



High-Level Working Group
on U.S.-Ecuador Relations

Trade, Intellectual
Property, and Access
to Medicine



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HIGH-LEVEL WORKING GROUP ON U.S.-ECUADOR RELATIONS

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INTRODUCTION

The United States and Ecuador have long been connected. The two countries established diplomatic relations in the 1820s, not long after both countries had won independence from Europe. In subsequent decades, the United States and Ecuador deepened relations on the basis of values enshrined in the Inter-American System, such as democracy, the rule of law, and human rights. Whether culturally or economically, the threads that bind the countries together are many.

Economic ties in particular have contributed to shared prosperity for the people of the United States and Ecuador. Today, the United States is Ecuador's principal trading partner—making Ecuador one of only three countries in South America for which trade with the United States surpasses trade with China.¹ The United States' principal exports to Ecuador include petroleum, machinery, computers, fertilizer, and cereals and grains. In return, Ecuador sends crude oil, seafood, bananas, cocoa, and flowers to the United States.²

While Ecuador and the United States sought to deepen economic ties in the early 2000s, extensive negotiations ended amid political and social upheaval in 2006. The two governments did not resume discussions over trade and investment until the administration of President Lenín Moreno (2017-2021). His successor, President Guillermo Lasso, has emphasized the need for Ecuador to deepen trade relations with the United States, with a particular focus on labor rights, intellectual property, gender equality, and environmental sustainability. Indeed, recent developments in both countries—including the elections of new presidents in both countries—offer a unique opportunity to discuss how the two countries might work together to combat the COVID-19 pandemic, spark economic growth, and pursue other priorities.

On June 4, 2021, Global Americans announced the formation of a High-Level Working Group, comprised of seasoned current and former policymakers, foreign service professionals, business leaders, and scholars. In collaboration with Global Americans staff, the Working Group has produced a series of working papers, covering a diverse range of topics central to the United States-Ecuador relationship—and in particular, central to any discussion of deepening commercial and economic relations between the two countries. The High-Level Working Group has served as a forum for nonpartisan and transregional expert analysis, resulting in a series of recommendations regarding the future of United States-Ecuador relations.

¹ *Joe Biden is Determined That China Should Not Displace America*, THE ECONOMIST (July 17, 2021), <https://www.economist.com/briefing/2021/07/17/joe-biden-is-determined-that-china-should-not-displace-america>.

² U.S. Relations with Ecuador: Bilateral Relations Fact Sheet, U.S. State Department, Bureau of Western Hemisphere Affairs (Jan 19, 2021), <https://www.state.gov/u-s-relations-with-ecuador>.

Executive Summary

Patents are a key type of intellectual property (IP) protection, meant to incentivize research and development by granting inventors a temporary monopoly. As Chapter 1 explains, leaders in developing countries may also strengthen patents in a bid to attract more trade and foreign direct investment, both of which contribute to economic growth. The evidence for the benefits that patents provide is mixed: while the effect of patents on innovation is up for debate, there is strong evidence that IP regulations spur foreign investment and trade.

When it comes to the pharmaceutical sector, policymakers must address two issues: underinvestment in new drugs and high prices for existing medicines. Intellectual property regulations are part of the solution to both problems. Chapter 2 details several tools that policymakers can use to mitigate these issues: changing the duration of patents, considering alternatives to patents, issuing subsidies, relying on compulsory licensing, and using parallel imports for medicine.

International law on trade and intellectual property allows countries significant authority to use each of these tools. Chapter 3 explains the origins of international trade and IP law. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) established a baseline for international IP restrictions in 1993. Since then, several trade agreements have included TRIPS-plus provisions, which raise the bar for IP restrictions. Although bilateral agreements shortly after the signing of TRIPS made it more difficult for countries to use parallel imports and compulsory licensing, the 2001 Doha Declaration reaffirmed governments' rights to use both methods to improve access to medicines.

While economics and law are key to understanding trade and IP, Chapter 4 explains that politics also plays a role. During international negotiations, developed countries often shift the conversation on trade and IP to the forum that best suits their interests.³ Bilateral agreements are particularly beneficial to developed countries relative to multilateral forums. Countries may also pursue political interests, aside from their economic goals, during trade negotiations. The case study of the 2001 U.S.-Jordan Free Trade Agreement shows how these dynamics led Jordan to accept strict TRIPS-plus provisions, at a heavy cost to their domestic population. Domestic politics can also affect trade and IP, as the case study of the Trans-Pacific Partnership (TPP) shows. Opposition to strict IP provisions can derail trade negotiations, as occurred in the United States. It can also promote reform and lead to a stronger trade deal; when the U.S. withdrew from TPP, Chile and ten other countries resumed talks, altered provisions related to IP, and signed the Comprehensive and Progressive Trans-Pacific Partnership (CPTPP).

As Chapter 5 explains, IP and trade in Ecuador reflect the economic, legal, and political developments observed worldwide. The Andean Community, a trade bloc composed of Colombia, Ecuador, Peru, and Bolivia, affirmed TRIPS regulations in its decisions throughout the 1990s, and Ecuador's 1998 Intellectual Property Law was largely in line with TRIPS. The government of President Rafael Correa (2007-2017)

³ Laurence R. Helfer, *Regime shifting: the TRIPS Agreement and new dynamics of int'l intellectual prop. lawmaking* 1-83, 29 YALE J. INT'L L. 1 (2004), <https://digitalcommons.law.yale.edu/yjil/vol29/iss1/2/>.

reformed Ecuador's intellectual law in 2016. While the resulting Código Ingenios, which remains in effect today, intended to “radically modify the existing paradigms,”⁴ the substance of the law is only a modest departure from the 1998 legislation.

Chapter 6 offers recommendations to stakeholders in the U.S.-Ecuador economic relationship. Negotiators should view IP protections as a significant issue, together with access to healthcare. Governments should compensate consumers who are unable to access medicine, and both the U.S. and Ecuador must respect the right of countries to use compulsory licenses and parallel imports. Finally, governments should ensure that patents are used only to reward innovation, not to unnecessarily block competition.

⁴ Código Ingenios, Exposición de Motivos 1 (July 2015) [hereinafter Exposición de Motivos], available at FLACSO, <https://www.flacso.org.ar/wp-content/uploads/2015/07/Codigo-Ingenios.-MPI.pdf>.



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1. WHY INTELLECTUAL PROPERTY MATTERS

Intellectual property (IP) is one of the most contentious topics in trade agreements. When IP protections are too lenient, a country may be less competitive in trade and foreign investment. When regulations are too stringent, prices remain high and products become inaccessible.

This chapter explains the motivations behind IP regulations, particularly patents, and the benefits that they provide.

Purpose of IP Regulations

Traditional property rights include a right to exclude others from using a good and the right to earn income from that good.⁵ In contexts where governments and courts protect their citizens' rights to tangible property, people are less likely to fear that their property will be stolen and more likely to invest it towards future goals.

Intellectual property rights similarly include a right to exclude others from using an idea and the right to earn income from that idea. Since ideas are far easier to steal than tangible property, effective regulations and enforcement are even more important to encourage investment.

This paper will focus on one particular type of IP protection—the patent—by which a government grants an inventor an exclusive right to make, use, or sell an invention for a fixed period.

Governments accept that under a patent, prices will be higher and output lower than they would be with perfect competition. But in a world without patents, the theory goes, the product likely would not exist in the first place.

Companies incur a large, fixed cost when developing new inventions, but once they have completed the research and development (R&D) phase, the marginal cost of each new unit of the invention is often low. Without patents, other firms could copy an idea and make the same profits without incurring the same fixed costs. Economic theory therefore predicts that firms would have little incentive to engage in R&D in the first place.⁶

Patents are meant to encourage innovation, compensating firms that engage in R&D by granting them a temporary monopoly. In exchange, the company must disclose their idea to the public.

Governments accept that under a patent, prices will be higher and output lower than they would be with perfect competition. But in a world without patents, the theory goes, the product likely would not exist in the first place.⁷

Patents Across Borders

While the case for IP regulations within one country is relatively straightforward, international dynamics complicate the picture.

⁵ See Thomas W. Merrill, *Property and the Rt. to Exclude* 730, 736-737, 77 NEB. L. REV. (1998), <https://digitalcommons.unl.edu/nlr/vol77/iss4/7>.

⁶ See William D. Nordhaus, *An Econ. Theory of Tech. Change* 18-28, 59 AM. ECON. REV. 2 (1969); Paul M.

Romer, *Endogenous Tech. Change* S84-S85, 98 J. POLIT. ECON. 5 (Oct. 1990).

⁷ See Nordhaus, *supra* note 6.

Generally, more innovation occurs in developed countries than in developing countries, as the latter often have fewer resources to dedicate to investment. Technological know-how later reaches developing countries in a process that economists refer to as “diffusion.”⁸ Some knowledge spreads through professional networks, the internet, and academic journals. However, some know-how reaches developing countries only through trade, investment, and technology transfers.⁹

Ecuador is one country that has exhibited considerable dependence on technology transfers. As of March 2021, the country had a positive trade balance of \$699 million, with exports mostly going to the United States, China, and Russia.¹⁰ The overall trade balance masks a more complicated picture, however. While Ecuador exports many primary goods, it relies heavily on imports of technology. Ecuador currently has few limits on foreign investment, but foreign direct investment (FDI) inflow to Ecuador is low compared to other countries in the region.¹¹ Ecuadorean policymakers may look to IP provisions to stimulate greater FDI.

