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Xiang Li[1]

ABSTRACT

The Biden Administration announced its support for the initiative at the World Trade Organization (WTO) to suspend patent rights protections for COVID-19 vaccines, in the hope of providing equitable and affordable access to the vaccines to low-income countries. Since then, domestic pharmaceutical companies have been voicing vociferous opposition, claiming that "[e]liminating IP protections undermines our global response to the pandemic and compromises safety."[2] Passing a patent waiver at the WTO means eligible member countries can opt to free themselves from the obligations to enforce qualifying patents, and anyone within those countries can accordingly practice the patents without infringement liability. It follows that the adoption of the waiver would impair American patentees' rights in those eligible countries.

Americans, however, are protected by the Constitution of the United States, and the Takings Clause of the Fifth Amendment guards private property against unlawful seizure by the United States government. This Article examines the role the Takings Clause plays in prescribing United States actions committed to adopting and implementing a patent waiver, and concludes that the Takings Clause does not prevent the United States from supporting passage of the waiver at the WTO, but would prevent its domestic implementation if the United States were made an eligible country to invoke the waiver. The conclusion is consistent with the final waiver adopted by the WTO, where the United States is not an eligible country.

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[1] J.D. Candidate 2023, University of Washington School of Law; B.Sc., University of Toronto; M.Sc., Imperial College London. Thank you, Dr. Ewa Davison, Affiliate Instructor of Law at University of Washington School of Law, for providing invaluable comments and insights that guided me through the research and writing process.

[2] Brian Schwartz, *Big Pharma lobbyists launch campaign against Biden over Covid vaccine patent waiver*, CNBC (Jun. 1 2021), https://www.cnbc.com/2021/06/01/big-pharma-launches-campaign-against-biden-over-covid-vaccine-patent-waiver.html; *see also Jonathan Gardner & Ned Pagliarulo, Pharma erupts as Biden administration backs waiver of vaccine patent rights, BiopharmaDive (May 6, 2021),* https://www.biopharmadive.com/news/biden-vaccine-patent-waiver-pharma-opposition/599704/.

INTRODUCTION

It has been three years since the World Health Organization (WHO) declared the worldwide COVID-19 pandemic on March 11, 2020.[3] Through the concerted efforts of healthcare systems, vaccine manufacturers, governments, and members of the public, we may finally have the upper hand in the battle against that disease.[4] Inequality in vaccination rates between low-income countries and the rest of the world, however, remained strikingly substantial even 28 months after the first vaccine was made available to the public.[5] As of April 9, 2023, 79.9% of the population of high-income countries have received at least one dose of the COVID-19 vaccine, so have 83.4% of the population of upper-middle-income countries, and 65.6% of the population of lower-middle-income countries.[6] On the other end of the spectrum, only 29.3% of the population of low-income countries have received at least one dose of the vaccine.[7] The inequality was even more concerning during the height of the pandemic: while the one-dose vaccination rates plateaued around 78% and 80% by the end of March in 2022 for high-income and upper-middle-income countries, respectively, the same parameter in low-income countries was a disturbing 13.5%.[8] The disparity is largely caused by the unaffordability of vaccines to people in low-income countries.[9]

To address this problem, India and South Africa proposed to the World Trade Organization (WTO) that certain obligations of enforcing intellectual property protection, imposed by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS),[10] be waived for technologies related to COVID-19 vaccines.[11] The Biden administration announced its support for the proposal seven months later,[12] and it took a total of twenty months for the WTO members to finally agree on a binding patent waiver in June 2022.[13]

This Article will discuss how the Takings Clause confines the actions of the United States in supporting and implementing a patent waiver, and conclude that the Takings Clause does not prevent the United States from supporting passage of the waiver at the WTO, but would prevent

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[3] WHO Director-General's Opening Remarks, Media Briefing on COVID-19, March 11, 2020, https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020.

[4] Kathryn Watson, *Biden signs bill ending COVID-19 national emergency*, CBS News (April 10, 2023), https://www.cbsnews.com/news/biden-signs-bill-ending-covid-19-national-emergency/.

[5] *Covid-19: First vaccine given in US as roll-out begins*, BBC News (December 14, 2020), https://www.bbc.com/news/world-us-canada-55305720; *Share of people who received at least one dose of COVID-19 vaccine* (April 9, 2023), Our World in Data, https://ourworldindata.org/grapher/share-people-vaccinated-covid?country=High+income~Upper+middle+income~Lower+middle+income~Low+income.

[6] *Id*.

[7] *Id*.

[8] *Id*.

[9] *COVID vaccines: Widening inequality and millions vulnerable*, UN News (Sep. 19, 2021), https://news.un.org/en/story/2021/09/1100192.

[10] Agreement on Trade-Related Aspects of Intellectual Property Rights, April 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 (hereinafter "TRIPS Agreement").

[11] Waiver from Certain Provisions of the TRIPS Agreement for Prevention, Treatment and Containment of COVID-19, Communication from India and South Africa, WTO Doc. IP/C/W/669 (Oct. 2, 2020), pg. 3, https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True.

[12] Statement from Ambassador Katherine Tai on the Covid-19 TRIPS Waiver, Office of the U.S. Trade Representative (May 5, 2021), https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver.

[13] Ministerial Conference Twelfth Session, MINISTERIAL DECISION ON THE TRIPS AGREEMENT ADOPTED ON 17 JUNE 2022, https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/30.pdf&Open=True.

its domestic implementation if the United States were made an eligible country to invoke the waiver. Sections I-III of this Article summarize relevant background and applicable law. Specifically, Section I discusses the legal mechanism for waiving obligations imposed by the TRIPS Agreement, as well as developments in the waiver negotiations among the WTO members. Section II discusses the elements of the Takings Clause, and Section III summarizes its application in the patent context. Sections IV and V apply the Takings Clause to the actions of the United States here. Such actions are divided into two groups and analyzed separately: Section IV analyzes actions taken at the international level to urge passage of the waiver at the WTO; Section V analyzes domestic actions to implement a waiver, assuming that the United States is given the right by the WTO to do so.

BACKGROUND

I. WTO PASSED A TRIPS WAIVER DESPITE NATIONAL DIVERGENCE OBSERVED IN THE PROLONGED NEGOTIATION PERIOD

A. The TRIPS Agreement Establishes Minimum Protections for Intellectual Properties that WTO Members Must Provide

Becoming a WTO member means agreeing to and abiding by a line of international agreements that govern international trade, including the TRIPS Agreement.[14] The TRIPS Agreement prescribes the minimum level of protection for intellectual properties that each WTO member must provide.[15] Whether or not the member country decides to go beyond the minimum, the protection it accords to the "nationals of other [WTO] [m]embers" must be "no less favourable than that it accords to its own nationals."[16]

Part II of the TRIPS Agreement sets forth the standards for different protectable types of intellectual properties, as well as the rights that come with each type.[17] These protectable categories include copyright, trademarks, patents, industrial designs, layout designs of integrated circuits, and undisclosed information.[18] Part III of the TRIPS Agreement delineates the requirements for enforcing the rights recognized in Part II and remedies for infringement.[19] The enforcement requirements make a distinction between infringing activities in general, and those that are egregious, such as "wilful trademark counterfeiting or copyright piracy on a commercial scale."[20] While civil proceedings suffice for most infringing activities, an additional layer of protection, criminal proceedings and severer punishments, must be made available for blatant infringement.[21]

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[14] Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, 1867 U.N.T.S. 154 (hereinafter "Marrakesh Agreement"), Article II.2 (stating that "[t]he agreements and associated legal instruments included in Annexes 1, 2 and 3 . . . are integral parts of this Agreement, binding on all Members," while Annex 1C is the TRIPS Agreement).
[15] TRIPS Agreement, Part I, Article 1.1.
[16] *Id*. at Part I, Article 3.1.
[17] *Id*. at Part I, Article 1.2, and Part II Sections 1-7.
[18] *Id*.
[19] *Id*. at Part III.
[20] *Id*. at Part III, Sections 2 and 5.
[21] *Id*.

