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# What Remedies Are Available to Life Sciences Companies if Their IP Rights Are Exploited During the Global Pandemic?

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## Introduction

In October 2020, India and South Africa asked that the World Trade Organization ("WTO") waive the protection and enforcement of intellectual property ("IP") rights to ease access to Covid-19 vaccines.[1] In May 2021, 62 WTO members voiced their support of such a waiver.[2] They clarified that the waiver would apply to treatments, diagnostics, medical devices, protective equipment, and the material and components needed to produce the vaccines ("Waiver Proposal").[3] Countries including the United States and China supported the waiver, but many opponents considered it deterrent, anti-competitive, and counterproductive.[4] We do not assess the merits of the Waiver Proposal itself, but rather discuss the remedies IP right holders, such as multinational life sciences, healthcare, and biotech companies, may have as their IP rights are exploited by foreign states. Under the Waiver Proposal, foreign states may choose not to protect or enforce an investor's IP rights for at least three years, even if an errant party deliberately encroaches upon these IP rights. Foreign states may even authorize and oversee these encroachments. Rogue developers and unethical companies may surface, to "*legally*" infringe on IP rights. Case-sensitive analyses depend, of course, on the applicable investment treaties and whether and, if so, how the Waiver Proposal materializes. We stand ready to monitor the ongoing development.

## What Was the Waiver Proposal About?

The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS Agreement") is a multilateral agreement that came into effect on January 1, 1995.[5] It binds all WTO members including the United States, China, Singapore, the United Kingdom, Hong Kong SAR, and India. Under the TRIPS Agreement, if a member grants any privilege, advantage, favor, or immunity to the nationals of a country, it must grant the same to the nationals of all members.[6] It may yet adopt measures necessary to prevent IP rights abuses or resort to practices that unreasonably restrain trade or adversely affect international technology transfer.[7]

On October 2, 2020, India and South Africa made the Waiver Proposal to waive the members' obligations under the TRIPS Agreement to protect and enforce copyrights, industrial and textile designs, patents, and undisclosed information, to prevent, contain, and treat COVID-19, subject to two exceptions with which this article does not concern.[8] On May 25, 2021, an amended Waiver Proposal was tabled.[9] In this version, the Waiver Proposal applies with the same goals, but specifically: (a) to health products and technologies, their materials and components, and their methods and means of manufacture; and (b) for three years subject to extension.

## What Are IP Rights Holders Left With?

Negotiations are still ongoing at the WTO. If the Waiver Proposal or any IP rights waiver under it is accepted, life sciences, healthcare, and biotech companies will understandably inquire about their deserving remedies, if a foreign state abuses these waivers or otherwise exploits their IP rights. Companies cannot commence legal proceedings under the TRIPS Agreement itself. Hence, we discuss below the viable options for companies to resort to the applicable bilateral investment treaties and free trade agreements, if any,[10] to mount a challenge against the foreign state(s). These options apply to IP rights holders from both WTO and non-WTO countries.

First, as a prerequisite, an IP rights holder has to show that s/he/it made an investment, and thus qualifies as an investor, in the foreign state. In most legal texts,[11] this means an asset that any individual or company owns or controls, directly or indirectly, that has the characteristics of an investment (including the commitment of capital or other resources, a duration to implement the investment, the expectation of gain or profit, and an assumption of investment risks).[12] Equity interests in an enterprise, as well as IP rights (from patents, technical processes, trade secrets, and undisclosed information, to know-how and goodwill),[13] can be an investment. Hence, pharmaceutical, biotech, and life sciences companies that have been: (a) registering trademarks in the foreign state and commercializing them there by manufacturing and advertising products that bear the marks;[14] (b) granting trademark licenses and obliging the licensees to exploit the trademarks in the foreign state;[15] (c) patenting or licensing inventions and engaging in commercial activities in the foreign state;[16] or (d) developing their business and trade secrets in the foreign state, may qualify as investors.

