effective Jan. 8, 2011), art. 2, CLI.2.174915(EN) (Lawinfochina).

[106] Zhonggong Zhongyang Bangongting Guowuyuan Bangongting Yinfa Guanyu Shenhua Shenping Shenpi Jhihdu Gaige Guli Yaopin Yiliao Cisie Chuangxin de Yijian (中共中央办公厅、国务院办公厅印发《关于深化审评审批制度改革鼓励药品医疗器械创新的意见》) [The General Office of the CPC Central Committee and the General Office of the State Council on Issuing the Opinions on Deepening the Reform of the Evaluation and Approval Systems and Encouraging Innovation on Drugs and Medical Devices] (promulgated by the State Council People's Republic of

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innovation of new drugs and promoting generic medicines production, improving the accessibility and affordability of medicines to the public. In January 2020, the State Administration for Market Regulation issued Measures for the Administration of Drug Registration, Article 68 of which further emphasized that priority review and approval procedures can be applied for urgently needed drugs in short supply, innovative drugs and improved new drugs for the prevention and treatment of diseases when applying for drug marketing registration. At the same time, Article 72 grants the National Medical Products Administration special approval rights in response to public health emergencies. These two clauses have been effectively practiced in response to the pandemic of COVID-19. The National Medical Products Administration has urgently opened a "green channel" for emergency approval of drugs and medical devices and has urgently approved the clinical trials of five new drugs, such as Remdesivir and Favipiravir, for the prevention and treatment of COVID-19 and has also urgently approved the nucleic acid assays of seven companies.

3. Grounds and Coverages for Granting a Compulsory License — Concerning the grounds on which a compulsory license can be granted, it is necessary to distinguish whether licensed medicines are supplied to domestic or foreign markets. Articles 53 and 54 of the Patent Law 2021 stipulate that to supply the domestic market, issuing a compulsory license may happen in the event of "non-exploitation or insufficient exploitation of the patent, remedy for anti-competitive behavior, national emergency or extraordinary circumstances or the public interest so required." However, according to Article 55, only in response to a public health emergency the CNIPA may grant a compulsory license to manufacture a drug for exporting. Regarding the drug importing system under the compulsory license, Article 5 of Measures for Compulsory License on Patent Implementation Concerning Public Health Problems in 2005 stipulated:

> [W]here a patent right is granted to any medicine for treating a certain infectious disease in China, but China fails to possess the capacity of production of the medicine or has insufficient production capacity thereof, the relevant competent departments of the State Council may request the CNIPA to grant a compulsory license, allowing the licensee to import the aforesaid medicine that is produced by WTO members manufacture through the system determined in the General Council Resolution for the purpose of resolving the public health problems for China.

However, this measure was repealed on 15 March, 2012 by the Licensing

China, Oct. 1, 2017, effective Oct. 1, 2017), CLI.5.302835(EN) (Lawinfochina).

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Measures 2012. To be consistent with the TRIPS compulsory license system, the Implementation Regulations 2010 evade the problem by not specifying the subjects of drug importing under the compulsory license. To quickly respond to the epidemic of severe infectious diseases and other public health emergencies, compared with the Implementation Regulations 2010 and Licensing Measures 2012, which only stipulate the general proposing right of relevant departments, the Opinions 2018 further makes a non-exhaustive list of the departments with the right to proposing the issuance of compulsory license.

C. Compatibility Between China's FTAs and the TRIPS

While most free trade agreements (hereinafter "FTAs") of China are keeping silent on the interaction between IPRs and public health, some recently-signed FTAs have taken the first steps towards clarifying the priorities of the TRIPS waivers on public-health issues under TRIPS and the subsequent agreements. For the efficient and effective functioning of the law, BITs and the TRIPS Agreement need to be better aligned.

Until October 2022, China has twenty-one free trade agreements[107]; however, just six of them have a chapter on IPRs, but only the Regional Comprehensive Economic Partnership Agreement (hereinafter "RCEP") has provisions on compulsory licensing (other use without authorization of the right holder).[108] On the one hand, China–Peru FTA and China–New Zealand FTA adopt a general provision or principle. On the other hand, in addition to the interest-balanced principles, China–Costa Rica FTA, China–Korea FTA, China–Australia FTA and RCEP all have a separate article on "Intellectual Property and Public Health".[109] All of the six FTAs adopt a similar way to

[107] Including four upgraded versions, the second phase of the China–Pakistan FTA and the Central Government of China signed the Closer Economic Partnership Arrangement [hereinafter CEPA] with the Government of the Special Administrative Region of Hong Kong and the Government of the Special Administrative Region of Macao respectively. *See* Ministry Com. China, *China's Free Trade Agreements*, CHINA FTA NETWORK, http://fta.mofcom.gov.cn/english/fta_ qianshu.shtml (last visited Oct. 27, 2022).

[108] Including China–Peru FTA, China–New Zealand FTA, China–Costa Rica FTA, China–Korea FTA, China–Australia FTA and RCEP.

[109] *See* Free Trade Agreement Between China and Costa Rica, China-Costa Rica, art. 112, Apr. 1, 2010, http://fta.mofcom.gov.cn/topic/encosta.shtml (entered into force Aug. 1, 2011); Free Trade Agreement Between the Government of the People's Republic of China and the Government of the Republic of Korea, China-S. Kor., art. 15.5, June 1, 2015, http://fta.mofcom.gov.cn/korea/annex/xdzw_en.pdf (entered into force Dec. 20, 2015); Free Trade Agreement Between the Government of Australia and the Government of the People's Republic of China, Austl.-China, art. 11.7, June 17, 2015, https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/3454/download (entered into force Dec. 20, 2015) [hereinafter China–Australia FTA]. There is a little difference in RCEP, which adopt the "The TRIPS Agreement and Public Health" title. *See* Regional Comprehensive Economic Partnership art. 11.1.8, Nov. 15, 2020, https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/6032/download (entered into force Jan. 1, 2022).

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stress the balance between IP protection and public health by reiterating the TRIPS Agreement and the spirit of its subsequent agreements.[110] The RCEP is the most detailed one, showing China's attitude and compromise on public-health-related IP protection between developed and developing countries.[111] Articles 11.1.2 (objectives)[112] and 11.4 (principle)[113] reiterate the provisions in TRIPS Article 7 and Article 8. Article 11.3 clarifies the "Relation to Other Agreements" that the provision of the TRIPS Agreement shall prevail over that of this chapter in the event of any consistency in IP protection. Article 11.39 reaffirms the provisions on the compulsory license, noting that "For greater certainty, nothing in this Agreement shall limit a Party's rights and obligations under Article 31 and Article 31bis of the TRIPS Agreement, and the Annex and Appendix to the TRIPS Agreement." At this point, RCEP almost adopts similar flexibility; that is the provision on compulsory license should be read "in conjunction with the reference to the Doha Declaration on IP and Public Health (Article 11.8) and the Objectives and Principles mentioned above."[114] Therefore, it is the national discretion to define what constitutes a situation of "national emergency" or the grounds for issuing a compulsory license.[115]

[110] For example, China–Australia FTA, *id.* art. 11.7 (Intellectual Property and Public Health):

> 1. The Parties recognise the principles established in the Declaration on the TRIPS Agreement and Public Health adopted on 14 November 2001 by the Ministerial Conference of the WTO and confirm that the provisions of this Chapter are without prejudice to the Doha Declaration. 2. The Parties reaffirm their commitment to contribute to the international efforts to the implementation of the Decision of the WTO General Council of 30 August 2003 on the implementation of paragraph 6 of the Doha Declaration, as well as the Protocol amending the TRIPS Agreement, done at Geneva on 6 December 2005.

[111] Zhang Naigen (张乃根), Yushi Jujin de RCEP Zhishi ChanQuan Tiaokuan Ji Qi Bijiao (与时俱进的 RCEP 知识产权条款及其比较) [RCEP Clauses of International Property Updating with Time and Comparison], 2 WUDA GUOJIFA PINGLUN (武大国际法评论) [WUHAN U. INT'L L. REV.] 1, 1 (2021).

[112] Article 11.1.2 provides that the protection and enforcement of IPRs should be "in a manner conducive to social and economic welfare, and to a balance of rights and obligations."

[113] Article 11.4 recognizes the TRIPS flexibility, under which that member state can implement the IP protection standards meeting its own development need or protecting public interests.

[114] Vitor Henrique Pinto Ido, *TRIPS Flexibility and TRIPS-Plus Provisions in the RCEP Chapter on Intellectual Property: How Much Policy Space Is Retained?* 18 (S. Ctr., Rsch. Paper No. 131, 2021) https://www.econstor.eu/bitstream/10419/248630/1/RP-131.pdf.

[115] *Id*.