B. The WTO May Waive a TRIPS Obligation

Although the TRIPS Agreement binds every WTO member and imposes obligations on each member to protect intellectual properties irrespective of the owners' nationalities, the WTO has separately established a mechanism to waive such obligations.[22]

Specifically, Article IX.3 of the Marrakesh Agreement provides that "[i]n exceptional circumstances, the Ministerial Conference may decide to waive an obligation imposed on a Member by this Agreement or any of the Multilateral Trade Agreements, provided that any such decision shall be taken by three fourths of the Members . . . ."[23] "Multilateral Trade Agreements" includes the TRIPS Agreement.[24] Accordingly, the Ministerial Conference, a decision-making body of the WTO composed of representatives of all WTO members,[25] may waive a TRIPS obligation, if three-fourths of the WTO members are on board with the wavier.[26] Currently, there are 164 WTO members.[27] Any waiver passage, therefore, requires approval from at least 123 members.

Notwithstanding that Article IX.3 provides a voting path for a waiver decision, every decision-making process at the WTO shall always set out to arrive at a consensus.[28] Only "where a decision cannot be arrived at by consensus, the matter at issue shall be decided by voting."[29] For waiver decision-making, the Ministerial Conference shall establish a time period not exceeding 90 days for reaching a consensus, before moving on to decide the matter by voting.[30]

In practice, however, consensus-based decision-making predominates the way issues are resolved at the WTO, and very few decisions passed at the WTO are passed by voting.[31] This is because WTO members value the right to veto an unfavorable decision, and "have zealously protected the consensus rule."[32] This de facto norm of decision-making by consensus makes it less straightforward to pass a TRIPS waiver by a three-fourths majority than it would seem from reading the provisions in the Marrakesh Agreement.

In 2003, a TRIPS waiver was adopted by consensus to allow members to issue compulsory licenses for producing certain drugs for exporting to qualifying countries.[33] Absent this waiver, compulsory licensing can only be used to satisfy the domestic market.[34]

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[22] Marrakesh Agreement, Article IX.3.
[23] *Id*.
[24] *Id. at* Article II.2, and List of Annexes.
[25] *Id. at* Article IV.1.
[26] *Id. at* Article IX.3.
[27] UNDERSTANDING THE WTO: THE ORGANIZATION, Members and Observers, https://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm.
[28] Marrakesh Agreement, Article IX.1.
[29] *Id*.
[30] *Id*. at Article IX.3(a).
[31] Craig VanGrasstek, *The History and Future of the World Trade Organization*, 212-13 (2013).
[32] Joost Pauwelyn, *The Transformation of World Trade*, 104 Mich. L. Rev. 1, 26-27 (2005).
[33] Isabel Feichtner, *The Waiver Power of the WTO: Opening the WTO for Political Debate on the Reconciliation of Competing Interests*, 20 Eur. J. Int. Law 3, 615, 627-28 (2009); Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health, WT/L/540 and Corr.1 (Sept. 1, 2003), https://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm.
[34] TRIPS Agreement, Part II, Section 5, Article 31(f).

C. WTO Passed a Patent Waiver for COVID-19 Vaccines Overcoming Divergent National Interests.

A limited TRIPS waiver concerning patented ingredients and processes for making COVID-19 vaccines was passed at the WTO in June 2022.[35] This is the second TRIPS waiver passed in history and was achieved after many rounds of negotiation spanning a total of twenty months.[36]

On October 2, 2020, India and South Africa submitted a communication to the Council for TRIPS,[37] proposing under Article IX.3 of the Marrakesh Agreement that obligations of TRIPS members to enforce intellectual property rights "in relation to prevention, containment, or treatment of COVID-19" shall be waived.[38] It is believed that patents are hindering the "research, development, manufacturing and supply of medical products essential to combat COVID-19," and patent protections shall therefore be temporarily suspended to enable "global sharing of technology and knowhow" and to timely supply adequate and affordable vaccines throughout the world.[39] The proposal was clearly opposed by the United States at the TRIPS Council meeting right following its submission, where the United States representative stated that "[t]he United States does not support the waiver proposal of India and South Africa," because "IP has not been an obstacle in addressing the pandemic but rather has motivated global efforts to find treatments and cures."[40]

Surprisingly, seven months later, on May 5, 2021, the Biden Administration announced its support for the waiver proposal, declaring that the United States will "actively participate in text-based negotiations at the WTO needed to make that happen."[41]

A revised version of the waiver proposal was submitted on May 21, 2021, with 62 WTO members including South Africa and India as co-sponsors, almost all of them low and low-middle-income countries.[42] At the TRIPS Council meeting held several weeks later, China, Canada, Japan,

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[35] Ministerial Conference Twelfth Session, MINISTERIAL DECISION ON THE TRIPS AGREEMENT ADOPTED ON 17 JUNE 2022.

[36] *See supra* note 33.

[37] The Council for TRIPS (hereinafter "TRIPS Council") is the body that "shall monitor the operation of [the TRIPS] Agreement and, in particular, Members' compliance with their obligations . . . ." TRIPS Agreement, Article 68.

[38] Waiver from Certain Provisions of the TRIPS Agreement for Prevention, Treatment and Containment of COVID-19, Communication from India and South Africa, WTO Doc. IP/C/W/669 (Oct. 2, 2020), pg. 3 ("[t]he obligations of Members to implement or apply Sections 1, 4, 5 and 7 of Part II of the TRIPS Agreement or to enforce these Sections under Part III of the TRIPS Agreement, shall be waived in relation to prevention, containment or treatment of COVID-19"). Sections 1, 4, 5 and 7 of Part II of the TRIPS Agreement delineate the "[s]tandards concerning the availability, scope and use" of copyright, industrial designs, patents, and protection of undisclosed information, respectively; Part III of the TRIPS agreement specifies the enforcement proceedings to protect these intellectual property rights. *See supra* notes 17-21.

[39] *Id*. at pgs. 1-2.

[40] Council for Trade-Related Aspects of Intellectual Property Rights, Minutes of Meeting, Held in the Centre William Rappard on 15-16 October and 10 December 2020, WTO Doc. IP/C/M/96/Add.1, pgs. 111-12 (Feb. 16, 2021), https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/M96A1.pdf&Open=True.