Second, the IP rights holder may then, as an investor, make good of certain treaty protections. Subject to the language of the applicable investment treaties and free trade agreements, an investor may invoke the following grounds:

- Minimum standard: The foreign state failed to accord investments or investors fair and equitable treatment, as it:
  - imposed unreasonable, discriminatory, or arbitrary measures that impair the management, maintenance, use, enjoyment, or disposal of the investments.[17] The foreign state generally cannot subdue investors' reasonable and legitimate expectations that guided their investment decisions.[18] A stable and predictable legal and regulatory environment was among such expectations.[19] Accordingly, measures that authorize an outright disregard of confidentiality and non-disclosure agreements or unqualified entry into private properties may be unlawful; or
  - denied investors or investments justice in civil or administrative proceedings in accordance with the principle of due process.[20] Arrangements that void dispute resolution agreements, lift investors' access to courts, or dispense with giving prior notice to investors before exploiting their investments,[21] likely fall afoul of due process.
- National treatment: The foreign state infringed the right to national and non-discriminatory treatment, as it accorded investors or investments less favorable treatment than the best treatment it accorded to its own investors or investments in like circumstances.[22] A definitive example is where a state imposes restrictions on foreign investors or investments without at least imposing the same on domestic ones.
- Expropriation: The foreign state directly expropriated investments, or indirectly subjected them to measures with effects of expropriation.[23] The former requires seizure of property rights. The latter is established where, although the investors retain control over the

investments, the economic benefits the investors reasonably expected from them dropped to an extent tantamount to a deprivation of property by virtue of a foreign state act.[24] Factors from the extent of interference with investors' expectations, to the nature, purpose, character, and impact of the act are relevant. Although direct expropriation is difficult to establish, the examples in this article, and others, like the unreasonable levy of taxes and the revocation of prior approvals, are prone to challenges on indirect expropriation grounds.

- Transfer: The foreign state failed to permit or guarantee to investors the free and timely transfer of profits, dividends, income, royalties, and payments associated with investments.[25] A temporary suspension of licensors' right to receive or claim royalties could amount to a deliberate breach in this regard.

- Performance requirements: The foreign state forced the investors to transfer a technology, a production process, or proprietary knowledge to others.[26] This may be done by compelling investors to disclose clinical data, diagnostic kits, therapeutics, and formulas or open up production lines.

Third, the investor may need to dispel certain qualifications. There may be general ones that apply to all investor claims or specific ones that apply to a specific claim. One general exception allows the foreign state to adopt or maintain measures required to protect human life or health.[27] Another does not outlaw them if they are not applied in an arbitrary or unjustified manner, or do not constitute a disguised restriction on trade or investment.[28] Some exceptions specific to expropriation claims are:

- Expropriation by a foreign state is not unlawful if it is for public purposes, in accordance with due process, on a non-discriminatory basis,[29] and against compensation amounting to the market value of the investments.

- Except in rare circumstances, a non-discriminatory state measure designed and applied to protect public health is not an indirect expropriation.[30]

While some exceptions give rise to powerful state defenses, and despite the wide policy discretion enjoyed by foreign states, public health measures still have to satisfy the principles of reasonableness and proportionality.[31] State measures need to connect with their stated objectives.[32] At least one arbitral tribunal found state measures to constitute disguised restrictions on trade.[33] The question is whether the foreign states could have protected the investments and safeguarded public health, and at the same time also formed part of the assessment.[34] Finally, experts and professionals will foreseeably continue to dispute the necessity of the foreign state's anti-IP measures in improving vaccine affordability and accessibility and in protecting human life or health.[35]

After establishing a claim, investors will understandably pursue effective, prompt, and adequate damages. It is observed that while compensation is relevant to expropriation claims, it generally will not affect an investor's right to initiate legal actions on minimum standard, national treatment, transfer, or performance requirement grounds. Another remark is, while compensation is a prerequisite to absolving the foreign state of expropriation, it is also the most common remedy available to the investors and their investments. Other remedies include restitution (e.g., returning seized property or restoring a situation), specific performance, and declaratory and injunctive relief.[36]

