BOSTON UNIVERSITY Global Development Policy Center

GEGI WORKING PAPER 044 • 04/2021

Future Trade & Investment Commitments and Access to Medicines

U.S.-Kenya FTA and Safeguarding Public Health

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ABSTRACT

Given that the negotiating text of the U.S.-Kenya Free Trade Agreement is not yet public, this legal analysis compares the texts of other recently negotiated trade agreements to predict what the U.S. agenda will be, and provides recommendations for Kenya during the negotiating process. The analysis shows that apart from patent linkage, the intellectual property provisions common in U.S. agreements that appear most likely to be introduced are not accepted outside of that context. While the renegotiated United States-Mexico-Canada Agreement brought back many provisions that were hitherto suspended under the Comprehensive and Progressive Trans Pacific Partnership, the Regional Comprehensive Economic Partnership does not pursue the same agenda. Instead, the latter keeps some of the most important flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS), as enshrined in the Doha Declaration on the TRIPS Agreement and Public Health. Kenya should pursue a negotiating agenda in intellectual property that imitates the RCEP model rather than adopting the U.S. approach.

Keywords: free trade agreements, public health, access to medicines, investment agreements, Kenya

According to the Office of the United States Trade Representative (USTR), the United States has free trade agreements (FTAs) with about 20 countries (USTR n.d.). Usually, signing an FTA with the U.S. is presented as a matter of national pride, but there are inherent risks and danger that comes with it for an unprepared party. Consequently, it would be prudent for Kenya to closely study and learn from the experience of other countries that have signed an FTA with the U.S. in order to avoid mistakes that could prove to be costly including in the arena of public health and specifically in relation to access to medicines.

The U.S.-Kenya FTA negotiations were launched on July 8, 2020, and the talks are expected to be concluded by the end of 2021. Due to the COVID-19 pandemic, most discussions are happening online and the texts of the negotiation are secret. The lack of transparency in the process has made it hard for experts to contribute to the process.

This article therefore focuses on speculating about what Kenya should expect in the intellectual property (IP) chapter of the U.S.-Kenya FTA, and how it should deal with it. IP norms have continued to evolve rapidly and controversially in the recent past following the adoption of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) at the World Trade Organization (WTO). The TRIPS Agreement has effectively succeeded in making IP part of the global agenda in trade liberalization which is part of the free trade agenda or capitalist economic order.

The U.S., through FTAs, has taken upon itself to continue pushing for more and stronger protection and enforcement standards in the IP sector, signaling its dissatisfaction with the TRIPS Agreement standards. This article therefore analyzes the key provisions that are likely to be pursued by the U.S. as part of its agenda to enhance the standards under the TRIPS Agreement.

Much reliance will be made on the U.S.'s past experience in the renegotiations that led to the signing of the United States - Mexico - Canada Agreement (USMCA) in 2018, which entered into force in July 2020, effectively replacing the North American Free Trade Agreement (NAFTA), which entered into force in January of 1994 (USMCA 2020).

The U.S. predisposition in the U.S.-Kenya FTA is therefore expected to be maximalist because the USMCA has succeeded in entrenching provisions that go beyond what is required under the TRIPS Agreement (TRIPS-plus standards). Moreover, the U.S. will be looking to replicate the North American success in Africa in order to achieve a much broader consensus in its position regarding IP protection and enforcement standards.

The Comprehensive and Progressive Trans-Pacific Partnership (CPTPP) Agreement will also be utilized in this study to provide more emphasis on the agenda currently being pursued by the U.S. through FTAs, and how there have been a significant push back to defeat the agenda by other countries acting in concert and without the support of U.S.[1] The CPTPP is a revision of the massive Tans-Pacific Partnership (TPP) Agreement, signed in February 2016, involving 12 countries. An agreement to revise the TPP to the CPTPP was reached in May 2017 despite U.S. opposition. The CPTPP, unlike the USMCA, therefore reflects emerging international consensus on IP. The U.S., through other FTAs, will therefore seek to overturn this CPTPP hangover effect by trying to sign more FTAs with more countries including in Africa to shore up its numbers.