[41] Statement from Ambassador Katherine Tai on the Covid-19 TRIPS Waiver, Office of the U.S. Trade Representative (May 5, 2021).

[42] Council for Trade-Related Aspects of Intellectual Property Rights, Waiver from Certain Provisions of the TRIPS Agreement for Prevention, Treatment and Containment of COVID-19, Revised Decision Text, Communication from the African Group, the Plurinational State of Bolivia, Egypt, Eswatini, Fiji, India, Indonesia, Kenya, the LDC Group, Maldives, Mozambique, Mongolia, Namibia, Pakistan, South Africa, Vanuatu, the Bolivarian Republic of Venezuela and Zimbabwe, WTO Doc. IP/C/W/669/Rev.1 (May 21, 2021), https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669R1.pdf&Open=True.

New Zealand, Russia, and the United States, among other nations, expressed their support for the patent waiver and their willingness to move forward to a text-based terms negotiation.[43] On the other hand, the United Kingdom and Switzerland stood against the waiver proposal, stating that a patent waiver not only cannot solve inequitable vaccination, but also will deter innovation and significantly harm the pharmaceutical industry.[44] The European Union did not air any opinion on the revised waiver proposal, but instead urged members to consider its earlier proposal of compulsory licensing to address vaccine supply shortages.[45]

A follow-up TRIPS Council meeting discussing the waiver was held in July 2021.[46] The European Union aired strong opposition to an intellectual property waiver, characterizing it as a "false path" that "not only [] will not increase production of vaccines and medicines as it will not address any of the existing bottlenecks, but also it will have counter-productive effects on our common efforts to enhance access to COVID-19 vaccines and medicines."[47] Switzerland took a similar stance that the proposed TRIPS waiver would "have a counterproductive impact on our achieving, as soon as possible, the goal of broad and equitable access to COVID-19 vaccines."[48]

Nonetheless, in a turn of events not known to the public, the European countries changed course the following spring. Several news outlets reported in mid-March 2022 that the European Union, the United States, India, and South Africa (the "Quad") had reached a tentative agreement on the key terms of the waiver.[49] In May 2022, the WTO director-general submitted to the WTO the draft terms reached by the Quad (the "Quad text").[50] The Quad negotiation brought the most vehement opposers, the Europeans, on board and turned out to be determinative of the final deal.[51]

The Quad text concerns only patent waivers and is much limited in scope compared to the initial South Africa-India proposal.[52] The Quad text provides that an "eligible Member" may authorize "the use of patented subject matter required for the production and supply of COVID-19 vaccines without the consent of the right holder to the extent necessary to address the COVID-19 pandemic," the "patented subject matter" being defined as "ingredients and processes necessary

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[43] Council for Trade-Related Aspects of Intellectual Property Rights, *Minutes of Meeting*, Held in the Centre William Rappard on 8, 9 and 29 June 2021, WTO Doc. IP/C/M/100/Add.1, pgs. 49-59 (Oct. 20, 2021), https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/M100A1.pdf&Open=True.
[44] *Id*. at pgs. 53-56.
[45] *Id*. at pg. 62.
[46] Council for Trade-Related Aspects of Intellectual Property Rights, Minutes of Meeting, Held in the Centre William Rappard on 20 July 2021, WTO Doc. IP/C/M/101/Add.1 (Jan. 19, 2022), https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/M101A1.pdf&Open=True.
[47] *Id*. at pg. 9.
[48] *Id.* at pg. 21.
[49] Andrea Shalal and Emma Farge, *U.S., EU, India, S. Africa reach compromise on COVID vaccine IP waiver text*, Reuters (March 16, 2022), https://www.reuters.com/business/healthcare-pharmaceuticals/us-eu-india-s-africa-reach-tentative-pact-covid-vaccine-ip-waiver-sources-2022-03-15/; *see also* Ed Silverman, *A compromise is reached on an intellectual property waiver for Covid-19 vaccines, but does it go far enough?* STAT Pharmalot Newsletter (March 15, 2022), https://www.statnews.com/pharmalot/2022/03/15/covid19-vaccine-patents-wto/.
[50] Eileen Mcdermott, *Draft COVID Patent Waiver Text Officially Sent to WTO Membership*, IPWatchdog (May 4, 2022), https://www.ipwatchdog.com/2022/05/04/draft-covid-patent-waiver-text-officially-sent-wto-membership/id=148854/; Council for Trade-Related Aspects of Intellectual Property Rights, Communication from the Chairperson, WTO Doc. IP/C/W/688 (May 3, 2022), https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W688.pdf&Open=True.
[51] *See infra* note 61.
[52] *See supra* note 38 and accompanying text.

for the manufacture of the COVID-19 vaccine."[53] The Quad proposed two alternative definitions for "eligible Members."[54] One is to include "all developing country Members," but encourage those "with capacity to export vaccines [] to opt out" the right.[55] The other option is to include all developing countries except those "who exported more than 10 percent world exports of COVID-19 vaccine doses in 2021."[56]

A General Council meeting was conducted right following the submission of the Quad text.[57] China announced at the meeting that should the first option of defining eligible members in the Quad text is adopted, it will not avail itself of the waiver right.[58] China and several other members rejected the second option.[59]

The Ministerial Conference issued a final decision on June 17, 2022 to adopt a patent waiver.[60] The final waiver substantially tracks the Quad text in confining the patented subject matter covered by the waiver to ingredients and processes necessary for making the COVID-19 vaccines.[61] In addition, the decision adopts the first option in the Quad text to define "eligible Members" as "all developing country Members" while encouraging those with existing capacity to manufacture COVID-19 vaccines to make a binding commitment not to avail themselves of the waiver.[62] Binding commitments include those previously made at the General Council meeting on May 10, 2022.[63] The decision also sets a five-year term of the waiver.[64]

Moreover, the decision provides that "[n]o later than six months from the date of this Decision, Members will decide on its extension to cover the production and supply of COVID-19 diagnostics and therapeutics."[65] Although the deadline has already passed, a stand-off on the issue persists at the WTO, and the United States backed postponing the decision.[66]

II. THE TAKINGS CLAUSE PREVENTS THE UNITED STATES GOVERNMENT FROM TAKING PRIVATE PROPERTIES WITHOUT PAYING JUST COMPENSATION

The Takings Clause, found in the Fifth Amendment of the United States Constitution, expressly prohibits the government from taking private property for public use without paying just

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[53] Council for Trade-Related Aspects of Intellectual Property Rights, Communication from the Chairperson, WTO Doc. IP/C/W/688. at pg. 3, Article 1 and footnote 2.
[54] *Id*. at pg. 3, Article 1 and footnote 1.
[55] *Id*.
[56] *Id*.
[57] Members welcome Quad document as basis for text-based negotiations on pandemic IP response, WTO News (May 10, 2022), https://www.wto.org/english/news_e/news22_e/gc_10may22_e.htm#:~:text=At%20a%20General%20Council%20meeting,property%20response%20to%20COVID%2D19.
[58] *Id*.
[59] *Id*.
[60] Ministerial Conference Twelfth Session, MINISTERIAL DECISION ON THE TRIPS AGREEMENT ADOPTED ON 17 JUNE 2022.
[61] *Id*. at Article 1 and footnote 1; *supra* note 53 and accompanying text.
[62] Ministerial Conference Twelfth Session, MINISTERIAL DECISION ON THE TRIPS AGREEMENT ADOPTED ON 17 JUNE 2022 at pg. 1, footnote 1.
[63] *Id*.
[64] *Id*. at Article 6.
[65] *Id*. at Article 8.
[66] *U.S. backs delay to decision on COVID patent waiver extension*, Reuters (Dec. 7, 2022), https://www.reuters.com/markets/us-backs-delaying-wto-decision-covid-therapies-tests-2022-12-06/.

