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Japan's emerging role in the global pharmaceutical intellectual property regime: A tale of two trade agreements

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This paper explores Japan's role in reshaping the global pharmaceutical intellectual property regime by examining its position on the expansion of intellectual property rights (IPR) in negotiations for two regional trade agreements: the Trans Pacific Partnership Agreement (TPP) and the Regional Comprehensive Economic Partnership (RCEP). Through systematic analysis of leaked negotiating texts documenting its positions on key issues, we demonstrate Japan is now playing a pivotal role in promoting the adoption of expanded IPRs. We show that its position as IPR champion in the Asia Pacific region reflects a domestic strategy initiated in 2013 to bolster pharmaceutical export growth. Drawing on past experience and focusing on the RCEP negotiations, we explore ways in which low and middle income countries might respond to this shift in order to protect and promote access to medicines.

KEYWORDS
access to medicines, intellectual property, RCEP, Regional Comprehensive Economic Partnership Agreement, TPP, Trans Pacific Partnership Agreement

1 | INTRODUCTION

Japan's recent role in promoting the expansion of IPRs in regional trade agreements signals a shift in the landscape once dominated by the United States (US) and European Union (EU). Japan was a latecomer to the Trans Pacific Partnership Agreement (TPP); to date it is one of only two countries to have ratified the text, and

has played a key role in attempting to revive the agreement with the 10 remaining parties since the US withdrawal in early 2017. Japan is also one of 16 countries currently participating in the Regional Comprehensive Economic Partnership agreement (RCEP) negotiations across the Asia Pacific region. The final text of the TPP mandated expanded IP rights that, if maintained by the remaining parties, will likely delay the market entry of cheaper generic medicines in several of the countries (Labonte, Schram, & Ruckert, 2016). Of potentially greater concern is that the countries participating in RCEP include key generic medicine producers like India, posing *global* ramifications for access to medicines if high levels of IP protection are included in the final agreement.

This paper explores the emerging role of Japan in reshaping the global pharmaceutical intellectual property regime by examining its position in relation to the expansion of intellectual property rights (IPRs) in negotiations for the TPP and RCEP. Through systematic analysis of leaked negotiating texts that document Japan's positions on key issues, we demonstrate that as an artefact of the particular dynamics involved in these trade negotiations, Japan is now playing a pivotal role in promoting the adoption of expanded IPRs—arguably one approaching that of the United States or the European Union. We show that Japan's newfound position as IPR champion in the Asia Pacific region reflects a domestic strategy initiated in 2013 to bolster pharmaceutical export growth. Drawing on past experience and focusing particularly on the current RCEP negotiations, we explore ways in which low and middle income countries (LMICs) might respond to this shift so as to protect and promote access to medicines. We find that LMICs are best placed to maintain an ASEAN-centred response that reflects the different economic and social needs of negotiating countries.

2 | BACKGROUND—THE PURSUIT OF TRIPS-PLUS IPRS AND BARRIERS FOR ACCESS TO MEDICINES

The TPP and RCEP represent the most recent forums in a progressive expansion of IPRs through bilateral and regional trade agreements over the last two decades. The World Trade Organization's Trade Related-Aspects of Intellectual Property Rights agreement (TRIPS) came into force in 1995 and effectively established a global intellectual property rights regime. It was brought about through the United States and European Economic Commission's extensive trade pressure on low and middle-income countries (LMICs) and the global lobbying efforts of multinational IP-intensive industries, in particular the pharmaceutical industry (Drahos, 1995; Sell, 2003). TRIPS obliges WTO member states to implement certain standards of IP protection, including the grant and enforcement of pharmaceutical product and process patents for a minimum period of 20 years (World Trade Organization, 2013).

High levels of IP protection can create barriers to access to medicines when market monopolies enable unrestrained pricing. Shortly after TRIPS was signed, newly developed, patented lifesaving HIV/AIDS drugs were priced out of reach for many patients, at more than ten thousand dollars (US) per patient per year (McNeil, 2002). The South African government introduced legislation to obtain more affordable generic versions of the drugs and faced a multinational pharmaceutical industry lawsuit that claimed the legislation violated TRIPS (Mandisa, 2013:139; Pharmaceutical Research and Manufacturers of America, 1999). Subsequent international protests and the development of cheaper generic AIDS drugs by Indian firms bolstered a common position amongst developing countries at the WTO, leading to the 2001 Doha Declaration in 2001 which confirmed that TRIPS contained flexibilities for governments to override IPRs in order to protect public health (World Trade Organization, 2001a).

In the years since TRIPS, the United States and European Union (EU) have each shifted the locus of their respective expansionist IP agendas to bilateral and plurilateral trade and investment agreements, with the United States successfully managing to secure TRIPS-Plus levels of IP protection in some 20 countries between 1995 and 2011 (Correa, 2006; Office of the United States Trade Representative, 2016). Text proposed by the EU to India,

leaked online, also demonstrates that the EU is pressuring India to adopt higher standards of IP protection in its negotiations for an EU-India trade agreement (Chatterjee, 2013).