Lastly, reference will also be made to the world's largest FTA, the Regional Comprehensive Economic Partnership (RCEP), which was recently signed on November 15, 2020 by fifteen nations in the Asia-Pacific region comprising of the Association of Southeast Asian Nations (ASEAN) members

[1] The countries that are part of CPTPP include Australia, Brunei Darussalam, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, United States, and Vietnam.

plus another five among the Asia-Pacific countries.[2] The FTA is significant for two reasons. The first is that it was negotiated for eight years and covers a population region of 2.2 billion, representing a third of the economies in the world, including China, and as such it reflects a significant consensus on matters of trade (dw.com 2020). Second, RCEP has a best practice model provision in relation to IP, public health and access to medicines (RCEP Ch. 11 2020).

Other areas that will be briefly discussed in this article are the *Bolar* exceptions, patent opposition and investor state dispute settlement (ISDS) system.

THE CONTEXT OF U.S.-KENYA FTA NEGOTIATIONS

The U.S. and Kenya have been trading partners for many years. The nature of this trade has reflected the economic strength of each country. Kenya's imports into the U.S. is therefore largely agricultural, whilst U.S. exports to Kenya are largely knowledge or technology-based, and therefore IP is more crucial to the U.S. than Kenya. It is expected therefore that the Agriculture and IP chapters will be most controversial during the ongoing negotiations.

Both the U.S. and Kenya recognize the imperative of negotiating a bilateral FTA. The most pressing matter is that the African Growth Opportunity Act (AGOA) is expected to expire in 2025 and Kenya is desirous of maintaining its duty free market access in the U.S. Since the AGOA may not be extended, a freely negotiated FTA based on the principle of reciprocity and international trade law will most likely fill the gap in order to at least ensure that Kenya in particular continues to receive preferential U.S. market access for some of its key exports to the U.S. The U.S. on the other hand will be keen to ensure that it uses this platform to continue building international consensus in terms of the new and controversial IP provisions aimed at stronger protection and enforcement. The WTO framework continues to be the basis upon which the negotiations must be hinged.

The journey towards this bilateral trade relationship started in in 2018 when President Uhuru Kenyatta and President Donald Trump entered into a strategic partnership arrangement and established the Trade and Investment Working Group (TIWG). The TIWG's objectives covered the following thematic areas: maximizing the remaining years of AGOA; strengthening commercial cooperation between the two countries; developing short-term solutions to reduce barriers to trade and investment; and exploratory talks of future Kenya-U.S. bilateral trade and investment relations (MoITED 2020a). The work done by the TIWG, especially in the last objective, led to the launch of the U.S.-Kenya FTA negotiations.

On February 6, 2020, the U.S. and Kenya, formally communicated their intention to enter into negotiations. Despite the raging COVID-19 pandemic, especially in the U.S., both countries have stayed the course (MoITED 2020a).

On July 8, 2020, less than six months later, the Office of the United States Trade Representative (USTR) released a joint statement announcing the formal launch of trade agreement negotiations between the United States and Kenya.[3] The launch of the talks and much of the negotiation has continued to be done online. So far, civil society and other actors have not been invited to participate

[2] The RCEP signatory states include China, Japan, South Korea, Australia, New Zealand and the 10 countries of the Association of Southeast Asian Nations (ASEAN), i.e. Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand, and Vietnam.

[3] 'Joint Statement Between the United States and Kenya on the Launch of Negotiations Towards a Free Trade Agreement' (*U.S. Embassy in Kenya,* 9 July 2020) <https://ke.usembassy.gov/joint-statement-between-the-united-states-and-kenya-on-the-launch-of-negotiations-towards-a-free-trade-agreement/> accessed 11 January 2021.

and the drafts have not yet been released to the public. The lack of transparency in the process has made many stakeholders concerned, especially in the area of access to medicines.