compensation.[67] Implied in the Takings Clause is that the government may not take private property for private use under any circumstance, regardless of how much money it might be willing to pay.[68] Accordingly, analysis of a Takings Clause claim involves two main inquiries. The first is whether the government's action constitutes an unconstitutional taking within the meaning of the Takings Clause.[69] If the answer is in the affirmative, then the next inquiry is whether the taking is for public or private benefit. If the taking is for public benefit, then the government can proceed with the taking by paying just compensation, but if the taking is for private benefit, the government can do nothing but stop its action to not violate the Constitution.[70]

As to the first inquiry, the government will effect a taking regulated by the Fifth Amendment when: (1) the property or right affected constitutes "private property";[71] (2) the government contributes sufficiently directly and substantially in affecting the private property;[72] and (3) the governmental action crosses the line from being regulatory to an unlawful "taking."[73] If any one of these requirements is not met, there is no governmental taking within the meaning of the Takings Clause, and the government can lawfully proceed with its action without paying anything.[74]

A. The Takings Clause Protects Private Property.

What constitutes "private property" is nowhere to be found in the Constitution.[75] Rather, courts shall consult other sources of law that create private property rights.[76] Private property cognizable by other laws and therefore protected by the Takings Clause includes real property, tangible property, and intangible property.[77] The Supreme Court of the United States has

[67] U.S.C.A. Const. amend. V.
[68] Kelo v. City of London, 545 U.S. 469, 476-77 (2005).
[69] Arkansas Game & Fish Comm'n v. United States, 568 U.S. 23, 30-34 (2012).
[70] Kelo, 545 U.S. at 476-77.
[71] Ruckelshaus v. Monsanto Co., 467 U.S. 986, 1000 (1984) (in analyzing a taking clause claim, courts need to decide whether there is a property interest protected by the Fifth Amendment Taking clause).
[72] Erosion Victims of Lake Superior Regul.v. United States, 833 F.2d 297, 299 (Fed. Cir. 1987) (quoting Langenegger v. United States, 756 F.2d 1565, 1571 (Fed. Cir. 1985)).
[73] Penn Cent. Transp. Co. v. City of New York, 438 U.S. 104, 123-24 (1978).
[74] *Supra* notes 71-73.
[75] Ruckelshaus, 467 U.S. at 1001 (citing Webb's Fabulous Pharmacies, Inc. v. Beckwith, 449 U.S. 155, 161 (1980)) ("Property interests . . . are not created by the Constitution. Rather, they are created and their dimensions are defined by existing rules or understandings that stem from an independent source such as state law.").
[76] *Id*.
[77] Conti v. United States, 291 F.3d 1334, 1338–39 (Fed. Cir. 2002) (citing Lucas v. S.C. Coastal Council, 505 U.S. 1003, 1019 (1992), Ruckelshaus v. Monsanto Co., 467 U.S. 986, 1003–04 (1984), and Andrus v. Allard, 444 U.S. 51, 65 (1979)) ("Real property, tangible property, and intangible property, all may be the subject of takings claims").

recognized liens,[78] contracts,[79] going-concern value and goodwill,[80] trade secrets,[81] and patents[82] as intangible private properties guarded by the Takings Clause. Patents as private property will be further discussed in Section IIIA.

Protection by the Takings Clause is not confined to private property located within the United States. "It is settled law that the United States is bound by our Constitution when it takes actions that affect citizens outside our territory"; "therefore the government must provide just compensation for takings by its forces which occur abroad, when not acts of war."[83] Courts have applied the Takings Clause to real and personal properties located abroad.[84]

B. United States Can Be Held Liable for Takings Even Though It Did Not Directly Perpetrate the Action

In many takings claims, the United States government did not perpetrate the final taking action or had final authority in making the taking decision.[85] Nevertheless, the United States will still be liable if its involvement in the decision-making is "sufficiently direct and substantial."[86] When the final decision maker or perpetrator is a foreign sovereign or an international organization, courts consider two factors in determining what constitutes sufficient involvement of the United States.[87] The first one is "the nature of the United States' activity," and the second is "the level of benefit the United States has derived."[88]

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[78] Armstrong v. United States, 364 U.S. 40, 45-46 (1960) (holding that materialmen's liens on uncompleted hulls and buildings are private properties within the meaning of the Takings Clause); Louisville Joint Stock Land Bank v. Radford, 295 U.S. 555, 596–602 (1935) (bank's liens on real estates protected).

[79] Lynch v. United States, 292 U.S. 571, 579 (1934) (rights arising from a valid contract protected).

[80] Kimball Laundry Co. v. United States, 338 U.S. 1, 11(1949). *Kimball* describes "going-concern value" as intangible properties resulting from the inertia of human behaviors: customers will continue patronizing a business in the future because of their habits formed in the past. "Goodwill" consists of "[a] business's reputation, patronage, and other intangible assets that are considered when appraising the business." Black's Law Dictionary 715 (8th ed. 2004).

[81] Ruckelshaus, 467 U.S. at 1003-04 (1984) ("to the extent that Monsanto has an interest in its health, safety, and environmental data cognizable as a trade-secret property right under Missouri law, that property right is protected by the Taking Clause of the Fifth Amendment").

[82] *See Infra* Section IIIA.

[83] Langenegger v. United States, 756 F.2d 1565, 1570 (Fed. Cir. 1985), cert. denied, 474 U.S. 824 (1985); s*ee also* El-Shifa Pharm. Indus. Co. v. United States, 378 F.3d 1346, 1351 (Fed. Cir. 2004), *cert. denied*, 545 U.S. 1139 (2005) (noting that the language of the Takings Clause does not require the property be located within the United States to qualify for protection).

[84] *See, e.g.*, Langenegger, 756 F.2d. at 1567 (U.S. citizen's coffee plantation in El Salvador); Seery v. United States, 127 F. Supp. 601, 602–03 (1955) (U.S. citizen's house and personal properties located in Austria). There are three types of extraterritorial application of the Takings Clause: to American property located abroad, to alien property located in the U.S, and to alien property located abroad. *See* Andrea Paraud, *Foreign National and Principles of Extraterritoriality: Why Atamirzayeva v. United States Was Decided Incorrectly*, 59 Cath. U. L. Rev. 559 (2010). It is settled law that the Takings Clause protects the first type of properties. *Id*. This Article focuses on takings of Americans' patent rights, and it will therefore not go into the complexities of the latter two categories.

[85] Langenegger, 756 F.2d at 1572.