Since patents are meant to encourage domestic innovation, developed countries have an incentive to create an intellectual property system. Since firms are unlikely to trade with or invest in

countries that lack IP regulations, developing countries have the same incentive.

Evidence for the Effectiveness of Patents

Patents aim to spark innovation, and for developing countries, they promise to encourage investment and trade. Taken together, innovation, investment, and trade should have a positive effect on a country’s economic growth. What evidence is there for the effectiveness of patents on each of these metrics?

The effect of patents on innovation is up for debate, but there is strong evidence that IP regulations spur foreign investment and trade, thereby contributing to economic growth.

When it comes to domestic innovation, economist Josh Lerner studied 177 changes to intellectual property law in 60 countries over a 150-year period.¹² He found no evidence that stricter laws resulted in more innovation. Professor Petra Moser finds that, historically, innovation has often occurred outside of the patent system.¹³ Overly broad patents can even discourage innovation if they prevent new competitors from entering the market.

The case for a strong patent system is stronger when it comes to encouraging FDI and exports

⁸ See Dany Bahar, Ricardo Hausmann, and César A. Hidalgo, *International Knowledge Diffusion and the Comparative Advantage of Nations* 3 (Harvard U. Ctr. for Int’l Dev. Working Paper No. 235, May 2012), https://dash.harvard.edu/bitstream/handle/1/8830781/RWP12-020_Hausmann.pdf.

⁹ See Bronwyn H. Hall, *Patents, Innovation, and Development* (Nat’l Bur. of Econ. Res. Working Paper 27203, May 2020), <https://www.nber.org/papers/w27203>.

¹⁰ See Ecuador (ECU) exports, imports, and trade partners. Observatory of Econ. Complexity, 2020, <https://oec.world/en/profile/country/ecu>.

¹¹ See 2020 Investment Climate Statements: Ecuador Report, U.S. State Department, Bureau of Economic and Business Affairs (July 19, 2021), <https://www.state.gov/reports/2020-investment-climate-statements/ecuador/>.

¹² See Josh Lerner, *Patent Protection and Innovation over 150 Years* (Nat’l Bur. of Econ. Res. Working Paper 8977, June 2002), <https://www.nber.org/papers/w8977>.

¹³ See Petra Moser, *Patents and Innovation: Evidence from Economic History* 40, 27 J. ECON. PERSPECTIVES 1 (Winter 2013), <https://www.aeaweb.org/articles?id=10.1257/jep.27.1.23>.

from developed to developing countries. Several studies find a high correlation between the strength of a country's patent system and the volume of FDI and exports the country receives. Others go further, finding evidence for a causal connection between IP protections and higher investment and trade.¹⁴

The relationship between intellectual property regulations and economic growth is less clear. Economists E. Richard Gold, John-Frederic Morin, and Erica Shadeed find inconsistent results in a literature review on the topic.¹⁵ To the extent that IP-related growth does exist for middle-income countries, Gold, Morin, and Shadeed find strong evidence that it is mostly due to trade and foreign investment rather than domestic innovation.

In Ecuador, recent growth rates have been discouraging. During the five-year period between 2014 and 2019, the country's GDP grew at an average of 1.27 percent per year. The economies of Peru and Colombia, meanwhile, grew at an average annual rate of 3.66 percent and 3.35 percent, respectively. Stronger IP regulations may improve Ecuador's economic performance.¹⁶

The effect of patents on innovation is up for debate, but there is strong evidence that IP regulations spur foreign investment and trade, thereby contributing to economic growth. By

speeding up growth, a developing country such as Ecuador can afford to invest more in social programs and raise the standards of living for all its citizens. But there are also negative consequences to stronger IP regulations. The following chapter will address those consequences, particularly for access to medicine.

¹⁴ See Hall, *Patents, Innovation, and Development*, *supra* note 9; Bronwyn H. Hall, *Does Patent Protection Help or Hinder Tech. Transfer?* 11-32, in Sanghoon Ahn, Bronwyn H. Hall, and Keun Lee Lee (eds.), *Intellectual Property for Econ. Dev.* (KDI Series Econ. Policy and Dev.); Olena Ivus, *Do Stronger Patent Rights Raise High-Tech Exports to the Developing World?* 38-47, 81 *J. OF INT'L ECON.* 1 (2010); Keith E. Maskus and Mohan Penubarti, *How Trade-Related Are Intellectual Property Rts?* 227-248, 39 *J. INT'L ECON.* 3 (1995); Jerry G. Thursby and Marie C. Thursby, *HERE OR THERE? A SURVEY OF FACTORS IN MULTINAT'L R&D LOCATION* (2006).

¹⁵ See E. Richard Gold, Jean-Frederic Morin, and Erica Shadeed, *Does Intellectual Property Lead to Econ. Growth? Insights from a Novel IP Dataset*, 13 *REG. & GOVERNANCE* 1 (2017), <https://doi.org/10.1111/rego.12165>.

¹⁶ See GDP Growth (Annual %) – Ecuador, Colombia, Peru, World Development Indicators, World Bank, <https://data.worldbank.org/indicator/NY.GDP.MKTP.KD.ZG?end=2020&locations=EC-CO-PE&start=2014&view=chart>.

2. CONSEQUENCES OF PATENTS FOR ACCESS TO MEDICINE

Given the life-saving potential of many medicines, it is unsurprising that the debate over intellectual property regulations often hinges on pharmaceutical products.

In the context of the COVID-19 pandemic, access to medicine is more important than ever when it comes to negotiating trade agreements. This chapter explains how leaders have recognized access to medicine as a human right, as well as the need for leaders to grapple with the practical challenges of guaranteeing that right.

Underinvestment in new drugs and high prices for existing drugs are the two principal challenges when it comes to access to medicine. Policymakers have a variety of tools to address those challenges: changing the duration of patents, considering alternatives to patents, issuing subsidies, relying on compulsory licensing, and using parallel imports.

Access to Medicine as a Human Right

Two billion people around the world lack access to essential medicines.¹⁷ Up to 90 percent of families in low- and middle-income countries pay out-of-pocket for medicines, often leaving them in dire financial straits.¹⁸

As in many countries, many impoverished Ecuadoreans are unable to afford basic healthcare.

¹⁷ See *Access to Medicines: Making Market Forces Serve the Poor* 14, WORLD HEALTH ORG. (2017) [hereinafter *Access to Medicines Report*].

¹⁸ *Id.*, at 15.

¹⁹ See Ecuador, Including the Galápagos Islands – Traveler View, U.S. Centers for Disease Control and Prevention, <https://wwwnc.cdc.gov/travel/destinations/traveler/none/ecuador>.

In addition to COVID-19, Ecuador faces a high burden of hepatitis A, malaria, and typhoid fever.¹⁹ Each of these conditions could be alleviated with affordable drugs.

Even when the right to medicine is inscribed in a country's constitution, codifying a right does not make it a reality.

World leaders recognize this problem. The United Nations' Sustainable Development Goal 3.8 states:

“SDG 3.8 consists of achieving universal health coverage (UHC), including financial risk protection, access to quality essential health care services, and access to safe, effective, quality, and affordable essential medicines and vaccines for all.”²⁰

International human rights bodies have also established that intellectual property rights are not absolute:

“Intellectual property is a social product and has a social function. States' parties thus have a duty to prevent unreasonably high costs for access to essential medicines ... from undermining the rights of large segments of the population to health.”²¹

²⁰ See UN General Assembly, Transforming our world : the 2030 Agenda for Sustainable Dev., 21 October 2015, U.N. Doc. A/RES/70/1, Goal 3.8, <https://www.refworld.org/docid/57b6e3e44.html>.

²¹ See e.g., U.N. Cmte. on Econ., Soc. and Cultural Rts., General Comment No. 17: The Right of Everyone to Benefit from the Protection of the Moral and Material Interests

Like many countries in Latin America, Ecuador inscribes the right to health in its constitution:

“Health is a right guaranteed by the State and whose fulfillment is linked to the exercise of other rights... The State shall guarantee this right by means of economic, social, cultural, educational, and environmental policies; and the permanent, timely and non-exclusive access to programs, actions and services promoting and providing integral healthcare, sexual health, and reproductive health.”²²

The problem is that no one country is accountable for the failure to meet a UN objective.²³ And even when the right to medicine is inscribed in a country's constitution, codifying a right does not make it a reality.

Policymakers must align incentives between the firms that produce drugs and the people who currently lack medicine, making sure that prices are affordable, output is sufficient, and medicines arrive where they are most needed.

To improve access to medicine, policymakers must build reliable healthcare systems and supply chains. They must establish relationships with local populations, ensuring that people trust their doctors and can report their healthcare needs.