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IV. REVAMPING THE COMPULSORY LICENSE SYSTEM OF PHARMACEUTICAL PATENTS IN CHINA: THE WAY FORWARD

A. Lack of Implementation of the Compulsory License for Pharmaceutical Patents

While the rules and sources of interpreting the TRIPS Agreement affirm the members' regulatory power of implementing the compulsory license system, the blackness and uncertainty of flexibility, for example, the qualification of the initiating subject, also posed a challenge to China's practical implementation. Broadly speaking, the subsequent developments of the TRIPS Agreement sought to "clarify" TRIPS Article 31, emphasizing the "flexibilities" already written into the Agreement.[116] However, the space for different interpretations deriving from general expressions or ambiguities in the text, daunts the interpreter or policymaker to interpret or clarify these general terms.[117] In addition, coping with political pressure and trade friction, China might implement the compulsory license for pharmaceutical patents with modesty.[118] Accordingly, China's compulsory license legal system for pharmaceutical patents doesn't fully transplant the TRIPS flexibility mechanism. More specifically, China has made progress in integrating China's compulsory license legal system with the TRIPS flexibility. However, China's zero-implementation status mirrors how far it is to implement the legal system into practice effectively. According to Article 6 of Licensing Measures 2012, where a national emergency or any extraordinary affair occurs, or where the public interest so requires, only the relevant competent departments of the State Council can be the subject of the application. Article 7 stipulates that for public health, only the entity satisfying the conditions for patent exploitation can apply for a compulsory license.[119] The result of this system is that the individual cannot become the subject of compulsory licensing applications. Furthermore, lacking quantifiable criteria on "conditions for patent exploitation" makes it difficult for an entity to initiate a compulsory license.[120] The Opinions 2018 also

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[116] Bryan Mercurio, *Resolving the Public Health Crisis in the Developing World: Problems and Barriers of Access to Essential Medicines*, 5(1) NW. J. INT'L HUM. RTS. 1, 6 (2006).

[117] Carlos M. Correa, *Interpreting the Flexibilities Under the TRIPS Agreement*, *in* ACCESS TO MEDICINES AND VACCINES 1, 2 (Carlos M. Correa & Reto M. Hilty eds., 2022).

[118] Wu Di (武迪), Woguo YaoPin Zhuanli Qiangzhi Xuke Zhidu de Shishi yu Kunjing (我国药品专利强制许可制度的实施与困境) [Implementation and Dilemma of My Country's Pharmaceutical Patent Compulsory License System], 2 SIFA (私法) [PRIV. L. REV.] 338, 355-56 (2020) (Implementing pharmaceutical-patents compulsory licensing, in effect, is an economic competition and political game between developed and developing countries.).

[119] *See* Zhuanli Shishi Qiangzhi Xuke Banfa (2012) (专利实施强制许可办法(2012)) [Measures for Compulsory License for Patent Exploitation (2012)] (promulgated by the State Intell. Prop. Off., Mar. 15, 2012, effective May 1, 2012), arts. 6, 7, CLI.4.169893(EN) (Lawinfochina).

[120] Feirong Peng et al., *China's Challenges in Implementing Compulsory Drug Patent Licenses and*

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shows the procedure defects. While the second sentence of point 12 of the Opinions indicates that only a qualified entity or individual may request the CNIPA for a compulsory license, it fails to provide the criteria for evaluating the qualification. Additionally, the third sentence makes things more confusing since it specifies that in the case public health crisis, it is the National Health Commission, the Ministry of Industry and Information Technology, and the National Medical Products Administration evaluate the situation and propose an initiation for a compulsory license. Even though both the non-official entity and suggestion-giving authorities have the right to initiate compulsory licenses, the opaque licensing procedure under the Opinions demonstrates that CNIPA has the power to reject the motion even without showing what this rejection will be based on.[121] In practice, the compulsory license system for pharmaceutical patents has been in place for many years, and there have been several public health crises in the past, but the system has never been practiced in response to the public's demand for drugs.[122] Therefore, it is doubtful that the entity and individual have the substantial rights or status to initiate a compulsory license in a situation of a public health crisis.

On 18 May 2008, the non-profit organization Beijing Yirenping Center, together with 1,843 persons with hepatitis B virus (hereinafter "HBV") and AIDS, initiated the application to the Ministry of Commerce to implement compulsory licensing of "lamivudine". As an antiretroviral medication used to prevent and treat AIDS and HBV, Lamivudine was a monopoly of the British GlaxoSmithKline. Under the condition that the supply of lamivudine on the mainland was in short supply, the application for granting a compulsory license was refused.[123] In 2005, Influenza A Virus (hereinafter "H1N1") pandemic spread worldwide. The anti-influenza drug "Tamiflu" was developed by Swiss pharmaceutical giant Roche and has been granted a patent in many countries. When the Guangzhou Baiyunshan Pharmaceutical Company, a company that had sufficient capacity to manufacture the generic product of "Tamiflu", named "Futai", applied for a compulsory license, its

Its Response in the Context of COVID-19, 41(3) BIOTECH. L. REP. 154, 155 (2022).

[121] Ma, *supra* note 96, at 145.

[122] Yuan Quan (袁泉) & Shao Rong (邵蓉), Cong Baiyunshanban "Dafei" Shijian Kan Woguo Yaopin Zhuanli Qiangzhi Xuke Zhidu (从白云山版"达菲"事件看我国药品专利强制许可制度) [Consideration of Medicine Patents Compulsory License System in China: From the "Tamiflu" Case of Guangzhou Baiyunshan Pharmaceutical Company], 19(16) ZHONGGUO XINYAO ZAZHI (中国新药杂志) [CHINESE J. NEW DRUGS] 1392, 1392 (2010). See also Cao et al., supra note 79, at 3718.

[123] Li Shanshan (李珊珊) et al., Fagaiwei Tiaozheng 53 Zhong Xiahuaxitonglei Yaopin Zuigao Lingshou Xianjia, Shenzhen Yigai Yinren Zhumu (发改委调整 53 种消化系统类药品最高零售限价，深圳医改引人注目) [The National Dev*elopment and Reform Commission Adjusts the Maximum Retail Price Limits of 53 kinds of Digestive System Drugs, Shenzen's Healthcase Reform Is Eye-Catching]*, 29 ZHAOSHANG ZHENGQUAN MEIZHOU YAOLAN (招商证券每周药览) [CHINA MERCHANT SECURITES WEEKLY PHARMACY] 1, 19 (2012).

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application was rejected.[124] On 11 June 2009, the WHO signaled that the pandemic of H1N1 was underway by raising the worldwide pandemic alert level to Phase 6.[125] However, the storage volume of "Tamiflu" in China at that time was only 6% of the national population; thus, the supply was still extremely insufficient. Therefore, Baiyunshan Pharmaceutical Factory once again proposed to the State Food and Drug Administration to produce the "Fortai" to realize the large-scale production of the drug.[126] Unfortunately, this application was finally rejected because two domestic companies had obtained authorization for legal production.[127] In 2011, Shanghai Aurisco stated that it plans to cooperate with non-governmental organizations to apply for a compulsory license for the "Tenofovir disoproxil" as treatment of HBV and AIDS.[128] In the Lu Yong case in 2015, Lu was diagnosed with chronic myeloid leukaemia in 2002 and began taking Gleevec, priced at around 23,500 yuan ($3,777) per box, developed by Swiss pharmaceutical giant Novartis for use in the treatment of multiple cancers. In 2004, Lu began to turn to Gleevec's Indian generic version, which had a similar effect yet cost only 4,000 yuan. He shared this information with other leukemia patients and even helped them purchase the drug. He was prosecuted in Yuanjiang, Hunan province, in July 2014, being charged with "the sale of fake drugs" and "impairing credit card administration".[129] Later, the procuratorate decided not to prosecute Lu Yong, and in 2019, China amended the legislation to delete the rules for classifying generic drugs as counterfeit drugs while simultaneously expanding the types of anticancer drugs in medical insurance.[130] Therefore, even though China has adopted an

[124] Yuan & Shao, *supra* note 122, at 1393, 1395.

[125] *WHO Pandemic Declaration*, CTR. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/h1n1flu/who/ (last visited Mar. 10, 2022).

[126] He Haining (何海宁), *Shui Youquan Fangz*hao Jialiu Texiao Yao (谁有权仿造甲流特效药) [Who Has the Right to Manufacture Generic Products for Influenza A], NANFANG ZHOUMO (南方周末) [S. WKLY.] (June 24, 2009), http://www.infzm.com/contents/30551.

[127] Zhongguo Shifou Hui Yin Shishi Yaopin Zhuanli Qiangzhi Xuke Er Chengwei Xiayige Yindu (中国是否会因实施药品专利强制许可而成为下一个印度？) [Will China Become the Next India Due to the Implementation of Compulsory Licensing of Drug Patents?], ZHONGHUA RENMIN GONGHEGUO SHANGWU BU (中华人民共和国商务部) [MINISTRY OF COM. PEOPLE'S REPUBLIC OF CHINA] (Sept. 23, 2015), http://gpj.mofcom.gov.cn/article/zuixindt/201509/201509011203 66.shtml.

[128] Weigui Du, On the Perfection of Compulsory Licensing System of Drug Patents in China (2022) (Master thesis, Liaoning University).

[129] Zuigao Renmin Jianchayuan Fabu 2015 Niandu Jiancha Jiguan Shida Falu Jiandu Anli (最高人民检察院发布 2015 年度检察机关十大法律监督案例) [Ten Cases involving Legal Supervision from Procuratorial Authorities in 2015 Issued by the Supreme People's Procuratorate] (promulgated by the Sup. People's Proc., Feb. 1, 2016, effective Feb. 1, 2016), CLI.3.288366 (Lawinfochina). *See also* Xin Wang, *When Patients Get Caught Between Cancer and Crime*, CHINA DAILY (Dec. 24, 2014, 10:02 AM), https://www.chinadaily.com.cn/china/2014-12/24/content_19155746.htm.