[86] *Id*.

[87] *Id*.

[88] *Id*.

For the first factor to weigh in favor of finding a taking, the United States must have "pervasive" influence over the foreign sovereign or international organization.[89] This is a very high bar to meet, and regular types of diplomatic persuasion fall short of the pervasive requirement.[90] One case that has found the United States liable for final actions of a foreign government is *Turney v. United States*.[91] There, the United States requested the Philippines government to embargo radar equipment mistakenly sold to plaintiff.[92] The Court held that the embargo resulted in takings of plaintiff's property, for which the United States was responsible because its relations with the Philippines government were so "close" that the Philippines government "naturally, readily complied" with the embargo request.[93]

Turney was distinguished by almost all later cases involving United States' responsibilities in takings by the hand of foreign or international sovereigns, on the basis that the "then-pervasive military and economic presence" of the United States in the Philippines was not seen elsewhere.[94] Specifically, all of the following actions were not pervasive enough to hold the United States accountable: "friendly" diplomatic persuasion, including planning, implementing, and financing a reform program of a foreign government, which demanded plaintiff's property confiscated;[95] requesting a bi-national organization headed by equal numbers of American and Canadian officers to take actions that caused flooding of plaintiff's property;[96] participation in an international "joint venture," which decided to occupy and delay the return of plaintiff's property.[97] Notwithstanding the United States' obvious involvement in the above cases, courts believed that the foreign sovereign or international organization retained the power to make the final call, independent of the United States' interest.[98]

One case decided against the United States is *Sharifi v. United States*.[99] There, the court held that the United States was "directly and substantially involved in the taking," since it acted alongside, not through the hands of, a foreign government, given that it appeared as a signatory to an agreement with the foreign government contemplating construction on the plaintiff's lands.[100]

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[89] Erosion Victims, 833 F.2d at 300.
[90] *Id*.; Langenegger, 756 F.2d at 1572.
[91] Turney v. United States, 115 F. Supp. 457, 463–65 (1953).
[92] *Id*. at 463.
[93] *Id*. ("Our armed forces had just liberated the Philippines from the Japanese. Our Government had given one hundred million dollars worth of surplus property to the Philippines, including the property at the Leyte Air Depot, and had sold the property for the account of the Philippine Government").
[94] Erosion Victims, 833 F.2d at 300; Langenegger, 756 F.2d at 1567, 1572.
[95] Langenegger, 756 F.2d at 1567, 1572. The U.S., hoping for "hemispheric stability," "strongly supported" the newly-established El Salvador government in implementing reforms, under which plaintiff's coffee plantation was expropriated. *Id*.
[96] Erosion Victims, 833 F.2d at 298-300; The Boundary Waters Treaty of 1909, Article VII. In accordance with the U.S.' request, the International Joint Commission, an independent, bi-national organization that regulated boundary water, reduced outflow from an upstream lake to manage downstream flooding, leading to flood at the upstream lake and destruction of plaintiff's property. Erosion Victims, 833 F.2d at 298-300.
[97] Standard-Vacuum Oil Co. v. United States, 153 F. Supp. 465, 466 (Ct. Cl. 1957) (no taking by the United States where the Supreme Commander for the Allied Powers, an international military coalition, refused to return plaintiff's property), cert. denied, 355 U.S. 893 (1957); Anglo Chinese Shipping Co. v. United States, 127 F. Supp. 553, 130 (Ct. Cl. 1955), cert. denied, 349 U.S. 938 (1955).
[98] Erosion Victims, 833 F.2d at 300-301.
[99] 143 Fed. Cl. 806, 813-14 (2019), aff'd 987 F.3d 1063 (Fed. Cir. 2021), cert. denied, 142 S. Ct. 107 (2021).
[100] *Id*.

As to the second factor, the benefits derived by the United States that suggest its sufficient involvement include repossession of sold equipment,[101] "the ability to construct [] housing and protection for [United States'] forces,"[102] and domestic public benefits resulting from containment of domestic flood.[103] However, domestic public benefits arising from "hemispheric stability" or "political stability of [United States'] neighbors" do not count as benefits that support United States' involvement.[104]

C. Not All Governmental Actions That Impinge On Private Properties Are Takings.

Because all rules favor some members of the society while disadvantaging the others, not all governmental actions impinging on private property rights are unconstitutional takings; only those that go "too far" are.[105] Unconstitutional takings include not only physical takings, such as direct appropriation or physical invasion of a private property, but also regulatory taking, which happens when the government issues rules that are unfairly "burdensome" to some individuals.[106]

In determining what governmental actions amount to takings, the Supreme Court devised a per se rule and a balancing test. Specifically, two types of governmental action are considered per se or categorical takings: (1) permanent physical invasions of property;[107] and (2) deprivation of all economically beneficial use.[108] If, however, the action deprives "less than all economically beneficial use" and only leads to "at most a partial destruction of [the property's] value," it will not be treated categorically as a taking.[109] As long as some market value remains in the property after the governmental action, not all economically beneficial use is deprived.[110] Denial of certain "established property rights,"[111] including the right to pass on property at death[112] and the right to earn interest based on the principle,[113] is also generally treated as a categorical taking, if not labeled as such.

As for any governmental action that does not fall under one of the aforementioned categories, courts engage in "essentially ad hoc, factual inquiries" guided by balancing the "economic impact" of the action, the character of the action, and the action's interference with "reasonable investment-backed expectations."[114] The first and second factors are often discussed together: the more significant diminution in property value the governmental action causes, the

[101] Turney, 115 F. Supp. at 463–65.
[102] Sharifi, 143 Fed. Cl. at 813.
[103] Erosion Victims, 833 F.2d at 300.
[104] Langenegger, 756 F.2d at 1672.
[105] Murr v. Wisconsin, 137 S. Ct. 1933, 1942 (2017) (quoting Pennsylvania Coal Co. v. Mahon, 260 U.S. 393, 415 (1922)).
[106] *Id*.
[107] Loretto v. Teleprompter Manhattan CATV Corp., 458 U.S. 419, 426 (1982).
[108] Lucas v. South Carolina Coastal Council, 505 U.S. 1003, 1015 (1992) (holding that a regulation that prohibits constructions on plaintiff's land "denies all economically beneficial or productive use of [the] land," and thus constitutes a taking regardless of the "public interest advanced in support of the restraint").
[109] *Florida Rock Indus., Inc. v. United States*, 18 F.3d 1560, 1565 (Fed. Cir. 1994), cert. denied, 513 U.S. 1109 (1995).
[110] *Id*.
[111] Stop the Beach Renourishment, Inc. v. Fla. Dep't of Envtl. Prot., 560 U.S. 702, 716 (2010)
[112] Babbitt v. Youpee, 519 U.S. 234 (1997); Hodel v. Irving, 481 U.S. 704 (1987).
[113] Phillips v. Washington Legal Foundation, 524 U.S. 156 (1998); Webb's Fabulous Pharmacies, Inc. v. Beckwith, 449 U.S. 155, 162 (1980).
[114] Penn Central Transportation Co. v. City of New York, 438 U.S. 104, 124 (1978); Loretto v. Teleprompter Manhattan CATV Corp., 458 U.S. 419, 426 (1982).