## Conclusion

This article gives IP rights holders an overview of ideas, relevant where a foreign state decides to adopt or maintain measures that are at odds with its international law obligation to effectively defend IP rights. While we refrain from engaging in factual discussions and touching upon how states may

challenge one another at the WTO on the validity of the Waiver Proposal, we point to specific treaty provisions and seminal cases and come up with possible formulations of the Waiver Proposal, to entertain the issues IP rights holders may have already faced. With these, we continue to track, as the world now eyes, any recommendation by the Council for TRIPS, any decision by the WTO General Council, and any anti-IP state action.

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1 *Waiver from certain provisions of the TRIPS Agreement for the prevention, containment, and treatment of COVID-19*, IP/C/W/669 (October 2, 2020), Council for Trade-Related Aspects of Intellectual Property Rights of the World Trade Organization.

2 *Waiver from certain provisions of the TRIPS Agreement for the prevention, containment, and treatment of COVID-19*, IP/C/W/677 (May 18, 2021), Council for Trade-Related Aspects of Intellectual Property Rights of the World Trade Organization.

3 *Waiver from certain provisions of the TRIPS Agreement for the prevention, containment, and treatment of COVID-19*, IP/C/W/669/Rev.1 (May 25, 2021) Council for Trade-Related Aspects of Intellectual Property Rights of the World Trade Organization.

4 Blenkinsop, Philip, *What Does Waiving Intellectual Property Rights for COVID-19 Vaccines Mean?* (May 2021), World Economic Forum; Available at: www.weforum.org/agenda/2021/05/could-the-world-be-about-to-waive-covid-19-vaccines/; and Lee, Tom, et al., *Intellectual Property, COVID-19 Vaccines, and the Proposed TRIPS Waiver* (May 2021), AAF, Available at: www.americanactionforum.org/insight/intellectual-property-covid-19-vaccines-and-the-proposed-trips-waiver/.

5 The TRIPS Agreement is in annex 1C to the Marrakesh Agreement Establishing the World Trade Organization dated April 15, 1994.

6 Article 4 of the TRIPS Agreement.

7 Article 8.2 of the TRIPS Agreement.

8 See, footnote 1. See also, sections 1, 4, 5, and 7 of Part II of the TRIPS Agreement and Part III of it.

9 See, footnote 3.

10 It is noteworthy that India, one of the two countries which advanced the Waiver Proposal, has terminated its bilateral investment treaties with almost 60 countries, including China, in 2017.

11 The Investment Agreement ("PRC-HK Investment Agreement") as part of the Mainland and Hong Kong Closer Economic Partner Arrangement (in force since January 2018) has an Annex 2 that explores who and what entities qualify as an investor. Not many legal texts contain this much detail.

12 See, e.g., article 2(1) of the PRC-HK Investment Agreement, and article 1 of the Investment Agreement between the Government of Australia and the Government of the Hong Kong Special Administrative Region of the People's Republic of China (in force since January 2020) ("**Australia-HK Investment Agreement**"); *Salini Construttori S.p.A. and Italstrade S.p.A. v. Kingdom of Morocco*, ICSID Case No. ARB/00/4 (2001) (concerning the Italy-Morocco BIT in force



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since April 2000); and Sabahi, Borzu, and Rubins, Noah, et al., *Investor-State Arbitration* (2nd Edition, 2019), Oxford University Press, pp.351-357.

[13] See, e.g., article 2(1)(vi) of the PRC-HK Investment Agreement, article 1(d) of the Agreement Between the Government of the People's Republic of China and the Government of the Republic of South Africa concerning the Reciprocal Promotion and Protection of Investment (in force since April 1998) ("**PRC-South Africa BIT**"), article 1(a)(iv) of the Agreement between the Government of the United Kingdom of Great Britain and Northern Ireland and the Government of the People's Republic of China concerning the Promotion and Reciprocal Protection of Investments (in force since May 1986) ("**UK-PRC BIT**"), article 1 of the Australia-HK Investment Agreement, and article 1.3 of the Free Trade Agreement Between Hong Kong, China and Australia ("**Australia-HK FTA**").