Resulting from any Scientific, Literary or Artistic Production of Which He or She is the Author (Art. 15, Para. 1 (c) of the Covenant), U.N. DOC., E/C.12/GC/1712 (Jan. 2006); *see generally*, Paul Hunt, *Neglected Diseases: A Human Rights Analysis*, (World Health Org., Special Topics in Soc., Econ., and Behavioral Res. Report Series No. 6, 2007), WHO Doc. TDR/SDR/SEB/ST/07.2.

²² Ecuador, Constitution (2008), art. 32.

Most importantly, they must align incentives between the firms that produce drugs and the people who currently lack medicine, making sure that prices are affordable, output is sufficient, and medicines arrive where they are most needed. Intellectual property is the starting point for policymakers aiming to align incentives.

Problems with Patents: Underinvestment in R&D and High Prices

Intellectual property law can, in some contexts, facilitate access to medicine. R&D costs are remarkably high for pharmaceutical products—about \$2.6 billion for each product on average—given the time required to bring a product to market, the high regulatory burdens, and the risk that a drug will not be approved.²⁴ By compensating firms for R&D, patents can spark medical innovations that may otherwise have gone undiscovered.²⁵

Patents do not incentivize investment for all treatments, however. Some medical conditions occur almost exclusively in developing countries where the population cannot afford to pay high prices for a patented drug. Other medical conditions affect only a small number of people worldwide. For these conditions, the potential profit from a patented drug would not outweigh the costs of research and development, so no firm develops a treatment.

²³ *See generally*, William Easterly, *Democratic Accountability in Development: The Double Standard* 1075-1104, 77 SOCIAL RES. 4 (Winter 2010), <https://www.jstor.org/stable/23347120>.

²⁴ *See* Joseph A. DiMasi, Henry G. Grabowski, and Ronald W. Hansen, *Innovation in the pharmaceutical industry: New estimates of R&D costs* 20, 47 J. HEALTH ECON. (May 2016), <https://doi.org/10.1016/j.jhealeco.2016.01.012>.

²⁵ Access to Medicines Report, *supra* note 17, at 15-16.

Any policy to improve access to medicine must address the following two issues: underinvestment in promising new drugs and high prices for existing medicines.

Even when intellectual property regulations do incentivize firms to produce a new treatment, prices during the patent period may be too high for the patients most in need.

Any policy to improve access to medicine must address the following two issues: underinvestment in promising new drugs and high prices for existing medicines. To address both issues at once, policymakers must simultaneously raise the incentives for R&D and lower the prices that patients pay. The World Health Organization has recognized this principle and advocated for “delinking” R&D costs from prices.²⁶

Changing the duration of patents, considering alternatives to patents, issuing subsidies, relying on compulsory licensing, and using parallel imports for medicine are among the options that policymakers could take to make medicine more accessible.²⁷ The balance of this chapter will address each in turn.

Patent Duration

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS; see Chapter

²⁶ See *Research and Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination* 37, Consultative Expert Working Group on Research and Development: Financing and Coordination, WORLD HEALTH ORG (April 2012) [hereinafter R&D Report].

²⁷ The report emphasizes these five policy choices since they are relevant to trade agreements. Additional options to improve access to medicine include orphan drug legislation and direct grants to companies. For a detailed review of these options, outside of the context of trade agreements, see R&D Report at 142-213.

3) sets a global minimum of 20 years for the duration of a patent, but the precise figure varies according to national laws. After a patent has expired for a pharmaceutical product, other firms can enter the market and produce a generic drug. Competition drives output higher and prices lower, thereby making the medicine more accessible.

Decreasing the length of a patent might lower prices by allowing a generic alternative to come to market faster. However, shorter patent lengths might also decrease the incentive for firms to invest in R&D, particularly if a disease is rare in high-income countries.

Prizes, Not Patents

Noting the social costs of granting a temporary monopoly as compensation for research and development, several economists have proposed alternatives to patents. Perhaps the most well-known of these proposals is a global prize fund.²⁸ Since governments already spend a hefty sum on international aid and domestic health insurance benefits to treat disease, why not put the money instead toward incentives for drug manufacturers?

Changing the duration of patents, considering alternatives to patents, issuing subsidies, relying on compulsory licensing, and using parallel imports for

²⁸ See Joseph Stiglitz, *Prizes, Not Patents*, PROJECT SYNDICATE (March 6, 2007), <https://www.project-syndicate.org/commentary/prizes--not-patents>; see generally, Michael R. Kremer, *Patent buyouts: A mechanism for encouraging innovation* 1137-1167, 113 QUART. J. ECON. 4 (1998); Steven Shavell and Tanguy van Ypersele, *Rewards versus Intellectual Property Rights* 525-547, 44 J. LAW ECON. (2001); Brian D. Wright, *The Economics of Invention Incentives: Patents, Prizes, and Research Contracts* 691-707, 73 AM. ECON. REV. (1983).

medicine are among the options that policymakers could take to make medicine more accessible.

Experts could allocate prizes based on the costs of R&D and the social burden of the disease, rather than the ability of patients to pay. Companies that develop a treatment or cure would receive the prize, offsetting the R&D costs and entailing a profit, but the drug would be available immediately as a low-cost generic.

In most formulations, prizes do not completely replace all patents.²⁹ Instead, they can complement the patent system, with policymakers carving out certain conditions where a prize is more suitable than a patent.

Subsidies and Tax Incentives

Governments around the world use subsidies and tax incentives to promote certain behaviors. Goods and services with positive externalities are particularly apt for subsidies and tax incentives since the market would otherwise provide too few of these products.

Since R&D involves positive externalities and is undersupplied by the market, subsidies and tax incentives for firms could be a promising solution. An OECD review finds that on average,

²⁹ See Stiglitz, *supra* note 28.

³⁰ See *Tax Incentives for Res. and Dev.: Trends and Issues* 24-25, ORG. FOR ECON. COOPERATION AND DEV. (2002), <https://www.oecd.org/science/inno/2498389.pdf> [hereinafter *Tax Incentives*].

³¹ See *A Review of IP and Non-IP Incentives for R&D for Diseases of Poverty. What Type of Innovation is Required and How Can We Incentivise the Pvt. Sector to Deliver It?* 46, 69, UK GOV'T, OFFICE OF HEALTH ECONOMICS (April 2005), <https://www.who.int/intellectualproperty/studies/en/A.Towse.pdf>.

³² *Id.*; see also *Tax Incentives*, *supra* note 30, at 4.

“tax incentives can increase private research spending by an amount equal to the loss in tax revenue.”³⁰

While direct subsidies to firms may address the problem of inadequate supply of medicines, governments may also be concerned about insufficient demand.³¹ Subsidizing and regulating drug prices, purchasing medicines in bulk from manufacturers to distribute at a lower price, and offering partial subsidies for target populations are among the approaches that governments might take in this case.³²

Parallel Imports

The TRIPS Agreement (see Chapter 3) broadly raised the bar for international patent regulations, but it also includes provisions for governments to sidestep patents in extraordinary circumstances. One such provision is that involving parallel imports.

Parallel imports are patented products that are sold with the patent owner's permission in one country but that are imported or resold into another without the patent owner's approval.³³ Although a patent owner may have an exclusive right to manufacture and put their product on the market, the owner exhausts this right once the product enters the market.³⁴ The TRIPS Agreement

³³ See Fact Sheet: TRIPS and Pharmaceutical Patents: Obligations and Exceptions, World Trade Org. (Sept. 2006) [hereinafter *WTO Fact Sheet*],

https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm.https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm.

³⁴ See Sisule F. Musungu and Cecilia Oh, *The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines?* 27, COMMISSION ON INTELLECTUAL PROP. RTS., INNOVATION AND PUB. HEALTH (Aug. 2005), <https://www.who.int/intellectualproperty/studies/TRIPSFLXI.pdf>.

acknowledges this legal principle, known as “exhaustion,” stating that “even if a country allows parallel imports in a way that another country might think violates the TRIPS Agreement, this cannot be raised as a dispute in the WTO unless fundamental principles of non-discrimination are involved.”³⁵ As Chapter 3 details, parallel imports have generated significant controversy in the wake of the TRIPS Agreement. The 2001 Doha Declaration clarifies that members can decide to apply the principle of exhaustion within their national territory.³⁶

Although parallel imports aim to ensure that people in low- and middle-income countries have access to medicine, they are rarely used.³⁷ Out of the 176 instances where policymakers considered TRIPS flexibilities in 89 countries between 2001 and 2016, only one involved parallel imports.³⁸

Compulsory Licensing

Besides parallel imports, one way in which governments can sidestep patents while respecting TRIPS is through compulsory licensing—“the right granted by a government authority to make use of a patent during the patent term without the consent of the patent holder, for example, for the production or supply of generic medicines.”³⁹

Compulsory licensing, which appears as “other use without authorization of the right holder” in the TRIPS Agreement, is allowed as part of the Agreement’s overarching attempt at creating a balance between increasing access to existing pharmaceuticals and promoting R&D into new drugs.⁴⁰ It can only be done under a number of conditions—including “national emergencies” and ensuring the patent holder is adequately compensated—that are meant to protect the right holder’s interests.⁴¹

Compulsory licensing is frequently used, accounting for 100 out of the 176 instances of the use of TRIPS flexibilities between 2001 and 2016.⁴²

Reviewing the Options

There are several options that policymakers can use to improve global access to medicine. Offering prizes instead of patents would incentivize R&D costs and delink R&D from prices. More piecemeal reforms include reducing the length of patents, introducing subsidies or tax incentives for medicine, or drawing on parallel imports and compulsory licensing. As Chapter 3 explains, TRIPS and other international legal instruments discuss several of these options. Stakeholders

³⁵ See WTO Fact Sheet, *supra* note 33.