The United States and European Union have typically pushed for countries to implement TRIPS-Plus measures that (Correa, 2006: 399; Kessomboon et al., 2010):

1. broaden the scope of patentability by mandating patents for new forms and new uses of known substances;
2. mandate the extension of patent terms beyond 20 years to compensate for delays in patent office and/or marketing approval processes;
3. extend the period of time in which generic medicine manufacturers are prevented from relying on clinical trial test data produced by the originator in order to obtain marketing approval; and
4. create new border measures and higher standards of IP enforcement.

In addition the United States has pursued so-called "patent linkage" provisions, which can prevent the granting of marketing approval of a generic by a drug regulatory agency where there is an extant patent on the originator product, irrespective of whether the generic is likely to infringe the patent.

These measures are a concern for public health because higher levels of IP protection delay the entry of cheaper generic medicines, and as a result contribute to higher healthcare costs for governments and consumers. Broad patentability criteria enable firms to extend monopoly protections by obtaining secondary patents on new forms or uses of existing substances, or for minor modifications—this is referred to as patent "evergreening" (Collier, 2013). Evergreening practices in Thailand, for example, blocked the Government Pharmaceutical Organization from producing a generic version of the cholesterol-lowering medication atorvastatin (Lipitor) after the patent expired, because Pfizer had secured a secondary patent on a crystalline form of the drug (Treerutkuarkul, 2008). In the United States, 82 patents for two key HIV/AIDS drugs ritonavir and lopinavir/ritonavir have effectively extended monopolies on these medicines by up to 12 years and forced generic manufacturers into costly litigation, delaying the availability of cheaper products (Kesselheim, Fischer, & Avorn, 2006). The unnecessary costs associated with secondary patents have led researchers at the World Health Organization's South East Asia Regional Office (SEARO) to recommend that countries exclude new uses of known substances from the scope of patentability in order to protect public health (World Health Organization Regional Office for South-East Asia, 2004).

Another TRIPS-Plus measure, patent term extension, also creates additional healthcare costs for governments. A 2008 study of the potential impact of five-year patent term extensions in Thailand found that the additional cost to government after five years would be 822.1 million dollars (US), extending to over six billion dollars after 20 years (Kessomboon et al, 2010). A third provision, data exclusivity, delays marketing approval for generic medicines unless costly and arguably unethical clinical trials are repeated before the exclusivity protection period expires (Arkinstall, Childs, Menghaney, Ford, & von Schoen-Angerer, 2011). This measure is particularly significant for low and middle-income countries that have recently introduced pharmaceutical IP protection. Data exclusivity is a form of IP protection that is quite distinct from patent protection in that it is conferred by drug regulatory agencies not patent offices, and unlike patents, its validity cannot be challenged in court. Medicines for which patents have expired at the time of marketing approval can still be granted this type of exclusivity. Similarly, exercising public interest provisions like pre- and post-grant patent opposition, or compulsory licensing (which enables a government to override patents and facilitate generic competition) may be undermined if a drug's data exclusivity period has not yet expired (Acquah, 2014; Arkinstall et al., 2011; Correa, 2006; Krikorian & Szymkowiak, 2007).

Finally, adopting a host of TRIPS-Plus intellectual property rights can have a multiplicative effect (Lopert & Gleeson, 2013). The problem of pharmaceutical evergreening compounds the negative effects of patent linkage. Under patent linkage, depending on the system in place, drug regulatory authorities could be liable for compensation claims if they inadvertently block generic medicines based on patents covering other forms or uses, if a patent is later determined to be invalid or the generic non-infringing (Correa, 2006; Krikorian & Szymkowiak, 2007). The public health implications of these measures are significant and have led many governments, intergovernmental organizations, IP experts, public health academics and civil society groups to criticize the United States and

European Union for their aggressive pursuit of expanded IPRs in trade agreements (Kuanpoth, Kripke, & Weinberg, 2006; UNDP & UNAIDS, 2012).

3 | JAPAN'S ROLE IN THE TRANS PACIFIC PARTNERSHIP AGREEMENT

Since 2013, Japan has appeared to play an emerging role as a champion of expanded IPRs, signalling a shift in regional dynamics. Its entry to the TPP altered the dynamics of the negotiations on IP protections for medicines, a change that can be traced through analysis of successive leaked drafts of negotiating documents, supplemented with media reports on the status of negotiations. Furthermore, Japan ratified the agreement prior to the US withdrawal from the TPP in early 2017, and has since played a key role in attempting to revive the agreement with the remaining parties.

Negotiations for the TPP formally commenced in 2010 among eight Pacific Rim countries: Australia, Brunei Darussalam, Chile, New Zealand, Peru, Singapore, the United States and Vietnam. Malaysia joined later in 2010, followed by Mexico and Canada in 2012. Japan entered the negotiations in May 2013, making it the final entrant before the agreement was finalized in October 2015.