[14] Decision on Expedited Objections in *Bridgestone Licensing Services, Inc. and Bridgestone Americas, Inc. v. Republic of Panama*, ICSID Case No. ARB/16/34 ([2017]) (concerning the United States-Panama Trade Promotion Agreement in force since October 2012) at [172]-[174].

[15] Decision on Expedited Objections in the *Bridgestone* case at [195]-[198].

[16] *Eli Lilly and Company v. The Government of Canada,* ICSID Case No. UNCT/14/2 (concerning the North American Free Trade Agreement in force since January 1994 ("**NAFTA**")).

[17] See, e.g., article 3(1) of the PRC-South Africa BIT, article 2(2) of the UK-PRC BIT, article 8(1) of the Australia-HK Investment Agreement, articles 4(1) and 4(2) of the PRC-HK Investment Agreement; and Partial Award in S.D. Myers, Inc. v. Government of Canada 2004 FC 38, (2004) 244 FTR 161, IIC 252 (2004) (concerning NAFTA) at [263] (under article 1105 of NAFTA, the test is whether "an investor has been treated in such an unjust or arbitrary manner that the treatment rises to the level that is unacceptable from the international perspective").

[18] Potestàe, Michele, *Legitimate expectations in investment treaty law: Understanding the roots and the limits of a controversial concept*, 28 ICSID Review (2013) at p.30, et seq.; and *Tencnicas Medioambientales Tecmed S.A. v. The United Mexican States*, ICSID Case No. ARB (AF)/00/2 (2003) (concerning the Mexico-Spain BIT in force since April 2008) at [154].

[19] Award in *CMS Gas Transmission Company v. The Republic of Argentina*, ICSID Case No. ARB/01/8 (concerning the Argentina-United States BIT in force since October 1994) at [274]-[275] (the preamble of the treaty makes clear that a fair and equitable treatment is necessary to maintain a stable framework for investments).

[20] See, e.g., articles 8(1) and 8(2) of the Australia-HK Investment Agreement and articles 4(1) and 4(2) of the PRC-HK Investor Agreement.

[21] Award in *Waguih George Siag and Clorinda Vecchi v. The Arab Republic of Egypt*, ICSID Case No. ARB/05/15 (2009) (concerning the Egypt-Italy BIT in force since May 1994) at [442].

[22] See, e.g., article 3(2) of the PRC-South Africa BIT, articles 3(2) and 3(3) of the UK-PRC BIT, articles 4(1) and 4(2) of the Australia-HK Investment Agreement, articles 5(1) and 5(2) of the PRC-HK Investment Agreement, Award in *Marvin Roy Feldman Karpa v. United Mexican States*, ICSID Case No. ARB(AF)/99/1 (2002) (concerning NAFTA) at [166], [181], and [184]; Partial Award in the *S.D. Myers* case; and Award on the Merits of Phase 2 in *Pope & Talbot Inc. v. The Government of Canada*, IIC 192 (2000) (concerning NAFTA) at [42].

[23] See, e.g., article 4 of the PRC-South Africa BIT, article 5(1) of the UK-PRC BIT, article 10(1) of the Australia-HK Investment Agreement, and article 11(1) of the PRC-HK Investment Agreement; *Crawford, James, Brownlie's Principles of Public International Law* (2019), Oxford University Press (2019) at p.603; and Reinisch, August, *Expropriation*, The Oxford Handbook of International Investment Law (2008), Oxford University Press, p.422.