The U.S. vision in the negotiations that have been launched is "to conclude an agreement with Kenya that can serve as a model for additional agreements in Africa, leading to a network of agreements that contribute to Africa's regional integration objectives" (USTR 2020). Therefore, the U.S. has a futuristic vision, which is to sign many other FTAs with African countries, and the Kenyan FTA will be the template for future engagement with other African states.

Kenya, sitting on the other side of the negotiating table has also clearly communicated its expectations through its trade officials. According to Kenya, "[t]he success of the negotiations is particularly critical because of the need to secure a trade and investment relationship between the two countries ahead of the anticipated lapse of the [AGOA]" (MoITED 2020b). Kenya's interest in the FTA appears to be motivated by the need to safeguard preferential duty free market access under the AGOA.

OVERVIEW OF NEGOTIATION OBJECTIVES FOR KENYA AND U.S.

The negotiation objectives are usually the first place one looks for an indication of how a country intends to negotiate. Both Kenya and the U.S. have defined their negotiation objectives in relation to the IP chapter as subsequently elaborated.

Kenya's Negotiation Objectives for the IP Chapter

Before delving into the objectives, Kenya's principles that will guide its negotiations with the U.S. are stated as follows:

> (i) The FTA will be WTO compatible and will allow for application of the "Special and Differential Treatment"
>
> (ii) The FTA will be an instrument for economic and trade development.
>
> (iii) The FTA negotiations shall respect the commitments that Kenya has taken at the Multilateral (WTO), Continental (AfCFTA), Regional (EAC, COMESA, TFTA) and Bilateral levels
>
> (iv) The FTA will preserve and build on AGOA *acquis*
>
> (v) The Negotiations shall cover substantially all trade
>
> (vi) Any EAC Partner State that did not participate in these negotiations at the outset should be allowed to join the negotiations, subject to terms and conditions already agreed or accede to the concluded FTA. (MoITED 2020c)

From the above, it confirms that Kenya's focus is to extend the benefits already accrued under AGOA beyond the expiry date. However, the principle aimed at ensuring that the FTA is WTO compatible should not be interpreted as to allow for higher standards than those available under the WTO including TRIPS-plus provisions in relation to the IP chapter.

Further, in relation to the IP chapter, Kenya has outlined the following objectives to guide its negotiations with the U.S.:

> (i) The text on intellectual property in the Kenya - U.S. FTA shall aim to reduce IP-related barriers to trade and investment by promoting economic integration and cooperation in the utilization, protection and enforcement of intellectual property

> rights. It shall cover other intellectual property areas covered by the Convention on Biodiversity, including genetic resources, folklore, traditional knowledge, and benefit sharing.
>
> (ii) Capacity building and technical assistance will be provided to Kenya in order to fully implement the agreed provisions on IP rights. (MoITED 2020c)

From the above, Kenya's focus appears to be two-fold: first, to reduce IP-related barriers to trade and investment while expanding IP to cover new areas important to developing countries such as traditional knowledge and biodiversity; and second, to ensure the provision of technical assistance and capacity building by the U.S. to Kenya on IP.

Interestingly, Kenya's objectives did not expressly provide for the need to safeguard the policy space for development including in public health. A good way to ensure that the same is achieved is through including an objective for the implementation of the 2001 Doha Declaration on the TRIPS Agreement and Public Health.