[130] *See* Zhonghua Renmin Gonheguo Xingfa (2020 Xiuzheng) (中华人民共和国刑法(2020 修正)) [Criminal Law of the People's Republic of China (2020 Amendment)] (promulgated by the Standing Comm. Nat'l People's Cong., Dec. 26, 2020, effective Mar. 1, 2021), art. 142(I): "Whoever falls under any of the following circumstances in violation of the legislation on drug administration: . . .

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expanded interpretation of the scope of diseases covered by the compulsory license, as stated above, the question of whether chronic diseases can be the ground for issuing a compulsory license is still unsolved. While the compulsory license system for pharmaceutical patents has an actual demand in China, the strict requirement, or procedural defects for initiating a compulsory license make the situation more serious.

B. Dilemma of Implementing Compulsory License for Pharmaceutical Patents Under COVID-19

United Nations has recognized that the current implementation dilemma that dissuades governments from using the flexibility to protect public health is not so much a matter of the legal system but a political one.[131] The outbreak of the COVID-19 pandemic further shows the implementation dilemmas and political pressure China faces on implementing compulsory licensing of pharmaceutical patents to cope with a public health crisis. Undeniably, in terms of Opinion 2018, the COVID-19 pandemic already consists of a national emergency, which happens in the event of major infection and other public health emergencies or a shortage of drugs for serious and critical diseases which seriously threaten public health.[132] "Remdesivir" has entered the public eye as a treatment drug after clinical trials. In the research and development process of "Remdesivir", Gilead Sciences, Inc. of the US has carried out a perfect layout of patent protection. Gilead Sciences already has granted patents for compound structure and the manufacturing process of Remdesivir in several countries, including China, but did not apply for the use of Remdesivir for the treatment of new coronavirus.[133] On 4 February 2020, the Wuhan Institute of Virology published an article stating that Chinese researchers have made important progress in Anti-COVID-19 drug screening, and announced that it had applied for a Chinese patent on Gilead's Remdesivir for novel coronavirus

(2) Producing or importing any drug product without obtaining the documents certifying the relevant approval of the drug product or knowingly selling such a drug product." Therefore, contrasting with Amendment (X) to the Criminal Law of the People's Republic of China 2017, the new version of Criminal Law identifies the behavior of importing or producing generic drugs without approval or certification as a violation of the legislation on drug administration.

[131] U.N. Secretary-General's High-Level Panel on Access to Med., *Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines* 26 (Sept. 14, 2016), http://www.unsgaccessmeds.org/s/UNSG-HLP-Report-FINAL-12-Sept-2016.pdf.

[132] *See* Ma, *supra* note 96, at 145.

[133] Zhang Wujun (张武军) & Zhang Bohan (张博涵), Xinguanfeiyan Yiqing Xia Yaopin Zhuanli Qiangzhi Xuke Yanjiu—Yi Ruidexiwei Weili (新冠肺炎疫情下药品专利强制许可研究—以瑞德西韦为例) [Research on the Compulsory Licensing of Novel Coronavirus—Take Redcive as an Example], 37(20) KEJI JINBU YU DUICE (科技进步与对策) [SCI. & TECH. PROGRESS AND POL'Y] 83, 83 (2020).

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treatment to protect the national interests of China.[134] In fact, the Wuhan Institute of Virology just aims to establish a cross-licensing agreement with Gilead Sciences, so it will inevitably need to ask permission from Gilead licensing to use the compound-drug Remdesivir itself.[135] On 5 May 2020, Gilead announced that it had signed a non-exclusive voluntary licensing agreement with five generic drug manufacturers in India and Pakistan, authorizing the manufacturer to produce and sell "Remdesivir" in 127 countries, but China is not included. From a practical point of view, it is not the successful issuance of compulsory licensing for pharmaceutical patents that can solve the problem of drug accessibility, but the key is the further manufacture of the covered drugs after issuing a compulsory license. Therefore, it is necessary and reasonable to consider the question of whether Gilead refused to voluntarily license "Remdesivir", whether Wuhan Institute of Virology or other entities or even individuals are eligible to initiate a compulsory license. China's Patent Law provides that CNIPA may grant a compulsory license to exploit the patent for the invention or utility model upon the application of that entity or individual. On the one hand, such compulsory licenses do not take public health crises as a reason for application. On the other hand, the requirement for an entity or individual to initiate the compulsory license is strict. Specifically, the application of a special license under insufficient exploitation must meet the time requirement, and the anti-competition act only happens when the enforcement of the patent right has been determined as an act of monopoly.[136] The practical fact demonstrates that except for government authorities, the initiation mechanism for compulsory licenses related to public health should introduce third parties (such as the pharmaceutical company with the capability for further manufacture).

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[134] *Coronavirus Patents: China Files for Remdesivir Patent, But Gilead Sciences Will Still Come Out a Winner*, INQUARTIK (Feb. 20, 2020), https://www.inquartik.com/blog/case-china-coronavirus-patents-gilead-portfolio/.

[135] *Id.*

[136] *See* Zhonghua Renmin Gongheguo Zhuanli Fa (2020 Xiuzheng) (中华人民共和国专利法(2020修正)) [Patent Law of the People's Republic of China (2020 Amendment)] (promulgated by the Standing Comm. Nat'l People's Cong., Oct. 17, 2020, effective June 1, 2021), art. 53, CLI.1.346982(EN) (Lawinfochina):

> In any of the following cases, the CNIPA may, upon the application of that entity or individual, grant a compulsory license to exploit the patent for the invention or utility model.
> (1) where the patentee, after the expiration of three years from the date of granting the patent right, and the expiration of four years from the date of filing, does not exploit the patent or does not sufficiently exploit the patent without any justified reasons;
> (2) where the enforcement of the patent right by the patentee has been legally determined as an act of monopoly, and adverse effects of the act on competition need to be eliminated or reduced.

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C. Towards a Better Integration of China's Compulsory License Law and the TRIPS

1 Interpreting the Ministerial Decision on the TRIPS Under TRIPS Flexibility — On 17 June 2022, after nearly two years of heated debate, WTO members reached a decision on a five-year patent-related waiver for COVID-19 vaccines at the WTO's 12th Ministerial Conference (MC12). The WTO Ministerial Conference issued the Decision referring to "waiver and clarification".[137] This Decision is not a TRIPS waiver proposed by South Africa and India in October 2020, which was a more comprehensive waiver of TRIPS obligations to be able to produce and access Covid-19 countermeasures.[138] In contrast to TRIPS Article 31bis, which only limits the eligible importing countries,[139] the Ministerial Decision on the TRIPS defines eligibility for both importing and exporting in footnote 1. More specially, it recognized all developing country members could be qualified as eligible members, but it encouraged developing country members that have existing capacity to manufacture COVID-19 vaccines "to make a binding commitment not to avail themselves" of the Decision, which largely targeted China.[140] On 10 May 2022, the Chinese delegation announced that China would not use the flexibility under the waiver and opt out of the "eligible" members, which means China cannot be an exporter and importer of the COVID-19 vaccine under the compulsory license.[141] In terms of the TRIPS flexibility and treaty interpretation principles, the Ministerial Decision on the TRIPS does not deprive the national discretion for China to implement the compulsory license. First, it is inevitable to explore the legal

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[137] Shayerah I. Akhtar, *World Trade Organization: "TRIPS Waiver" for COVID-19 Vaccines*, CONG. RSCH. SERV. 1 (Aug. 31, 2022), https://crsreports.congress.gov/product/pdf/R/R47231.

[138] James Love, *The June 17, 2022 WTO Ministerial Decision on the TRIPS Agreement*, KNOWLEDGE ECOLOGY INT'L (June 17, 2022), https://www.keionline.org/37830.

[139] The TRIPS 31bis limits the importing eligibility through an opt-out process. Thirty-seven members (without China) of the WTO are listed as ineligible to import medicines manufactured in another country under a compulsory license. *See* James Love, *Open Letter Asking 37 WTO Members to Declare Themselves Eligible to Import Medicines Manufactured Under Compulsory License in Another Country, Under 31bis of TRIPS Agreement*, KNOWLEDGE ECOLOGY INT'L (Apr. 7, 2020), https://www.keionline.org/32707.

[140] WTO, Draft Ministerial Decision on the TRIPS Agreement: Communication from the Chair of the Council for TRIPS, WTO Doc. WT/Min(22)/W/15, at 1 n.1 (June 10, 2022). (stating in brackets: "For the purpose of this Decision, developing country Members who exported more than ten per cent of world exports of COVID-19 vaccine doses in 2021 are not eligible Members"). China is the only country that accounts for more than ten per cent of global export of COVID-19 vaccine doses, while the rationale for such "encouragement" was to protect domestic manufacturing of vaccines in other developing countries. *See also* Bryan Mercurio, *Sharpening the Tools in the Pandemic-Ending Toolbox*, THINK GLOB. HEALTH (June 23, 2022), https://www.thinkglobalhealth.org/article/sharpening-tools-pandemic-ending-toolbox.

[141] *Members Welcome Quad Document as Basis for Text-Based Negotiations on Pandemic IP Response*, WTO (May 10, 2022), https://www.wto.org/english/news_e/news22_e/gc_10may22_e.htm.