At the time of Japan's entry, negotiations on pharmaceutical IP had reached a stalemate. Initial proposals made by the United States in 2011 included multiple TRIPS-Plus IP protections such as expanding the scope of patentability, patent term extension, data exclusivity, and patent linkage—as well as a placeholder for special provisions for biologic products (Trans Pacific Partnership, 2011a, 2011b). These proposals had been met with unanimous opposition from the other countries involved in the negotiations (Inside US Trade, 2012), leading to a long hiatus while the United States reviewed its position and consulted internally with domestic stakeholders (Inside US Trade, 2013a). It is worth noting that the US pharmaceutical industry peak body, the Pharmaceutical Research and Manufacturers of America (PhRMA), supported Japan's request to join the TPP, claiming that Japan's own "high standards" on IPRs would assist the United States in the ongoing negotiations (PhRMA, 2012).

In September 2013, *Inside US Trade* reported that a group of countries including Chile and New Zealand had joined together to put forward a counter-proposal setting out a different approach to pharmaceutical IP (Inside U.S. Trade, 2013b). While this counter-proposal was not leaked, in November 2013, Wikileaks published a consolidated draft of the intellectual property chapter, dated 30 August 2013, in which country positions were documented (Wikileaks, 2013a). This leaked version clearly showed rifts between the United States and the other countries over many of the pharmaceutical provisions, with the United States isolated in almost all cases. Japan's position on most of the key pharmaceutical IP provisions is not indicated in this draft, which is perhaps unsurprising given the recency of its entry to the negotiations at that time. Soon after, however, Wikileaks published further leaked documents setting out country positions as at 6 November 2013, as well as the "state of play" following the Salt Lake City negotiating round of 19–24 November 2013 (Wikileaks, 2013b). These documents suggest a significant shift by Japan, which according to these documents, had been largely rejecting the US pharmaceutical proposals on 6 November—but by the Salt Lake City round had joined with the United States to present a shared discussion paper on pharmaceutical IP.

The convergence of the United States and Japanese positions is evident in the next leaked draft of the TPP IP chapter, dated May 2014 (Wikileaks, 2014). By this stage, Japan had joined with the United States and Australia in supporting patents for new uses and new methods of using existing products, a provision to which all the other countries remained opposed (Article QQ.E.1). Japan had also begun negotiating over the wording of Article QQ.E.12 (patent term extension to compensate for unreasonable delays in granting patents). A footnote to this provision also indicates that Japan was to join the United States in leading "work on an appropriate transition period for Parties who do not currently provide such a system" (Footnote 81). While Japan's position on other TRIPS-Plus provisions is not specifically documented, it is clear from this draft that the earlier impasse was over; negotiations had now begun in earnest on a TRIPS-Plus regime, covering expanded scope of patentability, patent term extension, data exclusivity, patent linkage, and data or market exclusivity for biologics. While square bracketed text indicated continuing

disagreement in some areas, the non-US countries had now moved from outright rejection to negotiating the final wording of these provisions.

While the final TPP intellectual property chapter does not include all the provisions initially sought by the United States, it does go well beyond the obligations of TRIPS. In the face of considerable opposition from the other countries, the United States abandoned its initial proposals to require parties to provide patents for new forms of existing products and for diagnostic and surgical methods, and to preclude pre-grant opposition of patent applications. However, several other TRIPS-Plus proposals remained in the final text, albeit softened to some degree with language allowing countries some flexibility in implementing the obligations. Nonetheless, the expansion of IP standards in several of the countries will likely delay the market entry of generic medicines in several of the countries, potentially creating problems for affordable access to medicines.

While the TPP negotiations were conducted out of the public eye, leaks suggest that Japan's entry to the negotiations was a significant factor in fracturing the hitherto near unanimous opposition to the US proposals. Through its willingness to work with the United States, Japan appears to have contributed to the ultimate retention of several TRIPS-Plus provisions in final text of the TPP IP chapter. Japan's role in the negotiations reflects its economic status within the group of negotiating countries; it has the second highest GDP next to the US, at $4.123 trillion (2015, US) (World Bank, 2016a) and $17.947 trillion (2015, US) (World Bank, 2016b), respectively. The combined GDP of these two countries represented 79.24% of total GDP of the TPP negotiating countries in 2015 (see Table 1), signaling substantial economic weighting in favor of the United States and Japan in the negotiations.

Japan ratified the TPP on 20 January 2017 shortly before the inauguration of President Trump, who had promised in his election campaign to exit the agreement. Since the United States withdrawal, Japan has led talks between the remaining 11 parties, arguing that the substance of the agreement should be retained (Gramer, 2017).