The above idea is not far-fetched because a review of the RCEP FTA reveals that one of its provisions, specifically Article 11.8, dealing with the TRIPS Agreement and public health is extensive and protects the public health and access to medicines in the most liberal manner. Article 11.8.1(a) provides that "the Parties reaffirm the *Doha Declaration on the TRIPS Agreement and Public Health* adopted on 14 November 2001" and specifically "the Parties affirm the right to fully use the flexibilities as duly recognized in the Doha Declaration on the TRIPS Agreement and Public Health" (RCEP art. 11.8.1)

US Negotiation Objectives for the IP Chapter

Unlike Kenya, the U.S. doesn't have negotiation principles but it has compensated for this by providing for some overall objectives guiding the negotiations as follows:

> (i) Seek a mutually beneficial trade agreement that can serve as a model for additional agreements across Africa.
>
> (ii) Support regional integration, where appropriate.
>
> (iii) Build on the objectives of the AGOA, promote good governance and the rule of law.

From the above and specifically from an IP perspective, the first overall objective is significant because it clearly illustrates that the U.S.-Kenya FTA will indeed be a model FTA for other similar agreements in Africa. Because of this, the FTA will be very important as it will influence future trade and investment landscape in the continent.

The specific objectives for the initiation of negotiations in the area of intellectual property are further stated as follows:

> Promote adequate and effective protection of intellectual property rights, including through the following:
>
> (i) Obtain commitments to ratify or accede to international treaties reflecting best practices in intellectual property protection and enforcement;
>
> (ii) Provide a framework for effective cooperation between Parties on matters related to the adequate and effective protection and enforcement of intellectual property rights;

(iii) Promote transparency and efficiency in the procedures and systems that establish protection of intellectual property rights, including making more relevant information available online;

(iv) Seek provisions governing intellectual property rights that reflect a standard of protection similar to that found in U.S. law, including, but not limited to, protections related to trademarks, patents, copyright and related rights (including, as appropriate, exceptions and limitations), undisclosed test or other data, and trade secrets; Provide strong protection and enforcement for new and emerging technologies and new methods of transmitting and distributing products embodying intellectual property, including in a manner that facilitates legitimate digital trade, including, but not limited to, technological protection measures;

(v) Ensure standards of protection and enforcement that keep pace with technological developments, and in particular ensure that rights holders have the legal and technological means to control the use of their works through the Internet and other global communication media, and to prevent the unauthorized use of their works;

(vi) Prevent or eliminate government involvement in the violation of intellectual property rights, including cyber theft and piracy;

(vii) Secure fair, equitable, and nondiscriminatory market access opportunities for U.S. persons that rely upon intellectual property protection;

(viii) Prevent or eliminate discrimination with respect to matters affecting the availability, acquisition, scope, maintenance, use, and enforcement of intellectual property rights;

(ix) Respect the Declaration on the TRIPS Agreement and Public Health, adopted by the WTO at the Fourth Ministerial Conference at Doha, Qatar, on November 14, 2001, and ensure that the Agreement fosters innovation and promotes access to medicines, reflecting a standard similar to that found in U.S. law;

(x) Prevent the undermining of market access for U.S. products through the improper use of Kenya's system for protecting or recognizing geographical indications, including any failure to ensure transparency and procedural fairness, or adequately protect generic terms for common use; and

(xi) Provide the means for adequate and effective enforcement of intellectual property rights, including by requiring accessible, expeditious, and effective civil, administrative, and criminal enforcement mechanisms. Such mechanisms include, but are not limited to, strong protections against counterfeit and pirated goods (USTR 2020).

From the above, the U.S. appears to have more negotiation objectives than Kenya and this confirms the fact that IP is as important for the U.S. as perhaps agriculture would be for Kenya. In the context of the current analysis, objectives number four, five and nine are interesting because there is a clear intention to import the IP standards from the U.S. into Kenya. It is not clear how such a move will be consistent with objective number nine, which is about respecting the Doha Declaration on the TRIPS Agreement and Public Health, since stronger IP protection beyond what is internationally

sanctioned by TRIPS has often led to adverse impacts on the public health system of many developing countries.