more important public interests it must serve.[115] Moreover, the second factor weighs in favor of a takings claim when the governmental action unfairly singles out an individual to bear the societal burden, as opposed to being sufficiently generalized or establishing a "public program adjusting the benefits and burdens of economic life to promote the common good."[116] As to the third factor, courts have considered two elements: "first, the extent of the plaintiffs' investment in reliance on the regulatory scheme in place at the time of the purchase; and second, the extent to which the regulation of their property was foreseeable."[117]

III. THE TAKINGS CLAUSE IN THE PATENT CONTEXT

A. The Takings Clause Protects Patent Rights

The Supreme Court of the United States has long and repeatedly recognized that, like property rights in a piece of land, patent rights are private properties subject to the protection of the Fifth Amendment Takings Clause.[118] In reaching this conclusion, the Supreme Court has emphasized that unlike the patent system in England, wherein the grant of a patent is based on exercise of royal prerogative, the patent system in the United States was built to promote "the progress of science and useful art" as prescribed by Article 1, § 8 of the Constitution of the United States.[119] Therefore, the United States government does not have any prerogative to use a patent, and cannot appropriate patent rights without paying just compensation.[120]

The Supreme Court's recent decision in *Oil States* is not to the contrary.[121] In considering whether the Patent Trial and Appeal Board (PTAB), a non-Article III court, has the power in *inter partes* review (IPR) to adjudicate the disputed validity of a patent, the Court noted that the decision to grant a patent involves a public right, as it is a decision to grant a "public franchise."[122] Because Congress has significant latitude to assign adjudication of matters involving public rights to non-Article III courts, the Court concluded that IPR does not violate Article III.[123] This decision is consistent with the Supreme Court's previous cases holding that patents are private property protected by the Takings Clause. First, the Court in *Oil States* holds only that "the determination

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[115] *Id*.
[116] Armstrong, 364 U.S. at 49 (1960); Penn Central, 438 U.S. at 123; Loretto 458 U.S. at 426.
[117] Walcek v. United States, 49 Fed. Cl. 248, 268 (2001), aff'd, 303 F.3d 1349 (Fed. Cir. 2002).
[118] Brown v. Duchesne, 60 U.S. (19 How.) 183, 197 (1856) ("[B]y the laws of the United States, the rights of a party under a patent are his private property; and by the Constitution of the United States, private property cannot be taken for public use without just compensation."); James v. Campbell, 104 U.S. 356, 358 (1881) ("[T]he government of the United States when it grants letters-patent for a new invention or discovery in the arts, confers upon the patentee an exclusive property in the patented invention which cannot be appropriated or used by the government itself, without just compensation, any more than it can appropriate or use without compensation land which has been patented to a private purchaser . . . "); Belknap v. Schild, 161 U.S. 10, 15-16 (1896); Horne v. Dep't of Agric. 135 S. Ct. 2419, 2427 (reaffirming the court's position in *James v. Campbell* that patent and other personal property is not "any less protected against physical appropriation than real property," 104 U.S. at 358).
[119] Campbell, 104 U.S. at 358; Belknap, 161 U.S. at 15-16.
[120] Campbell, 104 U.S. at 358; Belknap, 161 U.S. at 15-16. Note, however, that the government is given a license, under the Bayh–Dole Act, to practice inventions conceived or first actually reduced to practice by a contractor in the performance of work under government-funded projects. 35 U.S.C. §§201, 202.
[121] Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC, 138 S. Ct. 1365, 1372 (2018).
[122] *Id.*
[123] *Id.* at 1373-74.

to grant a patent is a 'matte[r] *involving* public rights,'"[124] which makes sense given that one of the long-accepted goals of patent law is to balance the interests of the public and the patentee. Nowhere does the *Oil States* decision suggest that the right of the patentee to exclude others from practicing its patent is not a private right. Second, the Court in *Oil States* expressly confined its holding to the Article III context, and cautioned that its "decision should not be *misconstrued* as suggesting that patents are not property for purpose[] of . . . the Takings Clause," citing with approval prior case law recognizing patents as private rights protected by the Takings Clause.[125]

B. Sovereign Immunity Does Not Limit a Patentee's Ability to Enforce the Takings Clause Against the Government

Under the long-established common law principle of sovereign immunity, the United States government is immune to lawsuit unless it expressly consents to be sued.[126] When the actions of the United States encroach upon private patent rights, two statutes come into play to waive its immunity.[127] The statute passed earlier is the Tucker Act (28 U.S.C. § 1491), which gives the Court of Federal Claims the jurisdiction to hear "any claim against the United States founded [] upon the Constitution . . . in cases *not sounding in tort*."[128] Based on this language, the Supreme Court has held that patentees cannot bring an infringement-based takings claim under the Tucker Act, because patent infringement is a tort, jurisdiction of which is expressly disclaimed in the Tucker Act.[129] In response to this holding, Congress enacted the Patent Act of 1910 (28 U.S.C. § 1498), which expanded the Court of Federal Claims' jurisdiction to cover patent infringement tort claims against the United States.[130] The Federal Circuit has since made it clear that "the Claims Court does not have jurisdiction to hear takings claims based on alleged patent infringement by the government[;] [t]hose claims sound in tort and are to be pursued exclusively under 28 U.S.C. § 1498."[131]

For non-infringement or non-tort-based takings claims, the Court of Federal Claims has jurisdiction under the Tucker Act.[132] The Federal Circuit held in *Golden* that the Claims Court has jurisdiction to hear a plaintiff's regulatory takings claim that the IPR proceedings "resulted in a reduction of value of his property, destroyed his competitive edge, and interfered with his 'reasonable investment-backed expectations.'"[133]

C. Courts Have Found That Reexamination Proceedings Are Not Takings

There are not many cases where courts have analyzed takings of patent rights. One line of cases challenged patent infringement by the government as takings, but courts declined hearing

[124] *Id.* at 1373 (quoting Murray's Lessee v. Hoboken Land & Improvement Co., 59 U.S. (18 How.) 272, 284 (1856)).
[125] *Id.* at 1379 (emphasis added).
[126] United States v. Sherwood, 312 U.S. 584, 586 (1941); United States v. King, 395 U.S. 1, 4 (1969).
[127] 28 U.S.C. § 1491; 28 U.S.C. § 1498;
[128] 28 U.S.C. § 1491 (emphasis added).
[129] Schillinger v. United States, 155 U.S. 163, 168-69 (1894); Golden v. United States, 955 F.3d 981, 986–88 (Fed. Cir. 2020), cert. denied, 141 S. Ct. 908 (2020).
[130] 28 U.S.C. § 1498; Golden, 955 F.3d at 988.
[131] *Id*.
[132] *Id*. at 988-89.
[133] *Id*.

such claims based on lack of jurisdiction as noted above.[134] Another line of cases challenged the issuance of secrecy orders as takings.[135] Courts in these cases held that even if the orders were a taking, plaintiffs would be compensated through another statute, and thus the government was not liable under the Takings Clause.[136]