4 | JAPAN'S ROLE IN THE REGIONAL COMPREHENSIVE ECONOMIC PARTNERSHIP AGREEMENT AND IMPLICATIONS FOR ACCESS TO MEDICINES

In contrast to its late entry in the TPP, Japan has been a key member of the Regional Comprehensive Economic Partnership agreement since the beginning of the negotiations. RCEP notably excludes the United States and is framed as an attempt to assert "ASEAN centrality" in the region, guided by objectives to foster "economic integration,

TABLE 1 TPP parties by GDP 2015 (US)

	GDP 2015 (US) trillion	% of TPP parties' total GDP (%)
United States	17.95	65.81
Japan	4.12	15.12
Canada	1.55	5.69
Australia	1.34	4.91
Mexico	1.14	4.20
Malaysia	0.30	1.09
Singapore	0.29	1.07
Vietnam	0.19	0.71
Peru	0.19	0.70
New Zealand	0.17	0.64
Brunei Darussalam	0.02	0.06
Total	27,268,886	100

Source: World Bank, World Bank database, at data.worldbank.org/country (last visited 8 August, 2016).

equitable economic development and economic cooperation" among the negotiating countries (Association of South East Asian Nations, 2012c). Japan played a key role in broadening an initial proposal by China for an ASEAN + 3 configuration (that excluded Australia, India and Japan) by pushing for an ASEAN + 6 agreement in regional discussions. RCEP negotiations commenced between the 10 ASEAN member states and the six countries[1] that had existing trade agreements with ASEAN in 2012. Commentators have noted that China likely agreed to broaden the membership in light of its exclusion from the TPP, while Japan's involvement in RCEP may have assisted its entry into the TPP (Hamanaka, 2014). It is noteworthy that former Japanese Prime Minister Yoshihiko Noda met with US President Barack Obama to ask for US support to join the TPP on the same day RCEP was launched (Hamanaka, 2014).

In February 2015, Japan's proposed intellectual property chapter for RCEP, dated 3 October 2014, was leaked online (Japan, 2015). The text showed that Japan was proposing a number of TRIPS-Plus measures that resemble those found in the final text of the TPP, such as expanded scope of patentability, patent term extension and data exclusivity (Table 2) (Townsend, Gleeson, & Lopert, 2016). Negotiating texts proposed by South Korea, ASEAN and India were also leaked in this period. The leaks revealed that the South Korea was also seeking high levels of IPRs (Korea, 2014), while ASEAN and India were seeking an agreement that did not go beyond TRIPS.

In April 2016, a leaked consolidated draft RCEP intellectual property chapter, dated 15 October 2015, was published by Knowledge Ecology International (RCEP, 2015). Some of Japan's initial proposals such as mandating the granting of patents for new uses and new forms of known substances, as well as a placeholder for patent linkage, did not appear in the draft, signalling the outright rejection of these measures by the other RCEP countries. Japan's proposal for patent term extension to compensate for delays in the marketing approval process (Article 5.13) and data exclusivity of "no less than five years" (Article 5.16) remained bracketed in the text and opposed by all the other negotiating countries.

Japan, together with South Korea and Australia, also pursued TRIPS-Plus intellectual property enforcement measures in RCEP (Médicins Sans Frontières, 2016). Japan sought compensation for damages via civil proceedings to be determined by "any legitimate measure of value the holder submits . . . which may include lost profits" (Article 9.2), a provision opposed by all other RCEP countries—including South Korea and Australia. In contrast, ASEAN and India proposed enforcement provisions that did not exceed TRIPS (Article 9.1) (Association of South East Asian Nations, 2016; India, 2014). Only Japan and South Korea appear to have opposed Article 5.7 "TRIPS Flexibilities on Compulsory Licenses and LDC Extensions," which acknowledges the right of parties to grant compulsory licenses, and supports the extension of the period for TRIPS compliance for least-developed countries.

RCEP is particularly significant for global access to medicines because it includes India, one of the world's major producers and exporters of generics. India is not only a source of generics for LMICs, but also supplies Japan, Europe and the United States. In 2014, more than a third of India's $11.7 billion pharmaceutical exports (including finished products and active pharmaceutical ingredients) went to the United States, representing 40% by volume of US' generic drug imports (Silverman, 2014; World's Richest Countries, 2016).

The apparent rejection of Japan's proposal to broaden and lengthen patent monopolies in RCEP is a positive move for health because it maintains flexibilities for countries to determine the criteria for patentable inventions. Japan's initial proposal to broaden the criteria for patentability appeared to particularly target recent developments in the Asia Pacific region led by India. Section 3(d) of India's Patents (Amendment) Act, 2005*Patents (Amendment) Act (2005)* excludes from patentable subject matter not only the mere discovery of a new form of a known substance where there is no enhanced efficacy, but also the new use of a known substance. Decisions to invalidate drug patents on these grounds have facilitated cheaper generic medicines in India but have been the subject of pharmaceutical industry litigation (Lawyers Collective, 2011; Third World Network, 2016).