³⁶ *Id.*; Richard Smith, Chantal Blouin, Zafar Mirza, Peter Beyer, and Nick Drager, *Trade and Health: Towards Building a National Strategy* 132, WORLD HEALTH ORG. (2015), <https://apps.who.int/iris/rest/bitstreams/825170/retrieve>.

³⁷ See Ellen FM ‘t Hoen, Jacquelyn Veraldi, Brigit Toebes, and Hans V Hogerzeil, *Medicine procurement and the use of flexibilities in the Agreement on Trade-Related Aspects of Intellectual Prop. Rts.*, 2001–2016 1, WORLD TRADE ORG. (2018), https://www.who.int/bulletin/online_first/BLT.17.199364.pdf; see also, Smith et al., *supra* note 36, at 13.

³⁸ The 176 instances involve “(i) a government announcement of the intent to invoke a TRIPS flexibility; (ii) a request or application by a third party to invoke a TRIPS flexibility; (iii) the actual use of a TRIPS flexibility; and (iv) a government’s declaration that there are no relevant patents in its territory.” See ‘t Hoen et al., *supra* note 37, at 1, 3; see also Smith et al., *supra* note 36, at 13.

³⁹ See ‘t Hoen et al., *supra* note 37, at 2.

⁴⁰ See WTO Fact Sheet, *supra* note 33.

⁴¹ *Id.*

⁴² Of the 176 considered uses of TRIPS flexibilities, 40 involved the least-developed countries pharmaceutical measure (See Chapter 3). Most other cases involved non-patent-related measures. See ‘t Hoen et al., *supra* note 37, at 1.

should carefully weigh the pros and cons of each of these options when deciding how to balance the incentive for R&D with the imperative for affordable medicines.

3. TRADE AND IP IN INTERNATIONAL LAW: FROM PARIS TO DOHA

Intellectual property rights are an important incentive to foreign trade and investment. They can also improve or inhibit access to medicine. The COVID-19 pandemic is a key example of the key role that intellectual property must play. This chapter examines how international law has incorporated both IP and trade.

In the 19th and 20th centuries, international law developed along two parallel tracks—one for intellectual property, another for trade. Only in the 1990s, with TRIPS, did an international legal instrument address the two topics together. Since then, international law has quickly evolved to encompass IP-related issues in trade, including those relevant to access to medicine.

International IP Law

One of the first international legal instruments to deal with IP was the 1883 Paris Convention for the Protection of Industrial Property. Originally signed by 11 countries, the convention remains in effect today with 177 signatories, requiring countries to evaluate patent applicants without discriminating on the basis of national origin.⁴³

If the Paris Convention was a precursor to modern patent law, the 1886 Berne Convention for the Protection of Literary and Artistic Works was a

precursor to modern copyright law.⁴⁴ The convention, which remains in effect today, requires that countries recognize the copyrights of all other members.

Governments met to revise the Paris and Berne Conventions throughout the 20th century. The conventions established an organization to harmonize intellectual property law across borders, and in 1970, it became the World Intellectual Property Organization (WIPO).

International Trade Law and the Uruguay Round

Modern trade law is largely based in the General Agreement on Tariffs and Trade (GATT), a treaty signed in 1947 to reduce trade barriers among countries.⁴⁵ Multilateral negotiations took place in the latter half of the 20th century to reduce tariffs, but they focused largely on goods.

Following the Uruguay Round of negotiations (1986-1993), 123 countries agreed to update GATT and form the World Trade Organization (WTO).⁴⁶ They signed the General Agreement on Trade in Services (GATS), expanding the scope of tariff reduction beyond goods, and they incorporated concerns about IP by signing TRIPS.

Provisions of TRIPS

TRIPS generally increased global standards for intellectual property. Article 28 confers exclusive rights to patent owners to make, use, sell, or import a product.⁴⁷ In exchange, patent holders

⁴³ Paris Convention for the Protection of Industrial Property, as last revised at the Stockholm Revision Conference, Mar. 20, 1883, 21 U.S.T. 1583; 828 U.N.T.S. 305 (1883).

⁴⁴ Berne Convention for the Protection of Literary and Artistic Works, Sept. 9, 1886, as revised at Paris on July 24, 1971 and amended in 1979 S. Treaty Doc. No. 99-27 (1986).

⁴⁵ General Agreement on Tariffs and Trade, Oct. 30, 1947, 61 Stat. A-11, 55 U.N.T.S. 194 (1947).

⁴⁶ Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, 1867 U.N.T.S. 154, 33 I.L.M. 1144 (1994).

⁴⁷ TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh

must disclose their invention.⁴⁸ Article 33 of the agreement requires that patents be enforceable for at least 20 years.⁴⁹

TRIPS does allow states to make exceptions to patent rights, “provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.”⁵⁰

Article 31 of TRIPS details the circumstances in which a state can grant a temporary license to a firm to make a product that is patented by another firm. In normal circumstances, a state must first attempt to negotiate a voluntary license with the patent holder; if those negotiations fail, then the government can issue a compulsory license.⁵¹

While the TRIPS Agreement set a high bar for global patent protections, several developing countries have conceded to stronger IP provisions in subsequent negotiations.

In case of “a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use,” a state can forgo negotiations with patent holders and immediately issue a compulsory license, provided they promptly inform the patent holder and limit the scope and duration of the license.⁵² Article 31 also requires that a compulsory license be non-

exclusive, non-assignable, liable, and “authorized predominately for the supply of the domestic market.”⁵³ Finally, the government issuing a compulsory license must pay “adequate remuneration” to the patent holder.⁵⁴

Article 6 of TRIPS allows countries to use parallel imports, another exception to patent rights.⁵⁵ Taken together, the provisions of TRIPS that permit parallel imports and compulsory licensing are known as “TRIPS flexibilities.”

TRIPS-Plus Provisions

While the TRIPS Agreement set a high bar for global patent protections, several developing countries have conceded to stronger IP provisions in subsequent negotiations, both to gain acceptance at the World Trade Organization and to finalize bilateral trade agreements with developed countries.⁵⁶ These clauses, known as “TRIPS-plus provisions,” are usually the result of pressure from developed countries (See Chapter 4).

The United States successfully lobbied for TRIPS-plus provisions in its free trade agreements with Jordan (2001), Chile (2004), Singapore (2004), Australia (2005), Morocco (2006), Bahrain (2006), and South Korea (2012), among other countries.⁵⁷ The European Union (EU) also incorporated TRIPS-plus provisions into its association agreements with Jordan (2002) and

Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994), art. 28 [hereinafter TRIPS Agreement].

⁴⁸ *Id.*, art. 29.

⁴⁹ *Id.*, art. 33.

⁵⁰ *Id.*, art. 30.

⁵¹ *Id.*, art. 31.

⁵² *Id.*, art. 31.

⁵³ *Id.*, art. 31.

⁵⁴ *Id.*, art. 31(h).

⁵⁵ *Id.*, art. 6.

⁵⁶ See Access to Medicines Report, *supra* note 17, at 94-95.

⁵⁷ *Id.*; see also, Free Trade Agreement between the Republic of Korea and the United States of America, U.S.-S. Kor., June 30, 2007, modified, Dec. 5, 2010, available at

<http://www.ustr.gov/trade-agreements/free-trade-agreements/korus-fta/final-text>.

Egypt (2004), among others.⁵⁸ Jordan, Saudi Arabia, and Oman also adopted TRIPS-plus provisions to facilitate their accession to the WTO.

TRIPS-plus provisions vary across trade agreements. Some agreements require governments to award patents for plants and animals, where the TRIPS agreement had provided an exception. Other agreements extend the minimum duration of patents to 25 years, beyond the 20-year minimum under TRIPS. TRIPS-plus provisions can require countries to adopt new legal instruments, increase enforcement for existing IP laws, and submit conflicts over IP to international dispute settlement procedures.⁵⁹

Doha Declaration, Compulsory Licensing, and Parallel Imports

One of the most controversial TRIPS-plus provisions was related to TRIPS flexibilities and arose during trade negotiations between the United States and Jordan in 2000 (see Chapter 4). The final agreement included provisions that limited Jordan's ability to use compulsory licenses and parallel imports.

While Article 31 of TRIPS contained broad provisions allowing governments to use compulsory licenses, the U.S.-Jordan FTA permits compulsory licenses only to remedy anti-competitive practices, for public non-commercial use, and in cases of "national emergency" or "extreme urgency."⁶⁰ TRIPS allows governments

to issue compulsory licenses to private enterprises, but the U.S.-Jordan FTA allows compulsory licenses only for government entities.