The only cases where courts have conducted substantive analysis on whether governmental actions amount to takings are those that challenged the patent reexamination proceedings of the United States Patent and Trademark Office (USPTO). Courts have applied the *Penn Central* balancing test to determine whether *ex parte* reexamination (EPR), IPR, and their retroactive applications amount to regulatory takings of patent rights.[137]

For EPR, courts have applied the balancing test in conjunction with the principle the Supreme Court put forward in analyzing challenges to the Fifth Amendment Due Process Clause: if the legislature did not act in an arbitrary or irrational way, "legislative Acts adjusting the benefits and burdens of economic life come to the Court with a presumption of constitutionality."[138] Courts have held EPR and its retroactive applications reasonable regulations rather than unconstitutional takings, based on the finding that EPR was an attempt by Congress to "adjust the benefits and burdens of economic life to promote common good," and it applies equally to all patent holders as opposed to singling out the plaintiffs.[139] Moreover, it only serves as a "curative" measure to remove patents that should not have been granted in the first place, and does not necessarily have an "adverse economic impact on the plaintiffs."[140] With respect to interference to investment-backed expectation by retroactive application of EPR, courts have opined that although no USPTO reexamination mechanisms existed before EPR, "it was possible that the patent might be lost in an infringement suit or in an interference with a pending application," and thus the interference to expectation was not significant.[141]

When IPR came into existence, its retroactive application was similarly challenged by owners of pre-America Invents Act (AIA) patents based on unfair interference of investment-backed expectation: it was unforeseeable that IPR would be created and applied to pre-AIA patents and reduce their values.[142] The Federal Circuit disagreed, and identified the key inquiry as "whether IPRs differ from the pre-AIA review mechanisms significantly enough, substantively or procedurally, to effectuate a taking," and held "they do not."[143] The Federal Circuit later upheld

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[134] *See supra* note 129.

[135] A secrecy order is an order issued by the Commissioner for Patents to keep the disclosure of a patent application in secret when it involves matters of national security. 37 CFR §§5.2, 5.3. A secrecy order can indefinitely delay the issuance of a patent thereby indefinitely preventing the patent owner from exploiting the patent. *Id.*; Constant v. United States, 16 Cl. Ct. 629, 632 (Ct. Cl. 1989); Hornback v. United States, 52 Fed. Cl. 374, 385-86 (Fed. Cl. 2002).

[136] 35 U.S.C. § 181; Constant, 16 Cl. Ct. at 632; Hornback, 52 Fed. Cl. at 385-86.

[137] EPR, *inter partes* reexamination (IPRE), and IPR are all USPTO reexamination proceedings for challenging patent validity. EPR was created by Congress in 1980 and still available today. IPRE was created by Congress in 1999, and superseded by IPR in 2011 through Leahy–Smith America Invents Act (AIA). *See* Celgene Corp. v. Peter, 931 F.3d 1342, 1359 (Fed. Cir. 2019).

[138] Patlex Corp. v. Mossinghoff, 585 F. Supp. 713, 723-24 (E.D. Pa. 1983), aff'd in part and vacated in part sub nom. Patlex Corp. v. Mossinghoff, 758 F.2d 594 (Fed. Cir. 1985), on reh'g, 771 F.2d 480 (Fed. Cir. 1985); Patlex Corp. v. Mossinghoff, 758 F.2d 594, 602 (Fed. Cir.), on reh'g, 771 F.2d 480 (Fed. Cir. 1985).

[139] Patlex Corp., 585 F. Supp. at 724.

[140] *Id.*; Patlex Corp., 758 F.2d at 603.

[141] Joy Technologies v. Quigg, 12 U.S.P.Q.2d 1112 (D.C. Cir. 1989); Joy Techs., Inc. v. Manbeck, 959 F.2d 226, 228 (Fed. Cir. 1992), cert. denied, 506 U.S. 829 (1992).

[142] Celgene, 931 F.3d at 1360-1362.

[143] *Id.* at 1358.

the constitutionality of the prospective application of IPR, against the regulatory takings challenge, by relying on *Celgene*.[144]

APPLICATION

In supporting the patent waiver, there are potentially two types of actions taken by the United States that require separate analyses. The first type is actions taken at the international level, such as voting and diplomatic activities in support of passing the waiver at the WTO. The second is actions taken at the domestic level to implement the waiver, assuming that the United States is made an eligible country to invoke the waiver. The first type of actions will limit United States citizens' foreign patent rights in COVID-19 vaccine-related inventions. The second type will limit their domestic patent rights. Sections IV and V discuss, respectively, whether the first and second types of actions constitute takings regulated by the Fifth Amendment.

IV. SUPPORTING THE PATENT WAIVER AT THE WTO IS UNLIKELY TO CONSTITUTE A TAKING

This section focuses on the collective actions taken by the United States at the international level that led to the adoption of the patent waiver by the WTO, and concludes that these actions do not constitute Fifth Amendment takings.

As discussed above in Section IIIA, the Takings Clause protects patent rights, and as discussed above in Section IIA, it also protects United States citizens' properties located abroad.[145] Although there appears to be no cases where courts have considered whether the Takings Clause applies to foreign patent rights owned by United States citizens, there is no reason to believe it does not. Particularly, the United States is bound by the Constitution when it takes actions that affect its citizens' property rights overseas, and private properties, whether tangible or intangible, are equally protected by the Constitution when located within the United States.[146] It follows that foreign patent rights shall be accorded with the same constitutional protection as foreign tangible properties. Nonetheless, even if the Takings Clause protection covers foreign patent rights, the United States' role in supporting the COVID-19 patent waiver is unlikely to constitute a taking, because its involvement is not sufficiently direct and substantial.

First, the United States' influence at the WTO cannot be characterized as pervasive. Although the United States may have the power to veto the passage of the waiver at the WTO in view of the de facto norm of decision-making by consensus at the WTO,[147] the fact that the United States takes the opposite path to support the waiver is insufficient for holding it liable for consequences resulting from the waiver.

According to case law, if the final decision resulting in a taking cannot be rendered without the approval of other sovereigns, then in the absence of a showing that the United States has pervasive influence over the other sovereigns, the United States will not be held accountable for the taking even when it desires and supports the taking.[148] Here, under the very high bar established in *Turney* and its following cases, the United States lacks pervasive influence over any of the 164

[144] Golden, 955 F.3d at 989.
[145] *See supra* note 84.
[146] *See supra* notes 75-82.
[147] *See supra* notes 31-32 and accompanying text.
[148] *See supra* Section IIB.

members of the WTO, while support from at least three-fourths of them are needed to pass the waiver.[149]

Second, the level of benefits the United States derives also weighs against finding sufficient involvement. The countries that directly benefit from the waiver are developing countries that may, under the waiver, authorize the use of patented ingredients and processes to manufacture COVID-19 vaccines without obtaining the patentees' consents.[150] The United States is not an eligible country that may invoke the wavier right.[151] Although the waiver would arguably accelerate the ending of the pandemic globally, and the economy and people of the United States would certainly be better off without the pandemic, such domestic public benefits are too attenuated, and resemble those arising from "hemispheric stability" which have been rejected by courts as insufficient.[152]

In light of the limited influence of the United States in the WTO's decision to pass the patent waiver, and the limited benefits the United States will derive from the waiver, the United States does not have sufficiently direct and substantial involvement in the WTO decision. Therefore, even though certain American patentees' rights in foreign countries will be taken by the waiver, the United States' actions at the international level are not violative of the Takings Clause.