The Philippines has legislated similar patentability criteria in its *Universally Accessible Cheaper and Quality Medicines Act (2008)* which excludes from patent protection "in the case of new drugs and medicines, the mere discovery of a new form or new property of a known substance which does not result in the enhancement of the known efficacy . . . or the mere use of a known process unless such known process results in a new product that employs at least one new reactant" (Sect 5. Art 22.1). China has also recently revoked patents for hepatitis B and cancer drugs on the grounds of lack of novelty. China has the greatest disease burden for chronic hepatitis B in the world and in 2014 lost funding support from the Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria, making the

TABLE 2 Select TRIPS-Plus provisions in Japan's 2014 proposed IP negotiating text to RCEP

Intellectual property measure	Japan's initial proposal to RCEP
Scope of patentable subject matter	"Each party shall ensure that a claimed invention is not excluded from the patentable subject matter solely on the ground that the invention is a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or that the invention is a new use for a known substance" (Article X.X.C.1 [2]).
Patent term restoration	"With respect to the patent which is granted for an invention related to pharmaceutical products, each Party shall, subject to the terms and conditions of its applicable laws and regulations, a compensatory term of protection for any period during which the patented invention cannot be worked due to the marketing approval process" (Article X.X.C.1 [5]).
Prohibition of requirement to demonstrate patents commercially worked	"No Party may require submission of information or statements as to the extent to which the patented invention has been commercially worked in the Party after the grant of such patent." (Article X.X.C.1 [11]).
Protection of pharmaceutical test data	"Each party shall prevent applicants for marketing approval for pharmaceutical products which utilize new chemical entities from relying on or from referring to test or other data submitted to its competent authority by the first applicant for a certain period of time counted from the date of approval of that application. As of the date of entry into force of this Agreement, such period of time is stipulated as being no less than six years by the relevant laws of each Party" (Article X.X.G.3 [1]).
Patent linkage	"Placeholder for provisions concerning the prevention of marketing approval procedure of pharmaceutical products infringing patent" (Article X.X.G.3 [2]).
Border enforcement measures—*ex-officio* suspension of release of suspected infringing goods, and on right holder's request	"Each party shall adopt or maintain procedures with respect to import and export shipments under which its customs authorities may act upon their own initiative to suspend the release of goods suspected of infringing rights to patents, utility models, industrial designs, trademarks, copyrights and related rights, and/or plant breeder's rights for new varieties of plants' (referred to as suspect goods) and a right holder may request its competent authorities to suspend the release of suspect goods" (Article X.X.H.1 [1])
Border enforcement measures—*ex-officio* seizure of suspected infringing goods in transit	"Each Party shall adopt or maintain procedures with respect to suspect goods in transit or in other situations where the suspect goods are under customs control under which hits customs authorities may act upon their own initiative to suspend the release of, or to detain, suspect goods. Note: For the purposes of this Article: (a) the term 'in transit' means under customs transit or transshipment; (b) the term 'customs transit'means the customs procedure under which goods are transported under

(Continues)

TABLE 2 (Continued)

Intellectual property measure	Japan's initial proposal to RCEP
	customs control from one customs office to another; and (c) the term 'transshipment' means the customs procedure under which goods are transferred under customs control from the importing means of transport to the exporting means of transport within the area of one customs office which is the office of both importation and exportation. (Article X.X.H.1 [2])
Rights holder determines damages (civil remedies)—compensation	"Each Party shall provide that, in civil judicial proceedings concerning the enforcement of intellectual property rights, its judicial authorities have the authority to order the infringer who, knowingly or with reasonable grounds to know, engaged in infringing activity to pay the right holder damages adequate to compensate for the injury the right holder has suffered as a result of the infringement" (Article XX.H.2 [1]).
Rights holder determines damages (civil remedies)—any legitimate measure of value the rights holder submits	"In determining the amount of damages referred to in paragraph 1, a Party's judicial authorities shall have the authority to: (a) consider, inter alia, any legitimate measure of value the right holder submits, which may include lost profits, the value of the infringed goods or services measured by the market price, or the suggested retail price" (Article XX.H.2 [2]).

Source: *Draft Text on Areas Not Covered in the Possible Common Elements from the 2nd WGIP1* Submitted by Japan October 3, 2014, at http://keionline.org/sites/default/files/RCEP_WGIP_JP_Revised_Draft_Text_3Oct2014. pdf (last visited 19 July, 2016).

need for affordable access to medicines critically important (Minghui, Scano, Sozi, & Schwartlander, 2015; Townsend, Gleeson, & Lopert, 2015). China's revocation of Novartis' cancer drug Glivec (Gleevec), on the grounds of lack of novelty and inventive step, has facilitated cheaper generic drugs, priced at US $603 compared to US $3,650 per month (Third World Network, 2016).