U.S.-Jordan negotiations also restricted the use of parallel imports.⁶¹ Whereas Article 6 of TRIPS affirms the right of countries to use parallel imports, Jordan amended its domestic laws after pressure from the United States to allow parallel imports only with the permission of patent holders.

The Doha Declaration on the TRIPS Agreement and Public Health reaffirmed governments' rights to resort to compulsory licensing and parallel importation.

The U.S.-Jordan trade agreement generated controversy in much of the developing world, especially given its signing amid the global HIV/AIDS epidemic. In response, Brazil, India, and a group of African countries raised IP as a key concern prior to the Doha Development Round in 2001.⁶² The resulting Doha Declaration on the TRIPS Agreement and Public Health reaffirmed governments' rights to resort to compulsory licensing and parallel importation as codified in TRIPS Article 31.⁶³

On some provisions, the Doha Declaration went beyond TRIPS. The least-developed countries (LDC) pharmaceutical transition measure, for example, waives the obligation of LDCs to respect medicine patent rights or data protection at least

⁵⁸ See Access to Medicines Report, *supra* note 17, at 94-95.

⁵⁹ *Id.*, at 95-98.

⁶⁰ See Rohit Malpani, *All costs, no benefits: How TRIPS-plus intellectual prop. rules in the US-Jordan FTA affect access to medicines* 27, (Oxfam Int'l Briefing Paper 102, March 2007), [hereinafter Malpani-Oxfam Study], <https://oxfamlibrary.openrepository.com/bitstream/handle/10546/114080/bp102-all-costs-no-benefits-trips-210307->

<en.pdf%3Bjsessionid%3D089750820CF675173F0C3204C369D63F%3Fsequence%3D1>.

⁶¹ *Id.*, 28.

⁶² Access to Medicines Report, *supra* note 17, 99-100.

⁶³ World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/1, 41 ILM 746 (2002).

until 2016.⁶⁴ The WTO TRIPS Council agreed to this measure and later extended the date to 2033.⁶⁵

Developing countries have subsequently expanded the exceptions to IP protections provided under TRIPS. Article 31(f) of the original agreement states that compulsory licenses should be primarily used for domestic purposes, but many developing countries do not have the capacity to produce pharmaceuticals. In 2005, the WTO amended TRIPS in an attempt to address this issue. Article 31*bis* now allows countries to waive Article 31(f), importing generic pharmaceuticals at a low cost.⁶⁶ However, invoking Article 31*bis* remains an expensive, bureaucratic hassle.⁶⁷ So far, it has been invoked in only one case, when Rwanda imported HIV/AIDS medicine from Canada in 2008.⁶⁸

Trade Negotiations Since Doha

TRIPS-plus provisions have largely remained a feature of trade agreements, even after the 2001 Doha Declaration and the 2005 amendment to the TRIPS Agreement.

However, the substance of TRIPS-plus provisions has changed. Whereas the U.S.-Jordan FTA, signed in 2000 and put into effect in 2001, discouraged TRIPS flexibility, subsequent trade agreements generally refrained from such language.

The next chapter explains how politics can shape the outcomes of IP provisions in international trade agreements.

⁶⁴ See t' Hoen, et al., *supra* note 37, at 2.

⁶⁵ *Id.*

⁶⁶ TRIPS Agreement, *supra* note 47, at Art. 31*bis*.

⁶⁷ See William Alan Reinsch, Sanvid Tuljapurkar, and Jack Caporal, *Compulsory Licensing: A Cure for Distributing the Cure?*, CTR. STRATEGIC & INT'L STUD., May 8, 2020, <https://www.csis.org/analysis/compulsory-licensing-cure-distributing-cure>.

⁶⁸ See World Trade Org. General Council, Ann. Rev. of the Special Compulsory Licensing System, Report to the General Council, WTO Doc. IP/C/84, https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?language=E&CatalogueIdList=259543,258863,249981,249794,239927,239708,237591,232793,225262,225232&CurrentCatalogueIdIndex=1&FullTextHash=&HasEnglishRecord=True&HasFrenchRecord=True&HasSpanishRecord=True.

4. POLITICS OF TRADE AND IP

While economics can inform policymakers (see Chapters 1 and 2) and the law is equally important (see Chapters 3 and 4), politics also plays a role in trade negotiations. This chapter illustrates how international and domestic politics can affect trade agreements and intellectual property provisions in particular.

Politics between countries inevitably affects the outcome of international negotiations, particularly in cases where one country is considerably more powerful than the other. The case of the U.S.-Jordan Free Trade Agreement illustrates the consequences of bilateral negotiations for developing countries.

Negotiators between the United States and Ecuador should be aware of both international and domestic political dynamics as they consider deepening commercial ties.

Politics within countries also exercise significant influence on the way in which international trade agreements are shaped and ultimately received by the public. The case of the Trans-Pacific Partnership, later the CPTPP, illustrates how domestic opposition to stringent IP regulations can not only imperil a trade agreement, but also lead to reform.

Negotiators between the United States and Ecuador should be aware of both international and domestic political dynamics as they consider deepening commercial ties.

International Politics and Trade

International trade negotiations can take place through international organizations, multilateral GATT/WTO negotiating rounds, regional negotiations, or bilateral talks. When advancing a new round of talks on trade, governments often choose the forum that they think will best suit their interests in a process called “regime shifting.”⁶⁹ In the 1960s, developed countries moved discussions of intellectual property from UN institutions to WIPO. In the 1980s, they again shifted the conversation to the Uruguay Round, under the auspices of GATT. In the 1990s, regional and bilateral agreements appeared a more promising area for favorable trade negotiations, so developed countries again moved the discussion.⁷⁰

Compared to global multilateral negotiations, regional and bilateral agreements are particularly favorable for developed countries. Regional and bilateral agreements involve fewer parties and therefore tend to be easier to negotiate.

Bilateral talks in particular give significant negotiating power to developed countries. Whereas a united bloc of smaller, developing countries can press for concessions in a multilateral forum, a lone developing country is more likely to yield to a developed country in bilateral talks. Moreover, in most bilateral relationships, economic integration is more important to the developing country than it is to the developed country. The developing country may concede on labor, environmental, and intellectual property issues to ensure an agreement.

While deepening economic ties is often at the top of the agenda for developing countries in trade negotiations, the goals of developed countries are

⁶⁹ See Helfer, *supra* note 3.

⁷⁰ See Access to Medicines Report, *supra* note 17, at 92-93.

often more political. Reaching an accord on trade can have consequences far beyond the economy, including bolstering foreign governments, providing alternatives to crime and terrorism, and encouraging further economic reform.

Case Study: U.S.-Jordan Free Trade Agreement

After the Uruguay Round, the United States and European Union continued to seek to strengthen IP protection around the world. Having accomplished what they could through GATT/WTO multilateral negotiations, the United States and the EU shifted regimes, pressing developing countries in regional and bilateral agreements.⁷¹

The first country where the United States experimented with TRIPS-plus provisions was Jordan. It would become only the fourth country to establish an FTA with the United States after Israel, Canada, and Mexico.

In 1994, Jordan had normalized its relations with Israel, paving the way for deeper economic and political ties with the United States. Following bipartisan pressure from Congress, U.S. President Bill Clinton launched FTA negotiations with Jordan in June 2000.

The United States' goals in FTA negotiations with Jordan were not primarily economic. At the time,

the daily volume of U.S.-Mexico trade exceeded the annual volume of trade between the United States and Jordan.⁷² A study by the U.S. International Trade Commission predicted an "insignificant impact on total U.S. exports, U.S. production, or U.S. employment" would arise from a U.S.-Jordan FTA.⁷³

Bilateral talks in particular give significant negotiating power to developed countries.

Rather, the United States' goals were primarily political. In their letters urging President Clinton to begin talks, some members of Congress argued that an FTA would express the United States' gratitude for Jordan's diplomatic opening toward Israel and cooperation in the fight against terrorism.⁷⁴ Others viewed economic growth in Jordan as a path toward stability and security in the greater region. Still, other members hoped that an FTA would speed up Jordan's budding economic reform. The administration shared these goals in public statements and wished to signal support for King Abdullah II, a major U.S. ally in the region.⁷⁵

For Jordan, a free trade agreement offered both political and economic benefits. An FTA would provide Jordan with a comparative advantage in a large export market, incentivize foreign direct investment, and boost the government's domestic

⁷¹ *Id.*

⁷² See Al Nasa'a, Marwa, John Chin, Shawn Leonard, Claudia Munoz, and Brooke Reilly, *The Jordan-U.S. Free Trade Agreement: Eight Years Later* 4 (U. Mich Int'l Econ. Dev. Program, March 2008), <http://websites.umich.edu/~ipolicy/Policy%20Papers/jordanusfta.pdf>.

⁷³ See Stephen Koplman, Deanna Tanner Okun, Lynn M. Bragg, Marcia E. Miller, Jennifer A. Hillman, and Thelma J. Askey, *Economic Impact on the United States of a U.S.-Jordan Free Trade Agreement* 5-9, U.S. INTERNATIONAL

TRADE COMMISSION (Sept. 2000), <https://www.usitc.gov/publications/docs/pubs/332/pub3340.pdf>; Two other studies prior to the 2001 implementation came to similar conclusions; see Al Nasa'a et al., *supra* note 72, at 7.