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status of the Decision as a kind of source of interpreting the TRIPS flexibility and the Member's binding commitment under that. According to Article IX Decision-Making (3) of the Marrakesh Agreement Establishing the WTO, in exceptional circumstances, the Ministerial Conference may adopt a decision to waive an obligation imposed on a Member by this Agreement or any of the Multilateral Trade Agreements based on the consent of a three-fourths of the participating members subject to the applicable time limits. None of the provisions of the Decision has a binding effect. They have great significance as a guide to interpretation, even though most of the provisions are framed as "clarifications" of TRIPS Article 31. The Decision is a voluntary but binding commitment, since it specified, "such binding commitments include statements made by eligible Members to the General Council."[142] In terms of the treaty interpretation rules, China will not be prevented from using the compulsory licensing mechanism provided under Articles 31 and 31bis TRIPS for producing and exporting therapeutics and diagnostics under COVID-19, not to mention the possibility and capability to implement the TRIPS flexibility to respond to other public health crises.[143]

On the one hand, based on the text meaning, the Decision stated waiver on the patent right only covers "ingredients and processes necessary for the manufacture of the COVID-19 vaccine."[144] On the other hand, the Decision also has provisions regarding how it relates to other WTO rules. The Decision Paragraph 9 states:

> [T]his Decision is without prejudice to the flexibility that Members have under the TRIPS Agreement, including flexibility affirmed in the Doha Declaration on the TRIPS Agreement and Public Health, and without prejudice to their rights and obligations under the TRIPS Agreement, except as otherwise provided for in paragraph 3(b). For greater certainty, this Decision is without prejudice to the interpretation of the above-mentioned flexibility, rights and obligations outside the scope of this Decision.[145]

Enforced by purpose limitation, the Decision does not apply to the same level of TRIPS flexibility to COVID-19 therapeutics and diagnostics.[146]

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[142] *See* WTO, Draft Ministerial Decision on the TRIPS Agreement: Revision [hereinafter Revised Ministerial Decision on the TRIPS], WTO Doc. WT/MIN(22)/W/15/Rev.2, at 1 n.1 (June 17, 2022): "such as those made at the General Council meeting on 10 May 2022, and will be recorded by the Council for TRIPS and will be compiled and published publicly on the WTO website."

[143] Matthias Lamping et al., *Declaration on Patent Protection: Regulatory Sovereignty Under TRIPS* 1, 2-4, (Max Planck Inst. for Innovation & Competition Rsch. Paper No. 14-19, 2014), https://papers.ssrn.com/sol3/Delivery.cfm/SSRN_ID2537266_code1137858.pdf?abstractid=25007 84&mirid=1.

[144] Revised Ministerial Decision on the TRIPS, *supra* note 142, at 1 n.2.

[145] *Id*. at 2 (¶ 9).

[146] Reto M. Hilty et al., *Position Statement of 5 July 2022 on the Decision of the WTO Ministerial Conference on the TRIPS Agreement Adopted on 17 June 2022*, 1, 3, (Max Planck Inst. for Innovation

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However, the Ministerial Decision on the TRIPS also left an unsolved question that might challenge China's future implementation of compulsory licenses in response to COVID-19. The Decision states that members are to decide whether to extend the Decision to cover the production and supply of COVID-19 diagnostics and therapeutics no later than six months from the decision date. The WTO TRIPS Council has begun a discussion on the possible extension.[147] WHO strongly recommends extending the waiver application also to diagnostics, therapeutics, and other tools to prevent, diagnose, and treat COVID-19.[148] Furthermore, there are propositions to apply the waiver to other medicinal products with indications related to COVID-19, since it is currently more critical to ensure access to therapeutics and diagnostics than vaccines.[149]

2. Comeback to the Interest-Balanced Guiding Principle — The provisions of the compulsory license system first appeared in the Paris Convention for the Protection of Industrial Property in 1883 (Paris Convention), which hoped to prevent the patentee from abusing his rights by establishing a compulsory license system to ensure the balance between the interests of the patentee and the public interest.[150] At the end of 1994, based on the Uruguay Round negotiations, countries incorporated IP rights into the scope of world trade and signed the TRIPS agreement, which further terms the "balance of interest" as the core principle of the treaty. The WTO issued a fact sheet on "TRIPS and pharmaceutical patent" in September 2006, emphasizing an attempt to strike a balance between patent holders and public health rights to ensure member states use the TRIPS flexibility mechanism.[151] A compulsory license for pharmaceutical patents reflects the TRIPS flexibility, giving member states the discretion to balance the interest between patent rights and public health. Improving the pharmaceutical-patents compulsory licensing system is a dynamic process of constantly

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& Competition Rsch. Paper No. 22-14, 2022), https://papers.ssrn.com/sol3/Delivery.cfm/SSRN_ID4166573_code1137858.pdf?abstractid=41665 73&mirid=1.

147 *TRIPS Council Welcomes MC12 TRIPS Waiver Decision, Discusses Possible Extension*, WTO (July 6, 2022), https://www.wto.org/english/news_e/news22_e/trip_08jul22_e.htm.

148 *See* John Zarocostas, *What Next for a COVID-19 Intellectual Property Waiver?*, 397 THE LANCET 1871, 1871 (2021).

149 Hilty et al., *supra* note 146, at 3; Philip C. Robinson et al., *COVID-19 Therapeutics: Challenges and Directions for the Future*, 119(15) PROC. NAT'L ACAD. SCI. 1, 4, 8 (2022); *Unmet Need for COVID-19 Therapies in Community Settings*, 21 THE LANCET INFECTIOUS DISEASES 1471, 1471 (2021), https://www.thelancet.com/pdfs/journals/laninf/PIIS1473-3099(21)00633-2.pdf. (It is somewhat ironic that the long-awaited Decision of the WTO comes at a time when we are witnessing a global "massive oversupply" of COVID-19 vaccines, with millions of doses being discarded.)

150 Eur. Comm'n, *Compulsory Licensing and Data Protection: Legal Issues Related to Compulsory Licensing Under the TRIPS Agreement: An EU Contribution*, CONCURRENCES 3 (2001), https://www.concurrences.com/IMG/pdf/eu_-_compulsory_licensing.pdf (last visited Dec. 19, 2021).

151 WTO, TRIPS AND PHARMACEUTICAL PATENTS 2, 4-5 (2006), https://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf.

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balancing interests.

It is necessary to adhere to the "balance of interests" as a guiding principle to improve the Chinese system, especially on the premise of giving priority to the public interest; the patentee's interest cannot be interfered with excessively, such as exceeding the statutory duration of compulsory licenses.[152] Referring to Opinions 2018, we can interpret the "balance of interests" principle: the government will encourage both the innovation of new drugs and the development of generic drugs. The initiatives will promote an IP system that adapts to China's economic and social development while balancing the interests of patentees and the public. The compulsory license system is an important mechanism for achieving a balance of interests. In addition, the legal principle can provide guidance and constraint for implementing the system and further achieve the balance of interests. China should take into account its own public health level, medical level, drug development level, institutional characteristics and other actual conditions to construct and improve the compulsory license system for pharmaceutical patents.[153] Even though there are scholars who state the TRIPS waiver on the compulsory license would not fully alleviate the burden of access to effective and affordable drugs,[154] perfecting the compulsory license legal system not only provides the reference to adjudication but also can act as a threat to rein in the prices of selected medicines.[155]

On the one hand, we need to improve the integrity of domestic legislation on the pharmaceutical-patents compulsory licensing system, to facilitate the practical operation and accurately position relevant documents. This paper argues that the richness and complexity of the compulsory licensing for pharmaceutical patents, make it difficult to be regulated in one or two documents; it is more appropriate and practical to regulate various kinds of matters on compulsory licensing at different layers.[156] In terms of China's compulsory license legal system for pharmaceutical patents, the "Patent Law", as the "substantive law", stipulates the specific rights and obligations in the compulsory licensing system, including the subjects, objects, grounds and scope of the license. The procedural requirements for implementing of compulsory licenses shall be incorporated into the Implementing Regulations and Licensing Measures. We are to build an effective compulsory licensing system for pharmaceutical patents,

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[152] Xiang Zhicai (向智才) et al., *Woguo Yaopin Zhuanli Qiang Zhi Xuke Zhidu de Falü Guizhi Yanjiu* (我国药品专利强制许可制度的法律规制研究) [Research on the Legal Regulation of Compulsory License System for Pharmaceutical Patents in China], 19 KEJI GUANLI YANJIU (科技管理研究) [SCI. & TECH. MGMT. RSCH.] 147, 147 (2020).

[153] Cao et al., *supra* note 79, at 3726.

[154] *See, e.g.*, Bryan C. Mercurio, *WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments: A Critical Review*, 62 VA. J. INT'L L. 9, 16 (2021).

[155] Xiang et al., *supra* note 152, at 151.

[156] Cao et al., *supra* note 79, at 3721.

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"classifying them according to the importance of the content and the smoothness of the procedure operation."[157]

On the other hand, currently, China is focusing on using government budgets and health insurance coverage to enhance the affordability of medicines. However, under major epidemics or other public crises, the contradiction between the supply and demand of therapeutic drugs in China is reflected in the availability of drugs. Therefore, China should clarify the policy orientation of "mainly dealing with the availability of patented drugs under major epidemics, supplemented by ensuring the affordability."[158] On the premise of giving priority to the public interest, it is necessary to strengthen and improve the protection of drug patents rights to promote the level of China's pharmaceutical research and development, and to implement compulsory licensing with caution to improve the availability of drugs through promoting drug import or generic drug production.