In fact, during this COVID-19 era, IP has been flagged as one of the main barriers to access to vaccines and needed medicines in both developing and developed countries. In fact, Kenya has joined other countries like South Africa and India to ask the WTO on October 2, 2020 for a waiver of their IP obligations during the COVID-19 pandemic more effectively (Medecins Sans Fontieres 2020).

SOME PROBLEMATIC TRIPS-PLUS PROVISIONS

The fourth objective of the USTR negotiating objectives is indicative of what is to be expected during the negotiations, and may be used to fundamentally alter the IP landscape in Kenya and the entire continent if left unchecked. It is therefore incumbent that a careful analysis of the same be done in order to understand its implications on future trade agreements in the continent with special focus on intellectual property and access to medicines.

The areas to watch out for during the Kenyan negotiations in particular include: secondary patents; patent term extensions; compulsory license restrictions; pharmaceutical data protection; biologics exclusivity; and patent linkage. These areas have been described in details below starting from the TRIPS standard and the way the U.S. has developed the same in other FTAs starting from the oldest to the newest FTA.

Secondary Patents

Secondary patents have the effect of prolonging the life of a patent as well as delaying the introduction of generic competition.

The TRIPS Agreement has clear provisions with regard to patents. Section 5 Article 27(1) of the TRIPS Agreement provides for the patentability criteria as follows:

> Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

The criteria for granting a patent is, as such, very clear from the above provision, and the test to be applied is threefold, to wit, (1) new, (2) involve an inventive step and (3) is capable of industrial application.

The FTAs signed by the U.S. however have continued to expand the patentability criteria by introducing lower standards for patentability.

In particular, USMCA Article 20.36(2) provides that "each party confirms that patents are available for inventions claimed as at least one of the following: new uses of a known product, new methods of using a known product, or new process of using a known product."

It is important to note that similar provisions as USMCA Article 20.36(2) could not be sustained under the CPTPP since its Article 18.37(2) was suspended pursuant to Article 17(b)(i). The suspended Article 18.37(2) stated as follows:

> ...each Party confirms that patents are available for inventions claimed as at least one of the following: new uses of a known product, new methods of using a known product, or new processes of using a known product....

RCEP on the other hand chose to maintain the patentability criteria provided for under the TRIPS Agreement pursuant to its Article 11.36.

Kenya continues to maintain a higher patentability standard in its Industrial Property Act (IPA), 2001. Section 22 provides that "[a]n invention is patentable if it is new, involves an inventive step, is industrially applicable or is a new use." However, in practice patents have been issued for new forms, uses and methods, which means that secondary patents are a problem in the country.

To deal with the problem of secondary patents, India has taken a very bold step in its patent legislation reforms that introduced an express provision, section 3(d), to prohibit any attempt to allow for secondary patents or eradicate the problem of 'ever-greening' of patents. The relevant section states as follows:

> The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant, is not patentable.

The Indian patent law reform is very important because it eliminates the problem of secondary patents, or ever-greening, including, as a matter of practice, as is the case in Kenya. Kenya should therefore consider adopting such a clear provision to avoid future policy restrictions included in the U.S.-Kenya FTA.

Patent Term Extensions

Patent term extension has the effect of prolonging the number of years in which a patent subsists by compensating for regulatory delays experienced after the filing date. This includes during patent exams or during the regulatory marketing approval stage.

The benchmark of the patent term is TRIPS Article 33, which provides as follows:

> The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.

From the above, the TRIPS Agreement only requires a minimum protection period of 20 years from the filing date and not from the approval date.

In the USMCA, the above provision has been enhanced under Article 20.44 dealing with patent term adjustment for unreasonable granting authority delays. Under Article 20.44(3), the patent term has been extended as follows:

> If there are unreasonable delays in a Party's issuance of a patent, that Party shall provide the means to, and at the request of the patent owner shall, adjust the term of the patent to compensate for those delays.