⁷⁴ See JOSHUA RUEBNER, CONG. RES. SERV., RL30652, U.S.-JORDAN FREE TRADE AGREEMENT 5-6 (May 2001), http://www.sice.oas.org/TPD/USA_JOR/Studies/CRS_E.pdf.

⁷⁵ *Id.*, 6; see also Al Nasa'a, et al., *supra* note 72, at 4.

standing. The Jordanian Parliament ratified the agreement with little debate on May 9, 2001.⁷⁶

In the United States, partisan debates over labor and environmental provisions delayed ratification of the FTA. Two weeks after the September 11 attacks, however, with the Middle East and the War on Terror particularly salient, Congress approved the agreement by voice vote. The FTA went into effect on December 17, 2001.

While the economic impact of the U.S.-Jordan FTA is beyond the scope of this report, the impact of the agreement on access to medicine does offer lessons for policymakers involved in potential U.S.-Ecuador trade negotiations.

A comparison between Egypt and Jordan reveals that TRIPS-plus provisions do not always succeed in attracting FDI to the pharmaceutical sector.

Jordan's negotiations with the United States and its accession to the World Trade Organization resulted in several provisions limiting parallel imports and compulsory licensing (see Chapter 3). The U.S.-Jordan FTA requires governments to extend patent protection beyond the 20-year minimum established by TRIPS to compensate for delays in marketing approval.⁷⁷ The agreement also requires an additional three years of data exclusivity under certain conditions beyond the TRIPS requirements.⁷⁸ Finally, as a condition for accession to the WTO, Jordan implemented laws to prevent registration and marketing approval for

generic drugs for five years, even in the absence of a patent.⁷⁹

In a 2007 study for Oxfam International, Rohit Malpani compared access to medicine in Jordan following the implementation of strict TRIPS-plus provisions to access to medicine in Egypt, which at the time met the minimum requirements under TRIPS.⁸⁰ The study found that prices for patented drugs in Jordan were between 167 and 800 percent higher than comparable generics medications in Egypt.⁸¹

While strong IP protections generally correlate with higher FDI (see Chapter 1), a comparison between Egypt and Jordan reveals that TRIPS-plus provisions do not always succeed in attracting FDI in the pharmaceutical sector.⁸² During the 12-year period analyzed by Malpani, Jordan received no investment in pharmaceutical manufacturing, while Egypt attracted \$223 million in pharmaceutical FDI.⁸³ A possible explanation is that Egypt's large population and market size, relative to that of Jordan, was a more important factor to potential investors than IP protections at the margin.⁸⁴

With no domestic pharmaceutical manufacturing, Jordan had to import 70 percent of its medicines while Egypt imported only 10 percent.⁸⁵ Jordan's reliance on medicine imports is borne out in price disparities. The Oxfam-Malpani study found that prices for imported drugs in Jordan were between

⁷⁶ Al Nasa'a et al., *supra* note 72, at 4.

⁷⁷ Malpani-Oxfam Study, *supra* note 60, at 27.

⁷⁸ *Id.* at 28.

⁷⁹ *Id.*

⁸⁰ *Id.*, at 15.

⁸¹ *Id.*, at 10-11.

⁸² See Hall, *Patents, Innovation, and Development*, *supra* note 9; see also Hall, *Does Patent Protection Help or*

Hinder Tech. Transfer? 11-32, *supra* note 12; Ivus, *supra* note 12; Maskus and Penubarti, *supra* note 12; Thursby and Thursby, *supra* note 12.

⁸³ Malpani-Oxfam Study, *supra* note 60, at 16.

⁸⁴ *Id.*

⁸⁵ *Id.*

220 and 1064 percent higher than comparable drugs produced under license in Egypt.⁸⁶

Lessons from the U.S.-Jordan FTA Case Study

In short, negotiations between the United States and Jordan resulted in strict TRIPS-plus provisions and lower access to medicine. The patterns observed in U.S.-Jordan negotiations reflect more general dynamics in the politics of international trade. The United States' primary motivation in negotiations was geopolitical, while Jordan viewed the trade agreement through an economic lens. Bilateral negotiations led to an outcome that favored the United States, particularly on intellectual property.

Stakeholders in U.S.-Ecuador relations can draw lessons from the case study. Policymakers in Ecuador should be cognizant of the benefits and drawbacks of bilateral negotiations relative to multilateral forums. Negotiators in both countries should be clear about their political, economic, and strategic motivations for pursuing deeper trade relations. All actors can also draw lessons from the effects of TRIPS-plus regulations on Jordan.

The lack of pharmaceutical investment in Jordan relative to Egypt could have specific implications for Ecuador. Ecuador, a small nation adjacent to the more populous countries of Colombia and Peru, may similarly find it difficult to attract pharmaceutical FDI even with TRIPS-plus provisions.

⁸⁶ *Id.*, 25-26.

⁸⁷ See MSF Access Missions: How It Works: MSF Access Campaign, Médecins Sans Frontières Access Campaign, <https://msfaccess.org/about-us>; Intellectual Prop. and Access to Medicine, Oxfam, <https://www.oxfamamerica.org/explore/issues/economic->

Domestic Politics and Trade

Domestic politics are as likely as international politics to affect trade negotiations. During trade talks, corporations lobby their governments to include provisions that favor their interests. Pharmaceutical companies often pressure the governments of developed countries to include TRIPS-plus provisions among their demands.

Resistance to TRIPS-plus provisions has the potential to derail trade negotiations, particularly if opposition is voiced only outside of institutions. However, it can also prompt reform.

Countervailing interest groups similarly lobby governments to reject TRIPS-plus provisions. Local activists raise awareness in meetings with legislators and in grassroots efforts. International NGOs such as Doctors Without Borders, Human Rights Watch, and Oxfam support these efforts from abroad.⁸⁷

Resistance to TRIPS-plus provisions has the potential to derail trade negotiations, particularly if opposition is voiced only outside of institutions. However, it can also prompt reform, and negotiations that include stakeholders who are skeptical of TRIPS-plus provisions can lead to more durable agreements.

Case Study: Trans-Pacific Partnership

The Trans-Pacific Partnership (TPP) was a multilateral trade agreement that would have involved the United States, Australia, Brunei,

[well-being/intellectual-property-and-access-to-medicine/](#); Access to Essential Medicines in U.S.-Morocco Trade Agreement, Human Rts. Watch (October 28, 2020), <https://www.hrw.org/news/2004/02/17/access-essential-medicines-us-morocco-trade-agreement>.

Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, and Vietnam. In 2008, the twelve countries began discussions on the TPP as a potential expansion of the Trans-Pacific Strategic Economic Partnership Agreement—an earlier accord signed by Brunei, Chile, New Zealand, and Singapore.

Negotiations involved a range of issues, including tariff reductions, harmonizing regulations, and raising the minimum for IP protections. In addition to the economic goal of increasing trade, several parties, particularly the United States, had a geopolitical goal of competing with China. The parties reached an accord on October 5, 2015.

Soon after negotiations ended, the TPP sparked debates within several countries. In the United States, candidates in both the Democratic and Republican presidential primaries criticized the accord. Democratic nominee Hillary Clinton and Republican nominee Donald Trump each expressed a desire to withdraw the United States from the TPP, with Trump referring to it as “the greatest danger yet.”⁸⁸ For Clinton, the goal was to “make sure we’re not putting the interests of drug companies ahead of patients and consumers.”⁸⁹ Other high-profile candidates such

as Bernie Sanders shared similar views, arguing that it “would significantly increase prices for prescription drugs” for lower-income communities.⁹⁰

In January 2017, newly inaugurated President Trump withdrew the United States from TPP.⁹¹ Figures on both the left and right celebrated the decision. Richard Trumka, President of the AFL-CIO, the largest U.S. labor union, promised to continue his “relentless campaign to create new trade and economic rules that end special privileges for foreign investors and Big Pharma.”⁹²

Scholars at the time emphasized that the TPP’s intellectual property provisions would have the greatest effect on developing countries—such as Chile, Peru, and Mexico—where the agreement would decrease access to low-cost generics.⁹³ However, these countries remained interested in other provisions of the TPP.

As the United States debated whether to withdraw from the TPP in November 2016, Chilean Foreign Minister Heraldo Muñoz promised that “whether it be with the United States or without the United

⁸⁸ See Antonio de la Jara, *Chile's Foreign Minister: TPP Not Dead, despite Trump Comments*, REUTERS (Nov. 22, 2016), <https://www.reuters.com/article/uk-chile-china-trade/chiles-foreign-minister-tpp-not-dead-despite-trump-comments-idUKKBN13H237>.

⁸⁹ See Dave Johnson, *Clinton’s Opposition to TPP Marks “A Critical Turning Point,”* United Steelworkers (Oct. 10, 2015), <https://m.usw.org/blog/2015/clintons-opposition-to-tpp-marks-a-critical-turning-point>.