V. CONCLUSION

The flexibility available in the TRIPS Agreement provides WTO member states with significant latitude to adopt and enforce their laws and policies to advance their national interests. As a TRIPS flexibility, compulsory license serves as an essential policy tool for governments to promote the accessibility and affordability of pharmaceuticals.[159] Yet, current WTO disputes on IP protection related to public health show numerous incoherence and troubling practices, which have obstructed the sovereign freedom of governments in using such flexibility to promote public health.[160] Maintaining this balance of interests is essential to realizing the public welfare and development objectives in the TRIPS patent systems.[161]

The TRIPS flexibility on compulsory license reserved a considerable room for members to devise and implement their policy in terms of needs and situations. However, the rich conceptual connotation of the term and unpredictability of the standard also pose challenges for members to

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[157] Xiang et al., *supra* note 152, at 151.

[158] Zhou Liangliang (周亮亮) et al., Yindu Yaopin Zhuanli Qiangzhi Xuke Zhidu ji dui Woguo de Qishi (印度药品专利强制许可制度及对我国的启示) [Compulsory Licensing System of Indian Medicine and Product Patents and Its Enlightenment to My Country], 20(1) NANJING ZHONGYIYAO DAXUE XUEBAO (SHEHUI KEXUE BAN) (南京中医药大学学报(社会科学版)) [J. NANJING U. TRADITIONAL CHINESE MED. (SOC. SCI.)] 58, 62 (2019).

[159] SISULE F. MUSUNGU & CECILIA OH, THE USE OF FLEXIBILITIES IN TRIPS BY DEVELOPING COUNTRIES: CAN THEY PROMOTE ACCESS TO MEDICINES? 27-28 (2006); Regarding TRIPS' flexibility, see generally INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE: THE TRIPS AGREEMENT (Carlos M. Correa & Abdulqawi A. Yusuf eds., 3d ed. 2016).

[160] SISULE F. MUSUNGU ET AL., UTILIZING TRIPS FLEXIBILITIES FOR PUBLIC HEALTH PROTECTION THROUGH SOUTH-SOUTH REGIONAL FRAMEWORKS 3-4 (2004).

[161] Solovy & Krishnamurthy, *supra* note 18, at 69-72.

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implement this legal system. From the above discussion, we can know the treaty interpretation rules and subsequent agreements and practices after TRIPS Agreement, are to clarify the legal status and scope of "flexibility". To avoid political pressure and legal risk, China is inclined to adopt a more prudential and modest attitude in implementing the compulsory license for pharmaceutical patents. Accordingly, China's compulsory license legal system for pharmaceutical patents does not fully transplant the TRIPS flexibility mechanism. More specifically, the overly strict regulations on the qualification for applying compulsory licensing have largely hindered the practice of the system.

It is recognized that the rules of treaty interpretation are so important that they provide a degree of consistency so that those who are part of that rules-based system can predict outcomes of potential and existing disputes; also as a guide to the boundaries that international agreements place on the formulation and interpretation of WTO Members' laws.[162] Even though China has made great progress in transplanting and implementing the TRIPS flexibility concerning the compulsory license into national legislation, still facing a practical implementation dilemma. To improve China's compulsory license system for pharmaceutical patents, we need to interpret the legal implication and scope of the compulsory license for pharmaceutical patents under the TRIPS flexibility; analyze the TRIPS compulsory license provisions in a detailed manner, with appropriate references to recent WTO case law that may be relevant for the interpretation of those provisions. Specifically, to envisage the future challenges that China might face when implementing the compulsory license in response to COVID-19, we need to explore the legal status of the Ministerial Decision on the TRIPS according to the interpreting rules of the TRIPS Agreement. Finally, according to the interest-balanced principle of the TRIPS Agreement, this article proposed a better integration of China's compulsory license system on pharmaceutical patents.

[162] Frankel & Gervais, *supra* note 25, at 1151-52.

臺灣大學學術期刊資料庫

REFERENCES

Books

CORREA, CARLOS M. & ABDULQAWI A. YUSUF (eds.) (2016), INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE: THE TRIPS AGREEMENT, 3d ed.

HILTY, RETO M. & KUNG-CHUNG LIU (eds.) (2014), COMPULSORY LICENSING: PRACTICAL EXPERIENCES AND WAYS FORWARD.

MUSUNGU, SISULE F. MUSUNGU & CECILIA OH (2006), THE USE OF FLEXIBILITIES IN TRIPS BY DEVELOPING COUNTRIES: CAN THEY PROMOTE ACCESS TO MEDICINES?

MUSUNGU, SISULE F. ET AL. (2004), UTILIZING TRIPS FLEXIBILITIES FOR PUBLIC HEALTH PROTECTION THROUGH SOUTH-SOUTH REGIONAL FRAMEWORKS.

STIGLITZ, JOSEPH E. (2006), MAKING GLOBALIZATION WORK.

Articles

Abbott, Frederick M. (2002), *The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO*, 5(2) JOURNAL OF INTERNATIONAL ECONOMIC LAW 469.

Amado, Rivka & Nevin M. Gewertz (2004), *Intellectual Property and the Pharmaceutical Industry: A Moral Crossroads Between Health and Property*, 55(3) JOURNAL OF BUSINESS ETHICS 295.

Bartelt, Sandra (2003), *Compulsory Licences Pursuant to TRIPS Article 31 in the Light of the Doha Declaration on the TRIPS Agreement and Public Health*, 6 JOURNAL OF WORLD INTELLECTUAL PROPERTY 283.

Borelli, Silvia (2015), *The (Mis)-Use of General Principles of Law:* Lex Specialis *and the Relationship Between International Human Rights Law and the Laws of Armed Conflict*, *in* 46 GENERAL PRINCIPLES OF LAW: THE ROLE OF THE JUDICIARY 265 (Laura Pineschi ed.).

Cao, Zhang et al. (2021), *The Legislative Approach and System Improvement of China's Compulsory Licensing for Drug Patents*, 15 DRUG DESIGN, DEVELOPMENT AND THERAPY 3717.

Champ, Paul & Amir Attaran (2002), *Patent Rights and Local Working Under WTO TRIPS Agreement: An Analysis of the US-Brazil Patent Dispute*, 27 YALE JOURNAL OF INTERNATIONAL LAW 365.

Chen, Xueyu (陈学宇) (2019), Woguo Yaopin Zhuanli Qiangzhi Xuke Zhidu Fenlei Shishi Tantao — Jiyu Fangzhiyao Gongying Baaozhang de Shijiao (我国药品专利强制许可制度分类实施探讨——基于仿制药供应保障的视角) [On Classified Implementation of Drug Patent Compulsory License System in China — From the Perspective of Supply Security of Generic Drug], 5 HUAQIAO DAXUE XUEBAO (ZHEXUE

臺灣大學學術期刊資料庫

SHEHUI KEXUE BAN) (华侨大学学报 (哲学社会科学版)) [JOURNAL OF HUAQIAO UNIVERSITY (PHILOSOPHY & SOCIAL SCIENCE)] 99.

Chen, Yongfa (陈永法) et al. (2018), Yindu Yaopin Zhuanli Qiangzhi Xuke Zhidu Yanjiu (印度药品专利强制许可制度研究) [The Drug Patent Compulsory Licensing System in India and Its Empirical Study], 8(1) JIAGE LILUN YU SHIJIAN (价格理论与实践) [PRICE: THEORY AND PRACTICE] 90.

Correa, Carlos M. (2022), *Interpreting the Flexibilities Under the TRIPS Agreement*, *in* ACCESS TO MEDICINES AND VACCINES 1 (Carlos M. Correa & Reto M. Hilty eds.).

Forman, Lisa et al. (2016), *Assessing the UN High-Level Panel on Access to Medicines Report in Light of the Right to Health*, 5 LAWS (SPECIAL ISSUE) 43.

Frankel, Susy & Daniel Gervais (2013), *Plain Packaging and the Interpretation of the TRIPS Agreement*, 46(5) VANDERBILT JOURNAL OF TRANSNATIONAL Law 1149.

Harshita, Mathur (2008), *Compulsory Licensing Under Section 92A: Issues and Concerns*, 13 JOURNAL OF INTELLECTUAL PROPERTY 464.

Jiang, Chaoyi (2019), *Who Is the God of Medicine—Deciphering China's Stance on Pharmaceutical Compulsory Licensing*, 14(4) ASIAN JOURNAL OF WTO & INTERNATIONAL HEALTH LAW AND POLICY 471.

Konde, Viren (2016), *Recent Developments in Compulsory Licensing of Pharmaceutical Patents in India*, 22(1) JOURNAL OF COMMERCIAL BIOTECHNOLOGY 64.

Li, Shanshan (李珊珊) et al. (2012), Fagaiwei Tiaozheng 53 Zhong Xiahuaxitonglei Yaopin Zuigao Lingshou Xianjia, Shenzhen Yigai Yinren Zhumu (发改委调整 53 种消化系统类药品最高零售限价，深圳医改引人注目) [The National Devel*opment and Reform Commission Adjusts the Maximum Retail Price Limits of 53 kinds of Digestive System Drugs, Shenzen's Healthcase Reform Is Eye-Catching]*, 29 ZHAOSHANG ZHENGQUAN MEIZHOU YAOLAN (招商证券每周药览) [CHINA MERCHANT SECURITES WEEKLY PHARMACY] 1.