The omission of Japan's placeholder for a patent linkage provision in the consolidated draft is also an indicator of successful opposition to TRIPS-Plus standards by other RCEP countries. Patent linkage provisions are intended to prevent regulatory agencies from granting marketing approval of generic versions of still-patented products—even where the market entry of the generic may be non-infringing. Most of the RCEP negotiating countries do not have a patent linkage mechanism. The Philippines removed its patent linkage system in 2008 following Pfizer's litigation against the Bureau of Food and Administration for permitting the importation of generic amlodipine before the patent had expired (Rathod, 2010).

The consolidated draft text also no longer includes Japan's initial proposal for border enforcement measures for allegedly infringing products "in transit." This provision would have allowed the seizure of medicines considered non-infringing in the host and destination country but which are alleged to infringe IPRs in the transit country. In 2009, legitimate medicines en route from India to Brazil and Nigeria were seized in the Netherlands because they were deemed infringing in the transit country (Mara & New, 2009). Some of these medicines were returned to India, delaying access to generics in the destination countries. The omission of "in transit" in the consolidated text shows that there was likely strong resistance on the part of other RCEP countries.

5 | MAKING SENSE OF JAPAN'S NEWFOUND ROLE AS IP CHAMPION IN REGIONAL TRADE AGREEMENTS

Japan's newfound role as IPR champion in the region reflects a strategic shift since 2013 by the Government of Japan toward pharmaceutical export growth. Japan's economy faces increasing pressures; in 2015 national debt was 129% of

GDP and government expenditure on health was 10.3%, the highest in the OECD (OECD, 2015a). In addition, Japan has seen continued high growth in pharmaceutical spending with *per capita* expenditure increasing from $363 (US PPP) in 2000 to $718 (US PPP) in 2011, compared with the OECD average of $300 (US PPP) in 2000 and $498 (US PPP) in 2011 (OECD, 2015b). Spending on pharmaceuticals in Japan totalled US $752 billion in 2013 (OECD, 2015c).

In 2013 the Prime Minister of Japan Shinzo Abe launched his economic strategy "Abenomics" to bolster Japan's economy under three pillars; fiscal stimulus, monetary easing and structural reforms. The third pillar, the "most crucial component'" according to the OECD (OECD, 2015a), was the government's economic revitalization strategy "*Japan is Back"* in which Japan aims to raise its share of trade with countries with which it has economic partnership agreements from 19% (2012) to 70% by 2018 (Prime Minister of Japan and His Cabinet, 2013a). A key feature of the strategy is to bolster pharmaceutical export trade so that Japan will "lead the world in developing pharmaceuticals, medical devices, and regenerative medical products" (Prime Minister of Japan and His Cabinet, 2013a). Several components of this strategy have already been rolled out. Japan has established a Headquarters for Healthcare and Medical Strategy Promotion headed by Japan's Prime Minister Shinzo Abe, to determine priority research areas for government funding and set R&D budgets (Prime Minister of Japan and His Cabinet, 2013b). In May 2014 Japan introduced its "Act to Promote Healthcare and Medical Strategy," which aims to support R&D "by facilitating connections between basic research and clinical trials and accelerating the approval process for pharmaceuticals and medical devices" (Law Library of Congress, 2014). In 2014, the Japanese Government allocated US $1.4 billion to support pharmaceutical R&D dedicated to nine priority areas, including oncology and regenerative medicine (Law Library of Congress, 2014). In 2015, the Japanese Government also established the Japan Agency for Medical Research and Development, a center akin to the US National Institutes of Health (Japan Agency for Medical Research and Development, 2015).

Japan's strategy to bolster pharmaceutical exports and capture five trillion yen of the global pharmaceutical market by 2020 includes an explicit focus on expanding IP protection in the countries that trade with Japan. Indeed, raising the level of IP protection in ASEAN and China through trade partnerships like the TPP, RCEP and Japan–China–South Korea FTA is part of Japan's global outreach strategy (Prime Minister of Japan and His Cabinet, 2013c). The ASEAN-Japan Comprehensive Economic Partnership agreement, which came into force in 2008, committed to "explore and undertake economic cooperation on intellectual property along with energy, informational and communication technology, human resource development, transportation, environment, and competition policy" (Agreement on Comprehensive Economic Partnership among Japan and member states of ASEAN, 2008). With two-way trade between ASEAN and Japan totaling US $229.1 billion dollars in 2014, Japan has become ASEAN's third largest trading partner and second largest source of foreign direct investment (Ministry of Economy, Trade and Industry, 2012). Through their Strategic Economic Cooperation Roadmap (2012–2025), ASEAN and Japan aim to double these trade and investment flows by 2022 (Ministry of Economy, Trade and Industry, 2012). The negotiation of a Regional Comprehensive Economic Partnership agreement is one of the roadmap's strategic priorities. Since 2012, Japan and ASEAN Heads of Intellectual Property Offices have met regularly and endorsed a Memorandum of Cooperation on IP to "exchange experience and knowledge on industrial property policies, improve systems for protecting IP, streamline examination procedures, and cooperate in human resource development to improve the capabilities of ASEAN IP offices" (Association of South East Asian Nations, 2012a). It is worth noting here that Japan was also a prime mover of the Anti-Counterfeiting Trade Agreement (ACTA), (Legge, Gleeson, Lofgren, & Townsend, 2014) another TRIPS-Plus agreement focused on IP enforcement, signed by 31 countries, but to date ratified only by Japan (Japan Patent Office, 2013).