⁹⁰ See Bernie Sanders, *Oregon Fair Trade Campaign: Presidential Candidate Questionnaire*, Oregon Fair Trade Campaign (May 2016), https://www.citizenstrade.org/ctc/oregon/files/2016/05/OR_FTCPresidentialQuestionnaire_Sanders2016.pdf.

⁹¹ See *The United States Officially Withdraws from the Trans-Pacific Partnership*, United States Trade Rep.

(January 2017), <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2017/january/US-Withdraws-From-TPP>.

⁹² See David Weigel, *Sanders, Joined by Rust Belt Democrats, Praises Trump for Nixing TPP*, WASHINGTON POST (March 31, 2019), <https://www.washingtonpost.com/news/powerpost/wp/2017/01/23/sanders-praises-trump-for-nixing-tpp-delighted-to-work-with-him-on-pro-worker-policies/>.

⁹³ See Joel Lexchin, Deborah Gleeson, Ruth Lopert, and Burcu Kilic, *The Trans Pacific Partnership Agreement, Intellectual Property and Medicines: Differential Outcomes for Developed and Developing Countries*, 18 GLOBAL SOCIAL POLICY 1 (April 2018), <https://journals.sagepub.com/doi/full/10.1177/1468018117734153>.

States, there's a willingness among the countries that make up the TPP to move forward."⁹⁴

Chile soon convened negotiations with the 11 remaining parties to TPP. In January 2018, the countries agreed to the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP). The new agreement removed 20 provisions from the initial TPP relating to investment, government procurement, and intellectual property, which were originally included at the insistence of the United States.⁹⁵ The choice to name the updated agreement a "comprehensive and progressive" TPP was a deliberate one. After a populist backlash in the United States derailed the original TPP, symbolic and substantive reform in the remaining 11 parties led to an agreement that would garner widespread support.

Lessons from the TPP Case Study

In the United States, domestic opponents of strict IP regulations formed a coalition to block the TPP. As the experience of the other 11 parties demonstrates, however, resistance to TRIPS-plus provisions can also lead to reform. The CPTPP was well received among signatory countries, and flexible provisions related to intellectual property were key to its success.

TPP negotiations offer a lesson for U.S.-Ecuador trade relations. Ecuadorean policymakers might consider the role that domestic groups and international NGOs play in advocating for access to healthcare. If discussions over deeper trade relations do take place, negotiators should be aware that domestic constituencies can both

strengthen and derail trade agreements, depending on the substance of negotiations and the level of public participation allowed.

⁹⁴ See de la Jara, *supra* note 88.

⁹⁵ See *6 Things to Know about the Trans-Pacific Trade Pact CPTPP*, THE STRAITS TIMES (January 31, 2021), <https://www.straitstimes.com/world/6-things-to-know-about-the-trans-pacific-trade-pact-cptpp>; Deborah Elms,

TPP11: Unpacking the Suspended Provisions, ASIAN TRADE CENTRE (Nov. 14, 2017), <http://asiantradecentre.org/talkingtrade//tpp11-unpacking-the-suspended-provisions>.

5. IMPLICATIONS FOR ECUADOR

Ecuador's intellectual property laws are shaped by the legal, economic, and political conditions detailed in Chapters 1-4. This chapter explains how Ecuador's IP laws developed alongside both TRIPS and decisions by the Andean Community. It also explains the motivations behind provisions of Ecuador's most recent IP law, the 2016 Código Ingenios.

Andean Community, TRIPS, and the Banana Wars (1993-2000)

Ecuadorean IP law has largely drawn on the decisions of the Commission of the Andean Community (CAN)—a trade block composed of Ecuador, Colombia, Peru, Bolivia, and (until 2006) Venezuela. In the early 1990s, as the GATT Uruguay Round increasingly emphasized the role of IP in international trade, CAN began issuing decisions to harmonize IP laws across its five member states.

In 1993, the Andean Community issued Decision 344, an IP-related law binding CAN members to a set of standards largely consistent with TRIPS.⁹⁶ While the Andean Community has had mixed results in promoting regional economic or political integration, harmonization of intellectual

property laws is one area in which the Community has been particularly effective.⁹⁷ Over 97 percent of preliminary references sent to the Andean Tribunal of Justice through the end of 2007 concerned intellectual property.⁹⁸

The Andean Community's involvement in intellectual property law has allowed countries to achieve a balance between respecting patent holders and providing access to medicine. Governments have often resisted IP-related pressure from the United States or pharmaceutical companies by pointing to their obligations to the Andean Community and resolving disputes through the Andean Tribunal of Justice.⁹⁹

The Andean Community's involvement in intellectual property law has allowed countries to achieve a balance between respecting patent holders and providing access to medicine.

The same year that the Andean Community adopted Decision 344, Ecuador signed a bilateral treaty with the United States, which increased patent protections for medicines. The legislature declined to ratify the deal, but the president implemented many of its provisions by decree.¹⁰⁰

⁹⁶ See Cartagena Agreement Commission, Decision 344: Common Regime on Industrial Property, available at <http://www.sice.oas.org/trade/junac/decisiones/Dec344e.asp>; see also Laurence R. Helfer, Karen J. Alter, and Florencia Guerzovitch, *Islands of Effective International Adjudication: Constructing an Intellectual Property Rule of Law in the Andean Community* 11, 109 AM. J. INT'L L. (2009), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1306318.

⁹⁷ See Laurence R. Helfer and Karen J. Alter, *The Influence of the Andean Intellectual Prop. Regime on Access to Medicines in Latin Am.* 1, in Rochelle Dreyfuss and César Rodríguez-Gavarito (eds.), *BALANCING WEALTH AND*

HEALTH: GLOBAL ADMIN. LAW AND THE BATTLE OVER INTELLECTUAL PROP. AND ACCESS TO MEDICINES IN LATIN AM. (2013), https://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=3064&context=faculty_scholarship.

⁹⁸ *Id.*, 1-2.

⁹⁹ *Id.*, 2.

¹⁰⁰ Tatiana Andia, *Pharmaceutical Intellectual Property Protection and Access to Medicines in Ecuador: State Sovereignty and Transnational Advocacy Networks* 198-201, Rochelle Dreyfuss and César Rodríguez-Gavarito (eds.), *BALANCING WEALTH AND HEALTH: GLOBAL ADMIN. LAW AND THE BATTLE OVER INTELLECTUAL PROP. AND ACCESS TO MEDICINES IN LATIN AM.* (2013).

The Ecuadorean Association of Pharmaceutical Laboratories (ALAFAR)—a trade association of domestic drug producers—objected to the agreement, arguing that it would increase Ecuador’s already significant dependence on foreign pharmaceutical imports.¹⁰¹ ALAFAR drew on support from the Latin American Association of Pharmaceutical Laboratories (ALIFAR), a regional organization, but it exercised resistance to the new IP regulations most effectively through the Andean Community. In 1993, Generic drug developers sued the government and the Andean Tribunal of Justice ruled in their favor, notifying the Ecuadorean government that their patent regime did not abide by CAN standards.¹⁰² The Ecuadorean government refused to comply, but after a similar ruling in 1996, the government modified their IP laws to abide by Decision 344.¹⁰³

The country’s approach to the Banana Wars was instead shaped by domestic political actors, especially the National Banana Council (Conaban)—a trade association of banana exporters.

Ecuador’s next major engagement in international IP law took place amid the “Banana Wars,” a series of disputes between the U.S. and Latin America, on the one hand, and the European Union, on the other, over the EU’s discriminatory tariffs on bananas. Drawing on the new conflict resolution mechanisms of the World Trade Organization, the United States launched a complaint against the European Union. Ecuador, a

major banana exporter, acceded to the WTO in 1996 to join the complaint.¹⁰⁴

After joining the WTO, Ecuador took a novel approach to pressure the EU into lowering banana tariffs. The government deployed a “cross-retaliation” measure—a mechanism that was approved by TRIPS but had never been used by a developing country—and threatened to disregard its patent obligations for European intellectual property unless the EU lowered its banana tariffs. By 2000, the European Union gave in.¹⁰⁵

Although Ecuador and the United States both rejected the EU’s tariffs, Ecuador’s strategy was independent from the United States. The country’s approach to the Banana Wars was instead shaped by domestic political actors, especially the National Banana Council (Conaban)—a trade association of banana exporters.¹⁰⁶

In 1998, shortly after joining the WTO, Ecuador introduced an intellectual property law in line with TRIPS.¹⁰⁷ The law also recognized the Paris and Berne Conventions and was compatible with Decision 344 of the Andean Community.¹⁰⁸

In 2000, the Commission of the Andean Community issued Decision 486, clarifying some provisions of its 1993 decision and altering others.¹⁰⁹ In one significant departure, Decision 486 removed a clause that had prohibited patents for “inventions relative to ... essential

¹⁰¹ Until 2000, over 80 percent of medicines consumed in Ecuador were imported; *id.*

¹⁰² Helfer and Alter, *supra* note 97, at 5.

¹⁰³ *Id.*

¹⁰⁴ Andia, *supra* note 100, at 202-207

¹⁰⁵ *Id.*

¹⁰⁶ *Id.*

¹⁰⁷ See Ecuador, Law No. 83 RO/320, *Ley De Propiedad Intelectual* (May 19, 1998), available at U.N. High Commissioner for Refugees, <https://www.acnur.org/fileadmin/Documentos/BDL/2008/6611.pdf>.