Ma, Le (2021), *Dilemmas and Countermeasures on Implementing Compulsory Licensing of Pharmaceutical Patents to Cope with Public Health Crisis*, 2(2) SCIENCE TECHNOLOGY AND LAW 141.

Marsoof, Althaf (2018), *Local Working of Patents: The Perspective of Developing Countries*, *in* MULTI-DIMENSIONAL APPROACHES TOWARDS NEW TECHNOLOGY: INSIGHTS ON INNOVATION, PATENTS AND COMPETITION 315 (Ashish Bharadwaj et al. eds.).

Mercurio, Bryan (2006), *Resolving the Public Health Crisis in the Developing World: Problems and Barriers of Access to Essential Medicines*, 5(1) NORTHWESTERN JOURNAL OF INTERNATIONAL HUMAN

臺灣大學學術期刊資料庫

RIGHTS 1.
Mercurio, Bryan C. (2004), *TRIPS, Patents, and Access to Life-Saving Drugs in the Developing World*, 8(2) MARQUETTE INTELLECTUAL PROPERTY LAW REVIEW 211.
Mercurio, Bryan C. (2021), *WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments: A Critical Review*, 62 VIRGINIA JOURNAL OF INTERNATIONAL LAW 9.
Peng, Feirong et al. (2022), *China's Challenges in Implementing Compulsory Drug Patent Licenses and Its Response in the Context of COVID-19*, 41(3) BIOTECHNOLOGY LAW REPORT 154.
Robinson, Philip C. et al. (2022), *COVID-19 Therapeutics: Challenges and Directions for the Future*, 119(15) PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCE 1.
Solovy, Eric M. & Pavan S. Krishnamurthy (2017), *TRIPS Agreement Flexibilities and Their Limitations: A Response to the UN Secretary-General's High-Level Panel Report on Access to Medicines*, 50(1) GEORGE WASHINGTON INTERNATIONAL LAW REVIEW 69.
Soyeju, Olufemi & Joshua Wabwire (2018), *The WTO–TRIPS Flexibilities on Public Health: A Critical Appraisal of the East African Community Regional Framework*, 17(1) WORLD TRADE REVIEW 145.
Wu, Di (武迪) (2020), Woguo YaoPin Zhuanli Qiangzhi Xuke Zhidu de Shishi yu Kunjing (我国药品专利强制许可制度的实施与困境) [Implementation and Dilemma of My Country's Pharmaceutical Patent Compulsory License System], 2 SIFA (私法) [PRIVATE LAW REVIEW] 338.
Xiang, Zhicai (向智才) et al. (2020), Woguo Yaopin Zhuanli Qiang Zhi Xuke Zhidu de Falü Guizhi Yanjiu (我国药品专利强制许可制度的法律规制研究) [Research on the Legal Regulation of Compulsory License System for Pharmaceutical Patents in China], 19 KEJI GUANLI YANJIU (科技管理研究) [SCIENCE AND TECHNOLOGY MANAGEMENT RESEARCH] 147.
Yuan, Jiaojiao (袁姣姣) (2019), Woguo Yaopin Zhuanli Qiangzhi Xuke Ling Shishi Yuanyin Tanxi (我国药品专利强制许可零实施原因探析) [Analysis on the Reasons for the Zero Implementation of Pharmaceutical Patent Compulsory License in China], 34 GUANGXI ZHENGFA GUANLI GANBU XUEYUAN XUEBAO (广西政法管理干部学院学报) [JOURNAL OF GUANGXI ADMINISTRATIVE CADRE INSTITUTE OF POLITICS AND LAW] 90.
Yuan, Quan (袁泉) & Shao Rong (邵蓉) (2010), Cong Baiyunshanban "Dafei" Shijian Kan Woguo Yaopin Zhuanli Qiangzhi Xuke Zhidu (从白云山版"达菲"事件看我国药品专利强制许可制度) [Consideration of Medicine Patents Compulsory License System in China: From the "Tamiflu" Case of Guangzhou Baiyunshan Pharmaceutical Company],

臺灣大學學術期刊資料庫

19(16) ZHONGGUO XINYAO ZAZHI (中国新药杂志) [CHINESE JOURNAL OF NEW DRUGS] 1392.

Zarocostas, John (2021), *What Next for a COVID-19 Intellectual Property Waiver?*, 397 THE LANCET 1871.

Zhang, Naigen (张乃根) (2020), Gonggong Jiankang Xiangguan Zhishi Chanquan de Guojifa Wenti (公共健康相关知识产权的国际法问题) [On International Law Concerning Public Health-Related IP Issues], 11 ZHISHI CHANQUAN (知识产权) [INTELLECTUAL PROPERTY] 3.

Zhang, Naigen (張乃根) (2021), Yushi Jujin de RCEP Zhishi ChanQuan Tiaokuan Ji Qi Bijiao (与时俱进的 RCEP 知识产权条款及其比较) [RCEP Clauses of International Property Updating with Time and Comparison], 2 WUDA GUOJIFA PINGLUN (武大国际法评论) [WUHAN UNIVERSITY INTERNATIONAL LAW REVIEW] 1.

Zhang, Weijun (张伟君) & Zhang Taolue (张韬略) (2009), TRIPS Xieyi he Woguo Zhuanli Qiangzhi Xuke Zhidu de Wanshan (TRIPS 协议和我国专利强制许可制度的完善) [TRIPS Agreement and Perfection of Compulsory Patents License System in China], 6 SHIJIE MAOYI ZUZHI DONGTAI YU YANJIU (世界贸易组织动态与研究) [WORLD TRADE ORGANIZATION FOCUS] 24.

Zhang, Wujun (张武军) & Zhang Bohan (张博涵) (2020), Xinguanfeiyan Yiqing Xia Yaopin Zhuanli Qiangzhi Xuke Yanjiu—Yi Ruidexiwei Weili (新冠肺炎疫情下药品专利强制许可研究—以瑞德西韦为例) [Research on the Compulsory Licensing of Novel Coronavirus—Take Redcive as an Example], 37(20) KEJI JINBU YU DUICE (科技进步与对策) [SCIENCE AND TECHNOLOGY PROGRESS AND POLICY] 83.

Zhou, Liangliang (周亮亮) et al. (2019), Yindu Yaopin Zhuanli Qiangzhi Xuke Zhidu ji dui Woguo de Qishi (印度药品专利强制许可制度及对我国的启示) [Compulsory Licensing System of Indian Medicine and Product Patents and Its Enlightenment to My Country], 20(1) NANJING ZHONGYIYAO DAXUE XUEBAO (SHEHUI KEXUE BAN) (南京中医药大学学报(社会科学版)) [JOURNAL OF NANJING UNIVERSITY TRADITIONAL CHINESE MEDICINE (SOCIAL SCIENCE)] 58.

Cases

Appellate Body Report, *European Communities — Customs Classification of Certain Computer Equipment*, WTO Doc. WT/DS62/AB/R, WT/DS67/AB/R, WT/DS68/AB/R (adopted June 22, 1998).

Appellate Body Report, *India — Patents Protection for Pharmaceutical and Agricultural Chemical Products*, WTO Doc. WT/DS50/AB/R (adopted January 16, 1998).

臺灣大學學術期刊資料庫

Kasikili/Sedudu Island (Botswana v. Namibia), Judgment, 1999 International Court of Justice (December 13).
Panel Report, *Canada — Patents Protection of Pharmaceutical Products*, WTO Doc. WT/DS114/R (adopted April 7, 2000).
Panel Report, *United States — Section 337 of the Tariff Act of 1930*, L/6439 (November 7, 1989), GATT BISD (36th Supplement).

Treaties

Agreement on Trade-Related Aspects of Intellectual Property Rights (Paragraph 6 of the Preamble), April 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994).
Free Trade Agreement Between China and Costa Rica, China-Costa Rica, April 1, 2010, http://fta.mofcom.gov.cn/topic/encosta.shtml (entered into force August 1, 2011).
Free Trade Agreement Between the Government of Australia and the Government of the People's Republic of China, Australia-China, June 17, 2015, https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/3454/download (entered into force December 20, 2015).
Free Trade Agreement Between the Government of the People's Republic of China and the Government of the Republic of Korea, China-South Korea, June 1, 2015, http://fta.mofcom.gov.cn/korea/annex/xdzw_en.pdf (entered into force December 20, 2015).
General Agreement on Tariffs and Trade, October 30, 1947, 61 Stat. A-11, 55 U.N.T.S. 194.
Regional Comprehensive Economic Partnership, November 15, 2020, https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/6032/download (entered into force January 1, 2022).
Vienna Convention on the Law of Treaties, May 23, 1969, 1155 U.N.T.S. 331.

U.N.- related Documents

Dispute Settlement: World Trade Organization 3.14 TRIPS, UNITED NATION CONFERENCE ON TRADE AND DEVELOPMENT (2003), https://unctad.org/system/files/official-document/edmmisc232add18_en.pdf.
UNITED NATION SECRETARY-GENERAL & CO-CHAIRS OF THE HIGH-LEVEL PANEL, REPORT OF THE UNITED NATIONS SECRETARY-GENERAL'S HIGH-LEVEL PANEL ON ACCESS TO MEDICINE: PROMOTING INNOVATION AND ACCESS TO HEALTH TECHNOLOGIES (September, 2016), https://www.politico.eu/wp-content/uploads/2016/09/HLP-Report-FINAL-Sept-2016.pdf.
United Nation Secretary-General's High-Level Panel on Access to

臺灣大學學術期刊資料庫

Medicines, *Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines* (September 14, 2016), http://www.unsgaccessmeds.org/s/UNSG-HLP-Report-FINAL-12-Sept-2016.pdf.