V. LIMITING DOMESTIC PATENT PROTECTION IS LIKELY TO CONSTITUTE A TAKING

In both the Quad text and the final waiver decision, the United States is not an eligible country that can choose not to provide the protections obligated by the TRIPS Agreement for qualifying patents.[153] One reason that the United States is willing to forgo the waiver right at the WTO maybe that even if the United States is given the right, implementing the waiver domestically will perpetrate a taking regulated by the Fifth Amendment, and therefore be very hard to accomplish. If a governmental action is a Fifth Amendment taking, the government can lawfully proceed with the action only if the action is for public benefits, and the government pays just compensation to the property owner.[154]

It is settled law that regardless of what treaties or international agreements allow the United States to do, the United States must always operate within the Constitution.[155] The Constitution trumps the international deal when the two are at odds.[156] In other words, even if the final waiver allows the United States to limit patentees' rights domestically, the United States can only do so by staying within the permission of the Takings Clause.

Under the final waiver decision, an eligible member may authorize the use of patented ingredients and processes necessary for the production and supply of the COVID-19 vaccines,

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[149] *Id.*; *supra* notes 26-27 and accompanying text.
[150] *See supra* notes 53, 60-61 and accompanying text.
[151] *See supra* notes 62-63 and accompanying text.
[152] *See supra* note 104.
[153] *See supra* notes 54-56, 60-64 and accompanying text.
[154] *See supra* notes 67-70 and accompanying text.
[155] Reid v. Covert, 354 U.S. 1, 16 (1957) ("No agreement with a foreign nation can confer power on Congress, or on any other branch of Government, which is free from the restraints of the Constitution." Supremacy clause does not allow treaties to exercise power free of constitutional prohibitions.); *see also* Boos v. Barry, 485 U.S. 312, 324 (1988); In re Aircrash In Bali, Indonesia on Apr. 22, 1974, 684 F.2d 1301, 1313 (9th Cir. 1982) (holding that plaintiffs have a right to compensation if their claims have been unreasonably impaired by the treaty).
[156] *Id.*

without the patentee's consents, for five years starting from the decision date.[157] Domestic implementation of such a waiver, should the United States were given the right by the WTO to do so, would constitute a taking regulated by the Fifth Amendment.

As discussed in Section II, a taking will be established if (1) "private property" rights are affected, (2) the government contributes sufficiently directly and substantially in affecting the rights; and (3) the governmental action crosses the line from being regulatory to an unlawful taking. Regarding the first requirement, domestic patent rights are private properties protected by the Takings Clause.[158] Because the United States would limit individuals' patent rights under the terms of the waiver, the first requirement is met. The second requirement only arises when the United States does not directly take or encroach on private properties, but does so through the hands of other sovereigns or organizations.[159] Here, no other authorities stand in between the United States and the final decision to implement a domestic waiver. This requirement is therefore also met.

Regarding the third requirement, the *Penn Central* balancing test would govern here, rather than the categorical takings rules.[160] The waiver clearly would not lead to permanent physical invasions of property.[161] In addition, the waiver would not deprive "all economically beneficial use" of the patent.[162] As long as there is some market value remaining after the governmental action, courts will apply the balancing test.[163] Accordingly, only waivers that eviscerate all values of qualifying patents would be regarded as categorical takings, for example, waivers that remove all rights conferred by a patent for the entire patent term.[164] Here, the waiver only authorizes use of patented ingredients and processes for a limited purpose (producing and supplying COVID-19 vaccines) and a limited time (5 years); use of the patented matters for other purposes are not affected by the waiver. Accordingly, the balancing test should govern here.

The first factor of the balancing test considers the economic impact of the action.[165] Here, the factor weighs against the government. Allowing others to use the patented matters to produce and supply COVID-19 vaccines will significantly diminish the value of such patents. Even though the patents may find some values in the production of other vaccines, the patented technologies were mainly created to tackle COVID-19. In addition, although the waiver only lasts 5 years, the demand of COVID-19 vaccines will significantly decrease after the waiver term as most people will be fully vaccinated by then.

The second factor, the character of the governmental action, also weighs against the government. It cannot be said that the public interest served by the domestic waiver is of pivotal importance to United States citizens, because not only do they have access to the vaccines, but the majority of them have been vaccinated by at least one dose, before the waiver goes into effect.[166] At the same time, the burden of serving the public interest of ending the pandemic globally would

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[157] *See supra* notes 60-64 and accompanying text.
[158] *See supra* Section IIIA.
[159] *See supra* Section IIB.
[160] *See supra* note 114 and accompanying text.
[161] *See supra* note 107 and accompany text.
[162] *See supra* note 108 and accompanying text.
[163] *See supra* note 114 and accompanying text.
[164] A patent owner has the exclusive right to make, use, offer to sell, or sell within the United States, or imports into the United States, the invention patented by his or her patent, for twenty years starting from the patent's application date. 35 U.S.C. §§ 154, 271.
[165] *See supra* notes 114-115 and accompanying text.
[166] *See supra* note 6 and accompanying text.

be unfairly borne by patentees who have invested a great deal in developing COVID-19 vaccines and related technologies. Moreover, the waiver is not a "curative" measure like those USPTO reexamination proceedings that deserve "relatively favored treatment."[167]

Lastly, the third factor, the waiver's interference with reasonable "investment-backed expectations," weighs against the government. Investors' expectations are interfered with if they have made substantial investment in reasonable reliance on an existing statutory scheme.[168] In the line of cases challenging USPTO reexamination procedures, courts upheld both EPR and IPR and their retroactive applications, because patent owners have always had the expectation that patent validity could be challenged in district court; EPR and IPR, merely providing additional avenues for contesting validity, do not unfairly interfere with investors' expectations.[169] Here, in contrast to those cases, the United States has always been pro patent protection, and has never decided to suspend domestic patent protection or authorized use of a patent without any compensation. Accordingly, owners of COVID-19 vaccine patents are reasonable in relying on patent protection to recoup their investments. To take away their patent rights without compensation therefore strongly interferes with their investment-backed expectations.

In view of the foregoing, all three factors of the balancing test weigh in favor of finding a taking regulated by the Fifth Amendment should the United States government decide to implement the patent waiver domestically. Therefore, to proceed lawfully with such a waiver, the United States must not only justify that the taking is for public use, but it must also pay just compensation to the patentees.[170]

[167] Patlex Corp., 758 F.2d at 603.
[168] *See supra* note 117.
[169] *See supra* Section IIIC.
[170] *See supra* notes 67-70 and accompanying text.

CONCLUSION

Against the interest of American-owned pharmaceutical companies, the United States can support the passing of the patent waiver at the WTO, because the Fifth Amendment Takings Clause poses no bar to that activity. However, if the United States were made an eligible country in the final waiver adopted, implementation of the waiver domestically would constitute a taking regulated by the Fifth Amendment.