Japan's IP "outreach" policy also reflects the ambitions of the Japan Pharmaceutical Manufacturers Association (JPMA), the lobbying body for the research-based pharmaceutical industry. Since the 1990s many Japanese firms have transferred core operations overseas, becoming "transnational" in scope (Umemura, 2011: 30). The highest grossing pharmaceutical firm in Japan in 2014, Takeda, conducts research and development in Japan, the United States, United Kingdom, Brazil, Germany, China and Singapore, with manufacturing sites across the globe including Japan, Italy, Ireland, Germany, Austria, Denmark, Belgium, Norway, Poland, Russia, China, Indonesia, Mexico, Brazil, Argentina, Columbia, Estonia and India (Takeda, 2016). Many Japanese firms operate closely with foreign multinational pharmaceutical firms, a historical legacy of foreign ownership restrictions in Japan (McKinsey & Company, 2011). Foreign firms have also acquired Japanese firms

which now act as subsidiaries of global conglomerates. In 2002, the Swiss multinational Hoffman-La Roche acquired the eighth-largest pharmaceutical firm in Japan; Chugai Pharmaceutical Co (Chugai Pharmaceutical Co, 2016). The JPMA thus represents more than seventy pharmaceutical firms that operate in Japan and transnationally (JPMA, 2016a). As a global lobbying body, JPMA has criticized the IP laws of other Asia-Pacific countries (JPMA, 2016b: 76) and argued that compulsory licensing and "movements toward limitation of enforceability of patent rights, denial of patentability of inventions regarding crystal polymorphism and use, invalidation of patents based upon utility issues, court cases and amendments of law and examination guidelines that limit scope of patent rights regarding medicines" have weakened IP rights and "damaged the business environment . . . for the delivery of new medicines" (JPMA, 2016b). It is in this context of economic pressures, rising healthcare costs and lobbying by the multinational pharmaceutical industry that, since 2013 in particular, Japan has emerged as an IP aggressor in the TPP and RCEP.

6 | HOW CAN LMICS RESPOND TO JAPAN?

Low- and middle-income countries in the Asia–Pacific region face increasing pressures to adopt TRIPS-Plus measures in regional trade agreements. This paper has demonstrated that through the TPP and RCEP Japan is playing a key role in the expansion of intellectual property rights in the region. Japan's entry to the TPP negotiations was a significant factor in fracturing the other parties' opposition to the US proposals. Japan has since driven efforts to revive the agreement and maintain the substantive text with the remaining eleven parties. In RCEP, Japan, together with South Korea, has played a key role in proposing elevated levels of IPRs.

As highlighted above, a leaked consolidated IP draft showed strong opposition on the part of LMICs to several of Japan's TRIPS Plus proposals in RCEP. India appeared to be playing a key role in this opposition, alongside ASEAN. India has much to lose if its generic industry is restrained by elevated IPRs. LMICs in ASEAN are net IP importers and face increasing pressures to ensure access to affordable medicines for their populations. This is reflected in ASEAN's Intellectual Property Rights Action Plan (2011–2015), developed before the RCEP negotiations began, which commits to take into account "the diverse needs and varying levels of capacity of its Members States, and especially development-oriented concerns to contribute to the promotion of knowledge creation, technological innovation and transfer business generation in a manner conducive to the welfare of the region" (Association of South East Asian Nations, 2010). One of five ASEAN strategic goals is a "balanced IP system that takes into account the varying levels of development of Member States and differences in institutional capacity of national IP Offices" (Association of South East Asian Nations, 2010: 79), as well as the need to "maximize" the exercise of flexibilities under existing agreements in the region.

The initial signing of the TPP may have presented a challenge to ASEAN's position in RCEP because four of its member states—Brunei, Malaysia, Singapore and Vietnam—agreed to broadened IPRs in TPP. The withdrawal of the United States from the TPP, however, has appeared to tip the balance in favor of low- and middle-income countries. In November 2017, the remaining TPP parties successively suspended a number of the IPR provisions that the United States and Japan sought, as part of an in-principle deal for a Comprehensive and Progressive Agreement for Trans Pacific Partnership (CPTPP). These now suspended provisions include those requiring patents for new uses, methods and processes of existing products; extensions to patent terms; and data exclusivity, including for biologic medicines (DFAT, 2017). While a stronger health outcome would have been the removal of these provisions all together, their suspension is a positive move for low income countries and will likely influence the RCEP negotiations. ASEAN in particular has an opportunity to set the standard for IPRs in the region, one that reflects its differing members' levels of development.