WTO-related Documents

Council for Trade-Related Aspects of Intellectual Property Rights, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment, and Treatment of Covid-19: Communication from India and South Africa*, WTO Doc. IP/C/W/669 (October 2, 2020).

Council for Trade-Related Aspects of Intellectual Property Rights, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of Covid-19 Revised decision text*, WTO Doc. IP/C/W/669/Rev.1 (May 25, 2021).

Ministry of Economy Industrial Property Protection Office, *Law on Industrial Property,* World Trade Organization (June, 2002), https://www.wto.org/english/thewto_e/acc_e/mkd_e/wtaccmkd24a2_leg_1.pdf.

Request for Consultations by Brazil, *European Union and a Member State — Seizure of Generic Drugs in Transit*, WTO Doc. WT/DS409/1, IP/D/29, G/L/922 (May 19, 2010).

Request for Consultations by India, *European Union and a Member State — Seizure of Generic Drugs in Transit*, WTO Doc. WT/DS408/1, G/L/921, IP/D/28 (May 11, 2010).

Request for the Establishment of a Panel by the United States, *Brazil — Measures Affecting Patent Protection*, WTO Doc. WT/DS199/3 (January 9, 2001).

TRIPS: Special Compulsory Licenses for Export of Medicines, WTO, https://www.wto.org/english/tratop_e/trips_e/guidenotifications_e.pdf.

World Trade Organization, *Amendment of the TRIPS Agreement,* WTO Doc. WT/L/641 (December 8, 2005).

World Trade Organization, *Declaration on the TRIPS Agreement and Public Health*, WTO Doc. WT/MIN(01)/DEC/2 (November 20, 2001).

World Trade Organization, Draft Ministerial Decision on the TRIPS Agreement: Communication from the Chair of the Council for TRIPS, WTO Doc. WT/Min(22)/W/15 (June 10, 2022).

World Trade Organization, Draft Ministerial Decision on the TRIPS Agreement: Revision, WTO Doc. WT/MIN(22)/W/15/Rev.2 (June 17, 2022).

World Trade Organization, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WTO Doc. WT/L/540/Corr.1 (July 29, 2005).

World Trade Organization, *Ministerial Decision on the TRIPS Agreement adopted on 17 June 2022*, WTO Doc. WT/MIN(22)/30, WT/L/1141 (June 22, 2022).

臺灣大學學術期刊資料庫

World Trade Organization, *Protocol Amending the TRIPS Agreement Done at Geneva on 6 December 2005*, WTO Doc. WLI/100 (January 30, 2017).

WORLD TRADE ORGANIZATION, TRIPS AND PHARMACEUTICAL PATENTS (2006), https://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf.

WTO Analytical Index: DSU — Article 3, WTO (August, 2022), https://www.wto.org/english/res_e/publications_e/ai17_e/dsu_art3_jur.pdf.

Statutes

Patent Act, R.S.C. 1985, c P-4.

Sheji Gonggong Jiankang Wenti de Zhuanli Shishi Qiangzhi Xuke Banfa (涉及公共健康问题的专利实施强制许可办法) [Measures for Compulsory License on Patent Implementation concerning Public Health Problems] (promulgated by the Instrumentalities of the State Intellectual Property Office, November 29, 2005, effective January 1, 2006), CLI.4.66212(EN) (Lawinfochina).

Tufa Gonggong Weisheng Shijian Yingji Tiaoli (2011 Xiuding) (突发公共卫生事件应急条例(2011 修订)) [Regulation on Responses to Public Health Emergencies (2011 Revision)] (promulgated by the State Council People's Republic China, January 8, 2011, effective January 8, 2011), CLI.2.174915(EN) (Lawinfochina).

Zhonggong Zhongyang Bangongting Guowuyuan Bangongting Yinfa Guanyu Shenhua Shenping Shenpi Jhihdu Gaige Guli Yaopin Yiliao Cisie Chuangxin de Yijian (中共中央办公厅、国务院办公厅印发《关于深化审评审批制度改革鼓励药品医疗器械创新的意见》) [The General Office of the CPC Central Committee and the General Office of the State Council on Issuing the Opinions on Deepening the Reform of the Evaluation and Approval Systems and Encouraging Innovation on Drugs and Medical Devices] (promulgated by the State Council People's Republic of China, October 1, 2017, effective October 1, 2017), CLI.5.302835(EN) (Lawinfochina).

Zhonghua Renmin Gongheguo Chuanranbing Fangzhi Fa (中华人民共和国传染病防治法) [Law of the People's Republic of China on Prevention and Treatment of Infectious Diseases] (promulgated by the Standing Committee of the National People's Congress, February 21, 1989; revised and effective August 28, 2004), CLI.1.54998(EN) (Lawinfochina).

Zhonghua Renmin Gongheguo Zhuanli Fa (2008 Xiuzheng) (中华人民共和国专利法(2008 年修正)) [Patent Law of the People's Republic of China (2008 Amendment)] (promulgated by the Standing Committee of the National People's Congress, December 27, 2008, effective October 1, 2009), CLI.1.111782(EN) (Lawinfochina).

臺灣大學學術期刊資料庫

Zhonghua Renmin Gongheguo Zhuanli Fa (2020 Xiuzheng) (中华人民共和国专利法(2020 修正)) [Patent Law of the People's Republic of China (2020 Amendment)] (promulgated by the Standing Committee of the National People's Congress, October 17, 2020, effective June 1, 2021), CLI.1.346982(EN) (Lawinfochina).

Zhonghua Renmin Gongheguo Zhuanli Fa (中华人民共和国专利法(1992 修正)) [Patent Law of the People's Republic of China (1992 Amendment)] (promulgated by the Standing Commmittee of the National People's Congress, August 25, 2000, effective July 1, 2001), CLI.1.5926(EN) (Lawinfochina).

Zhonghua Renmin Gongheguo Zhuanli Fa (中华人民共和国专利法(2000 年修正)) [Patent Law of the People's Republic of China (2000 Amendment)] (promulgated by the Standing Committee of the National People's Congress, December 27, 2008, effective January 1, 2009), CLI.1.31016(EN) (Lawinfochina).

Zhonghua Renmin Gongheguo Zhuanli Fa (中华人民共和国专利法) [Patent Law of the People's Republic of China] (promulgated by the Standing Committee of the National People's Congress, March 12, 1984, effective April 1, 1985), CLI.1.1943(EN) (Lawinfochina).

Zhonghua Renmin Gongheguo Zhuanli Fa Shishi Xize (2010 Xiuding) (中华人民共和国专利法实施细则(2010 修订)) [Implementing Regulations of the Patent Law of the People's Republic of China] (promulgated by the State Council People's Republic China, June 15, 2001; revised by the State Council January 9, 2010), CLI.2.126175(EN) (Lawinfochina).

Zhonghua Renmin Gonheguo Xingfa (2020 Xiuzheng) (中华人民共和国刑法(2020 修正)) [Criminal Law of the People's Republic of China (2020 Amendment)] (promulgated by the Standing Committee of the National People's Congress, December 26, 2020, effective March 1, 2021).

Zhuanli Shishi Qiangzhi Xuke Banfa (2012) (专利实施强制许可办法(2012)) [Measures for Compulsory License for Patent Exploitation (2012)] (promulgated by the State Intellectual Property Office, March 15, 2012, effective May 1, 2012), CLI.4.169893(EN) (Lawinfochina).

Zuigao Renmin Jianchayuan Fabu 2015 Niandu Jiancha Jiguan Shida Falu Jiandu Anli (最高人民检察院发布 2015 年度检察机关十大法律监督案例) [Ten Cases involving Legal Supervision from Procuratorial Authorities in 2015 Issued by the Supreme People's Procuratorate] (promulgated by the Supreme People's Procuratorate, February 1, 2016, effective February 1, 2016), CLI.3.288366 (Lawinfochina).

臺灣大學學術期刊資料庫

Internet Sources

Akhtar, Shayerah I., *World Trade Organization: "TRIPS Waiver" for COVID-19 Vaccines*, CONGRESSIONAL RESEARCH SERVICE (August 31, 2022), https://crs reports.congress.gov/ product/pdf/R/R47231.

Canada Is First to Notify Compulsory License to Export Generic Drug, WORLD TRADE ORGANIZATION (October 4, 2007), https://ww w.wto.org/english/news_e/news07_e/trips_health_notif_oct07_e.htm.

Compulsory Licenses, the TRIPS Waiver and Access to COVID-19 Medical Technologies, MEDECINS SANS FRONTIERES (May, 2021), https://ms faccess.org/sites/default/files/2021-05/COVID_TechBrief_MSF_AC_IP _CompulsoryLicensesTRIPSWaiver_ENG_21May2021_0.pdf.

Coronavirus Patents: China Files for Remdesivir Patent, But Gilead Sciences Will Still Come Out a Winner, INQUARTIK (February 20, 2020), https://www.inquartik.com/blog/case-china-corona virus-patents-gilead-portfolio/.