¹⁰⁸ *Id.*

¹⁰⁹ See Helfer, Alter, and Guertzovitch, *supra* note 97, at 11.

medicines.”¹¹⁰ CAN Decision 486 remains in effect to this day.

Negotiations with the United States (2000-2006)

For the early part of the 2000s, successive administrations in Ecuador balanced patent protections and access to medicine under the 1998 Law of Intellectual Property.

Attempts to increase IP protections created significant controversy. When Ecuador began negotiating a free trade agreement with the United States in 2004, the U.S. pressured Ecuador to accept TRIPS-plus provisions, including:

- 1) five-year data exclusivity protections;
- 2) obstacles to marketing approval for generic drugs that violated patent law;
- 3) compensation to patentholders for delays in approval;
- 4) constraints on parallel imports;
- 5) protection for second-use patents; and
- 6) patents for genetic resources.¹¹¹

The Pharmaceutical Researchers and Manufacturers of America (PhRMA) also lobbied to U.S. government to reject a trade deal with Ecuador that did not include these stipulations. Ecuadorean negotiators began to draw “red lines” regarding intellectual property, but disputes on the topic led Ecuador to suspend negotiations in late 2005.¹¹²

When the Ecuadorean government resumed negotiations in 2006, policymakers encountered significant domestic opposition from Indigenous Peoples’ organizations (see the report “Indigenous

Peoples’ Rights and Trade Relations: A Historical Perspective,” by the Global Americans High-Level Working Group on U.S.-Ecuador Relations). In addition to the Indigenous Peoples’ organizations, several ex-ministers of health and domestic NGOs wrote an open letter to the president, calling for negotiators to reject TRIPS-plus provisions. Transnational advocacy networks supported the strong domestic opposition.¹¹³ International human rights organizations—including Knowledge Ecology International (KEI), Médecins Sans Frontières (MSF), Health Action International, Oxfam, the Treatment Action Campaign, Act Up Paris, the Health Gap Coalition, and Public Citizen—released documents criticizing the FTA. Eventually the U.S. government terminated negotiations following an investment dispute.¹¹⁴

Rafael Correa and the LAC-Global Alliance (2007-2016)

The election of President Rafael Correa (2007-2017) marked a departure from Ecuador’s previous approach to economics and trade, including on the topic of intellectual property. Transnational advocacy networks for access to medicine became stronger, and the government was receptive.

In 2008, Correa promulgated a new constitution, recognizing the right to healthcare and medicine.¹¹⁵ The same year, CAN sought to negotiate an association agreement with the European Union. Health Action International and several Latin American civil society organizations joined to create the CAN-EU Alliance for Access

¹¹⁰ Andia, *supra* note 100, at 208-209.

¹¹¹ *Id.*, at 210.

¹¹² *Id.*

¹¹³ Margaret E. Keck and Katryn Sikkink, *ACTIVISTS BEYOND BORDERS: ADVOCACY NETWORKS IN INTERNATIONAL POLITICS* (1998).

¹¹⁴ Andia, *supra* note 100, at 210-212.

¹¹⁵ *Id.*, at 212-213.

to Medicines.¹¹⁶ The alliance successfully lobbied against expanded IP protections in Colombian and Peruvian negotiations with the EU. It later grew to include other Latin American countries, and in 2010, it became the LAC-Global Alliance, including KEI, Public Citizen, Brazil-MSF, and the Brazilian Working Group on Intellectual Property (REBRIP).¹¹⁷

In 2009, President Correa signed Decree 118, the first Ecuadorean law to allow compulsory licenses for pharmaceutical products following advocacy campaigns from the CAN-EU alliance.¹¹⁸ The decree paved the way for broader discussions on Ecuador's intellectual property law.¹¹⁹

Código Ingenios (2016-Present)

In December 2016, as trade negotiations with the European Union continued, Ecuador passed the Código Orgánico de la Economía Social de los Conocimientos, Creatividad e Innovación. The Código Ingenios, as it is widely known, remains in effect today and governs intellectual property in the country.¹²⁰

The legislation notes that the Intellectual Property Law of 1998 is not “harmonized with the rights and guarantees established in the Constitution of

the Republic of Ecuador.”¹²¹ The prior framework, according to the 2016 law, was a “hyper-privatist system of knowledge, in which only the owners/merchants of intellectual property corresponding to a few transnational monopolies have benefited.”¹²² The Código Ingenios aimed to “radically modify the existing paradigms.”¹²³

Although the 2016 law includes sweeping language and was the product of substantial public consultation, the substantive provisions related to patents present modest reforms to the 1998 Intellectual Property Law.¹²⁴

The Código Ingenios explicitly mentions that “nothing foreseen in this Code shall be able to be interpreted as contrary to the principles, rights and obligations established in [TRIPS and other international agreements to which Ecuador adheres].”¹²⁵ Article 253 of the Código adopts the TRIPS standards regarding what type of products and processes can be patented.¹²⁶

Ecuador's IP legislation today is largely in line with the TRIPS Agreement.

Like the 1998 Intellectual Property Law, the 2016 Código includes TRIPS flexibilities.¹²⁷ However, these flexibilities are more vaguely

¹¹⁶ *Id.*, at 213-214.

¹¹⁷ *Id.*, at 214.

¹¹⁸ *Id.*

¹¹⁹ See David James Jefferson, *Ingenuity and the Re-Imagining of Intellectual Prop.: An Introduction to the Códigos Ingenios of Ecuador* 23, 39 EUR. INTELLECTUAL PROP. REV. 1 (Jan. 2017), https://www.researchgate.net/publication/312521396_Ingenuity_and_the_Re-Imagining_of_Intellectual_Property_An_Introduction_to_the_Codigo_Ingenios_of_Ecuador.

¹²⁰ See Ecuador, *Código Orgánico de La Economía Social de Los Conocimientos Creatividad e Innovación*, Official Register Vol. 4, No. 899, (Dec. 2016) [hereinafter *Código Ingenios*], available at World Intellectual Prop. Org.,

<https://www.wipo.int/edocs/lexdocs/laws/es/ec/ec075es.pdf>

¹²¹ *Id.*, at 3.

¹²² Exposición de Motivos, *supra* note 4, at 3.

¹²³ *Id.*, at 1.

¹²⁴ See Jefferson, *supra* note 119, at 25.

¹²⁵ Código Ingenios, *supra* note 120, at art. 4(ii).

¹²⁶ *Id.*, at art. 253; see also, Sophia Espinosa Coloma, *Código Ingenios y el Sistema de patentes: ¿una propuesta innovadora o la receta hacia un estancamiento tecnológico?* 25, 17 IURIS DICTIO (Feb.-July 2016), <https://revistas.usfq.edu.ec/index.php/iurisdiccionario/articulo/view/737>.

¹²⁷ See Espinosa Coloma, *supra* note 126, at 30-31, 38.

defined in the 2016 Código. Article 87 of the Código states that “goods that guarantee fundamental rights and are protected by intellectual property rights” must be used to “satisfy the basic needs of society,” even if that means abridging patent rights.¹²⁸ Since it leaves the government to determine when a right is fundamental and when a need is basic, and provides no guidance when rights come into conflict, Article 87 gives governments strong discretionary authority. The 2016 Código also adds protections for traditional knowledge (see the report “Trade and Traditional Knowledge,”

by the Global Americans High-Level Working Group on U.S.-Ecuador Relations, currently pending publication).

Ecuador’s IP legislation today is largely in line with the TRIPS Agreement. Like IP regulations in other countries, the Código Ingenios has been shaped by developments in international law, domestic and global politics, and prevailing economic conditions.

¹²⁸ Código Ingenios, *supra* note 120, at art. 87.

6. RECOMMENDATIONS

Intellectual property (IP) protections are a key tool for countries to attract foreign direct investment and increase trade, but they also present legal, economic, and political challenges, particularly with respect to global access to medicine. The analysis in Chapters 1-5 details these challenges. In this section, we present recommendations to stakeholders on how to reconcile IP protections with access to medicine when deepening economic ties between the United States and Ecuador.

1. Intellectual property protections have become a major component of free trade agreements after TRIPS. **Policymakers seeking to deepen the U.S.-Ecuador trade relationship should emphasize the importance of intellectual property to trade.**
2. **Negotiators must consider intellectual property protections and access to medicine together.** There are several tools to improve access to medicine through IP regulations, including changing the duration of patents, considering alternatives to patents, issuing subsidies, relying on compulsory licensing, and using parallel imports for medicine.
3. **A key goal of governments should be to compensate consumers who are unable to access medicine due to intellectual property restrictions.** Parties that advocate for strict IP regulations should be responsible for implementing an adequate system of compensation.
4. The 2001 Doha Declaration reaffirmed the right of developing countries to use compulsory licensing and parallel imports of patented drugs. **A potential trade agreement between the U.S. and Ecuador must not abridge the right to use TRIPS flexibilities.**
5. **Patents must be used only to reward innovation, not to unnecessarily block competition.** Governments must ensure that their patent and competition laws respect this distinction.