The ability of LMICs to act as a bloc was key to the Doha Declaration on TRIPS and Public Health (2001), which came about through LMICs working on a shared position, supported by international advocacy groups. A group of African states led by Zimbabwe and supported by Latin American and Asia-Pacific countries called on other countries to agree in the World Trade Organization that "nothing in the TRIPS Agreement should prevent Members from taking

measures to protect public health" (World Trade Organization, 2001b). As Peter Drahos notes, "the Doha Declaration was about the weak networking networks that surrounded and eventually isolated the US and in the final instance its pharmaceutical industry" (Drahos, 2007). Drahos concluded that there are lessons from Doha for LMICs:

> *. . .they must have strategies for realizing the gains of negotiation, acting where they can on the basis of self-help and unilateral action. They have to avoid concessions that are encased in rule complexity. Most importantly, they have to find ways to develop a joint bargaining strategy on at least some intellectual property issues that will counter forum shifting. (Drahos, 2007: 39).*

In the TPP negotiations, LMICs Brunei, Chile, Malaysia, Mexico, Peru and Vietnam were not in an existing trade bloc, were geographically spread out, and had existing but variable arrangements with the United States. LMICs are likely to be in a stronger negotiating position with Japan and other high income countries in RCEP through the ASEAN bloc, in particular now that several contested IPR provisions have been suspended in the CPTPP.

In RCEP, ASEAN could point to the ASEAN-Japan Comprehensive Economic Partnership, signed in 2008, in which Japan agreed to recognize the different stages of economic development among ASEAN member states and between ASEAN and Japan. The agreement also set out to "be consistent with the rules and disciplines of the WTO," provide "special and differential treatment" to ASEAN Member States "in recognition of their different levels of economic development," and provide "additional flexibility" for newer ASEAN members (Association of South East Asian Nations, 2002). Furthermore, the ASEAN-Japan 10 year Strategic Economic Cooperation Roadmap (2012–2025) states that its goals and activities, including the negotiation of RCEP as a strategic priority, will be consistent with the ASEAN Framework for Equitable Economic Development: Principles for Equitable and Sustainable Development (Association of South East Asian Nations, 2012b). Japan's Patent Office has also recognized that the degree of IP protection and conditions for trade and investments differ significantly among developing countries, and that it is "essential to consider the priorities of each country" (Japan Patent Office, 2013: 138). Japan's TRIPS-Plus intellectual property proposal for RCEP is in many ways inconsistent with a focus on the needs of ASEAN countries.

LMICs can also point to the history of international norms and rules on IP prior to the signing of TRIPS. In the 1970s many countries, including high-income countries, did not provide pharmaceutical product and/or process patents (Townsend, 2016). Indeed, Japan's pharmaceutical industry emerged through import substitution industrialization policies in which Japan subsidized pharmaceutical production, placed quotas on pharmaceutical imports, prevented foreign firms from owning a majority stake in Japanese pharmaceutical firms, and importantly, did not provide product patents until 1976 (Umemura, 2011). Pharmaceutical production tripled in Japan between 1961 and 1975 while pharmaceutical trade quadrupled in this period, mainly through exports to developing countries. Japan's pharmaceutical industry was also bolstered by technology transfer between the United States and Japan after World War Two, and this has shaped Japan's role as a key global supplier of antibiotics today (Umemura, 2011: 18, 32). Japan's TRIPS-Plus stance in regional trade agreements is thus at odds with its own history of pharmaceutical development. Furthermore, OECD studies link the problem of rising pharmaceutical healthcare costs in Japan to its low use of generic medicines (OECD, 2015a, 2015b, 2015c). In 2013 generics accounted for 11% of Japan's pharmaceutical market (by value), compared to 24% in the OECD (average) (OECD, 2015b). Increasing the use of generics in Japan could moderate healthcare costs, but such a move may be limited by higher levels of IP protection that Japan is itself seeking in these trade agreements.

7 | CONCLUSION

High levels of intellectual property protection create barriers for access to medicines when monopoly protections enable unconstrained pricing. Despite the establishment of a global IP regime via TRIPS, the United States and

European Union have since pressured other countries to adopt increasingly TRIPS-Plus IPRs through bilateral and plurilateral trade agreements. These provisions broaden and lengthen medicine monopolies and contribute to high healthcare costs by delaying the entry of generic medicines. This paper has examined the emerging role of Japan in negotiations for two significant regional trade agreements: the Trans Pacific Partnership Agreement and the Regional Comprehensive Economic Partnership agreement, and the emergence of its key role as a proponent of elevated levels of IPR protection. Low and middle-income countries participating in RCEP discussions are best placed to maintain an ASEAN-centered position on IPR that reflects their respective needs and levels of development.

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ENDNOTE

[1] The six countries that have existing trade agreements with ASEAN include Australia, New Zealand, India, China, Japan and South Korea.

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