Correa, Carlos M., *Implications of the Doha Declaration on the TRIPS Agreement and Public Health*, WORLD HEALTH ORGANIZATION (June, 2002), https://apps.who. int/iris/bitstream/handle/10665/67345/WHO_ EDM_PAR_2002.3.pdf.

COVID-19 IP Policy Tracker, WORLD INTELLECTUAL PROPERTY ORGANIZATION, https://www.wipo.int/covid19-policy-tracker/#/covid19 -policy-tracker/ipo-operations.

European Union, *Compulsory Licensing and Data Protection: Legal Issues Related to Compulsory Licensing Under the TRIPS Agreement: An EU Contribution*, CONCURRENCES (2001), https://www.concurrences.com/ IMG/pdf/eu-com pulsory_licensing.pdf.

Government of Brazil Ministry of Economy National Institute of Industrial Property, *Directorate for Patents, Computer Programs, and Topographies of Integrated Circuits*, WORLD INTELLECTUAL PROPERTY ORGANIZATION (February 14, 2019), https:// www.wipo.int/export/s ites/www/scp/en/meetings/session_30/comments_receive d/brazil_1.pdf.

He, Haining (何海宁), Shui Youquan Fangzhao Jialiu Texiao Yao (谁有权仿造甲流特效药) [Who Has the Right to Manufacture Generic Products for Influenza A], NANFANG ZHOUMO (南方周末) [SOUTHERN WEEKLY] (June 24, 2009), http://www.infzm.com/contents/30551.

Hilty, Reto et al., *Covid-19 and the Role of Intellectual Property: Position Statement of the Max Planck Institute for Innovation and Competition of 7 May 2021*, MAX PLANCK INSTITUTE FOR INNOVATION AND COMPETITION RESEARCH PAPER (May 25, 2021), https://www.ip.mpg. de/fileadmin/ipmpg/content/stellungnahmen/2021_05_25_Position_stat ement_Covid_IP_waiver.pdf.

Love, James, *Open Letter Asking 37 WTO Members to Declare Themselves*

臺灣大學學術期刊資料庫

Eligible to Import Medicines Manufactured Under Compulsory License in Another Country, Under 31bis of TRIPS Agreement, KNOWLEDGE ECOLOGY INTERNATIONAL (April 7, 2020), https://www.keionline.org/32707.

Love, James, *The June 17, 2022 WTO Ministerial Decision on the TRIPS Agreement*, KNOWLEDGE ECOLOGY INTERNATIONAL (June 17, 2022), https://www.keionline.org/37830.

Members Welcome Quad Document as Basis for Text-Based Negotiations on Pandemic IP Response, WORLD TRADE ORGANIZATION (May 10, 2022), https://www.wto.org/english/news_e/news 22_e/gc_10may22_e.htm.

Mercurio, Bryan, *Sharpening the Tools in the Pandemic-Ending Toolbox*, THINK GLOBAL HEALTH (June 23, 2022), https://www.thinkglobalhealth.org/article/sharpening-tools-pandemic-ending-toolbox.

Miller, John W. & Geeta Anand, *India Prepares EU Trade Complaint*, WALL STREET JOURNAL (August 6, 2009 12:01 AM), https://www.wsj.com/articles/SB124949598103308449.

Ministry of Commerce People's Republic China, *China's Free Trade Agreements*, CHINA FTA NETWORK, http://fta.mofcom.gov.cn/english/fta_qianshu.shtml.

Notifications by Exporting WTO Members, WORLD TRADE ORGANIZATION, https://www.wto.org/english/tratop_e/trips_e/public_health_notif_export_e.htm (last visited November 20, 2022).

Rao, Weisun, *China Allows Compulsory Licensing*, LEXOLOGY (December 10, 2012), https://www.lexology.com/library/detail.aspx?g=2c0a5b56-b64f-4401-bd97-7d6b468cbb6b.

Reinsch, William Alan et al., *Compulsory Licensing: A Cure for Distributing the Cure?*, CENTER FOR STRATEGIC & INTERNATIONAL STUDIES (May 8, 2020), https://www.csis.org/analysis/compulsory-licensing-cure-distributing-cure.

Statement on the Second Meeting of the International Health Regulations (2005) Emergency Committee Regarding the Outbreak of Novel Coronavirus (2019-nCoV), WORLD HEALTH ORGANIZATION (January 30, 2020), https://www.who.int/news/item/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-(2019-ncov).

TG Team, *India and EU Reach an Understanding on Issue of Seizure of Indian Generic Drugs in Transit*, TAXGURU (July 28, 2011), https://taxguru.in/finance/india-eu-reach-understanding-issue-seizure-indian-generic-drugs-transit.html.

TRIPS and Public Health: Notifications, WORLD TRADE ORGANIZATION, https://www.wto.org /english/tratop_e/trips_e/public_health_e.htm.

TRIPS Council Welcomes MC12 TRIPS Waiver Decision, Discusses Possible Extension, WORLD TRADE ORGANIZATION (July 6, 2022), https://www.

臺灣大學學術期刊資料庫

wto.org/english/news_e/news22_e/trip_08 jul22_e.htm.

United States General Accounting Office, *U.S.-China Trade: Implementation of Agreements on Market Access and Intellectual Property*, REPORT TO THE HONORABLE HANK BROWN, U.S. SENATE (January, 1995), https://www.gao.gov/assets/ggd-95-61.pdf.

Unmet Need for COVID-19 Therapies in Community Settings, 21 THE LANCET INFECTIOUS DISEASES 1471 (2021), https://www.thelancet.com/pdfs/journals/laninf/PIIS1473-3099(21)006 33-2.pdf.

Using TRIPS flexibility to Promote Access to Medicines for PLHIV in Kenya and Uganda, AIDSFONDS, https://aidsfonds.org/work/using-trips-flexibility-to-promote-access-to-medicines-for-plhiv-in-kenya-and-uganda.

Verma, Santosh Kumar, *TRIPS Agreement and Access to Medicines* (December 1, 2006), https://www.kansai-u.ac.jp/ILS/publication/asset/nomos/29/nomos29-06.pdf.

Wang, Katherine, *China Announces New Initiatives to Level the Playing Field for Innovative and Generic Drugs*, ROPES & GRAY (April 17, 2018), https://www.ropesgray.com/en/newsroom/ alerts/2018/04/china-announces-new-initiatives-to-level-the-playing-field-for-innovative-and-generic-drugs.

Wang, Xin, *When Patients Get Caught Between Cancer and Crime*, CHINA DAILY (December 24, 2014, 10:02 AM), https://www.chinadaily.com.cn/china/2014-12/24/content_19155746.htm.

WHO Pandemic Declaration, CENTERS FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/h1n1flu/who/.

Zhongguo Shifou Hui Yin Shishi Yaopin Zhuanli Qiangzhi Xuke Er Chengwei Xiayige Yindu (中国是否会因实施药品专利强制许可而成为下一个印度？) [Will China Become the Next India Due to the Implementation of Compulsory Licensing of Drug Patents?], ZHONGHUA RENMIN GONGHEGUO SHANGWU BU (中华人民共和国商务部) [MINISTRY OF COMMERCE PEOPLE'S REPUBLIC OF CHINA] (September 23, 2015), http://gpj.mofcom.gov.cn/article/zuixindt/201509/20150901120366.shtml.

Working Paper, and Other Sources

Abughanm, Saad, The Protection of Pharmaceutical Patents and Data Under TRIPS and US–Jordan FTA: Exploring the Limits of Obligations and Flexibilities: A Study of the Impacts on the Pharmaceutical Sector in Jordan (2012) (SJD thesis, University of Toronto).

Du, Weigui, On the Perfection of Compulsory Licensing System of Drug Patents in China (2022) (Master thesis, Liaoning University).

Garrison, Christopher, *Exceptions to Patent Rights in Developing Countries* (UNCTAD & ICTSD, Issue Paper No.17, 2006).

Hilty, Reto M. et al., *Position Statement of 5 July 2022 on the Decision of*

臺灣大學學術期刊資料庫

the WTO Ministerial Conference on the TRIPS Agreement Adopted on 17 June 2022 (Max Planck Institute for Innovation and Competition Research Paper No. 22-14, 2022), https://papers.ssrn.com/sol3/Delivery.cfm/SSRN_ID4166573_code1137858.pdf?abstractid=4166573&mirid=1.

Ido, Vitor Henrique Pinto, *TRIPS Flexibility and TRIPS-Plus Provisions in the RCEP Chapter on Intellectual Property: How Much Policy Space Is Retained?* (South Centre, Research Paper No. 131, 2021) https://www.econstor.eu/bitstream/10419/248630/1/RP-131.pdf.

Lamping, Matthias et al., *Declaration on Patent Protection: Regulatory Sovereignty Under TRIPS* (Max Planck Institute for Innovation and Competition Research Paper No. 14-19, 2014), https://papers.ssrn.com/sol3/Delivery.cfm/SSRN_ID2537266_code1137858.pdf?abstractid=2500784&mirid=1.

Zarocostas, John, *Brazil and India File Complaint Against EU over Seizure of Generic Drugs*, THEBMJ (May 18, 2010), https://www.bmj.com/content/340/bmj.c2672.

臺灣大學學術期刊資料庫