[24] Award in *Metalclad Corporation v. The United Mexican States*, ICSID Case No. ARB(AF)/97/1 (2000) (concerning NAFTA) at [103] ("*expropriation under NAFTA includes not only open, deliberate and acknowledged takings of property, such as outright seizure or formal or obligatory transfer of title in favour of the host State, but also covert or incidental interference with the use of property which has the effect of depriving the owner, in whole or in significant part, of the use or reasonably-to-be-expected economic benefit of property even if not necessarily to the obvious benefit of the host State*"); Award in *Charanne and Construction Investments v. Spain*, SCC Case No. V062/2012 (2016) (concerning the Energy Charter Treaty in force since April 1998) at [464] ("*in order for a loss of value to be tantamount to expropriation, it has to be of such a magnitude as to amount to a deprivation of property*"); *Suez, Sociedad General de Aguas de Barcelona S.A. and Vivendi Universal S.A. v. The Argentine Republic*, ICSID Case No. ARB/03/19 (2010) (concerning the Argentina-France BIT in force since March 1993 and the Argentina-Spain BIT in force since September 1992) at [156]-[159].

[25] See, e.g., article 6 of the PRC-South Africa BIT, article 6(1) of the UK-PRC BIT, article 11(1) of the Australia-HK Investment Agreement, and article 14(1) of the PRC-HK Investment Agreement.

[26] See, e.g., article 7(1)(vi) of the PRC-HK Investment Agreement.

[27] Article 18 of the Australia-HK Investment Agreement.

[28] Article 22 of the PRC-HK Investment Agreement.

[29] It is noted that differential treatment is not in itself unlawful, but differential treatment without reasonable justification is: Award in *Crystallex International Corporation v. Bolivarian Republic of Venezuela*, ICSID Case No. ARB(AF)/11/2 (2016) (concerning the Canada-Venezuela, Bolivarian Republic of BIT in force since January 1998) at [616] and [715],

citing *Partial Award in Saluka Investments BV (The Netherlands) v. The Czech Republic*, ICGJ 368 (PCA 2006) (2006) (concerning the Czech Republic-Netherlands BIT in force since October 1992) at [313].

[30] See, e.g., Annex 3 to the PRC-HK Investment Agreement and paragraph 3 of Annex 8-A to the Comprehensive Economic and Trade Agreement Between Canada and the European Union (provisional application began in September 2017).

[31] Ortino, Federico, *Investment Treaties, Sustainable Development and Reasonableness Review, A case Against Strict Proportionality Balancing* (2017), Leiden Journal of International Law, Volume 30, Issue 1, pp.71-91.

[32] *Glamis Gold, Ltd. v. The United States of America*, IIC 380 (2009) (concerning NAFTA); and *AES Summit Generation Limited and AES-Tisza Eromu Kft v. The Republic of Hungary*, ICSID Case No. ARB/07/22 (concerning the Energy Charter Treaty in force since April 1998).

[33] *Tencnicas* case.

[34] *Suez* case.

[35] See, e.g., Thambisetty, Siva, and McMahon, Aisling, and McDonagh, Luke, and Kang, Hyo Yoon, and Dutfield, Graham, *The TRIPS Intellectual Property Waiver Proposal: Creating the Right Incentives in Patent Law and Politics to end the COVID-19 Pandemic* (May 24, 2021), LSE Legal Studies Working Paper No.06/2021; Rutschman, Ana, *The Covid-19 Vaccine Race: Intellectual Property, Collaboration(s), Nationalism and Misinformation* (2021), 64 Wash. U. J. L. & Pol'y 167; Correa, Carlos, *Expanding the Production of COVID-19 Vaccines and Reach Developing Countries: Lift the Barriers to Fight the Pandemic in the Global South* (April 2021), South Centre; Bacchus, James, *An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines* (December 16, 2020), Cato Institute, Free Trade Bulletin No.78 (2020).

[36] See, e.g., *Texaco Overseas Petroleum Company v. Libya*, 1978 ILM 1 (concerning fourteen deeds of concession concluded between Libya and two American companies); *ATA Construction, Industrial and Trading Company v. The Hashemite Kingdom of Jordan*, ICSID Case No. ARB/08/2 (concerning the Jordan-Turkey BIT in force since January 2006); Sabahi, Borzu, and Rubins, Noah, et al., *Investor-State Arbitration* (2nd Edition, 2019), Oxford University Press, p.708.