The FTA further defines what unreasonable delay means and notes that it must "include a delay in the issuance of a patent of more than five years from the date of filing of the application in the territory of the Party, or three years after a request for examination of the application has been made, whichever is later" (USMCA art. 20.44)

In this regard, therefore, the FTA allows for patent term extension beyond 20 years to compensate for the unreasonable delays described above.[4]

Another relevant provision in this category is Article 20.46 which deals with patent term adjustment for unreasonable curtailment. Article 20.46(3) provides for regulatory review compensation as follows:

> With respect to a pharmaceutical product that is subject to a patent, each Party shall make available an adjustment of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process.

The above provision, Article 20.46(3), has the same effect as Article 20.44(3) in that both provisions extends the time for patent protection to more than 20 years after the filing date as sanctioned by the TRIPS Agreement.[5]

RCEP on the other hand adopts a different approach to this issue. Instead of allowing for patent term extensions, it provides for a procedure known as expedited examination under its Article 11.46 as follows: "Each party shall endeavor to provide for domestic procedures for a patent applicant to request to expedite the examination of its patent application in accordance with that Party's laws, regulations and rules."

The U.S.-Kenya FTA should follow the CPTPP by fully excluding such provisions, or the RCEP route of providing expedited procedures to patent applicants, to avoid unnecessary patent term extensions beyond 20 years after the filing date. This is in accordance with the relevant section of the Kenyan patent law. Section 60 of the IPA, 2001 provides that "[a] patent shall expire at the end of twenty years from the filing date of the application."

Compulsory License Restrictions

The U.S. patent law allows for compulsory licensing without much restriction. In this regard, U.S. law provides that:

> "Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture" (28 U.S.C. § 1498(a))

Consequently, the only remedy available for infringement is a claim for "reasonable and entire" compensation in the United States Court of Federal Claims. Other than that, the government is free to infringe on any patents within its territory.

[4] A similar provision under CPTPP Article 18.46(3) was suspended according to Article 7(c) of the CPTPP Annex including its footnotes 36-39.

[5] A similar provision under CPTPP Article 18.48 was suspended according to Article 7(d), CPTPP Annex including footnotes 45-48.

At the international level, Article 31 of the TRIPS Agreement deals with the use of patented knowledge or products without the authorization of the patent holder. The majority of that section, however, provides for an elaborate set of conditions that must be met, the most controversial of which is found in subparagraph f. This paragraph requires 'any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use.'

The paragraph 31(f) provision among others was dealt with under the Doha Declaration on the TRIPS Agreement and Public Health which was adopted on November 14, 2001. Its paragraph 6 reiterated that:

> "We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002" (WTO 2001).

From the above, it became clear that limiting compulsory licensing to the domestic market alienated many poor countries and this restricted access to medicines.

Therefore, the Council for TRIPS in its decision of August 30, 2003 noted as follows:

> "The obligations of an exporting Member under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out below in this paragraph..." (WTO 2003, para. 2).

From the above, it became possible for compulsory licensing to be able to benefit least-developed countries deemed to have insufficient or no manufacturing capacities.

On December 6, 2005, The TRIPS Council further proposed an amendment of the TRIPS Agreement thereby effectively dealing with the challenge at hand (WTO 2005).

Despite the above developments, an FTA may undermine the capacity of a country to enjoy the provisions. Illustratively, the U.S. has succeeded in getting some conditions listed in FTAs including the U.S.-Jordan FTA, making it hard to exploit this flexibility. In this regard, it states as follows:

> 20. Neither Party shall permit the use of the subject matter of a patent without the authorization of the right holder except in the following circumstances:
>
> (a) to remedy a practice determined after judicial or administrative process to be anti-competitive;
>
> (b) in cases of public non-commercial use or in the case of a national emergency or other circumstances of extreme urgency, provided that such use is limited to use by government entities or legal entities acting under the authority of a government; or
>
> (c) on the ground of failure to meet working requirements, provided that importation shall constitute working.
>
> Where the law of a Party allows for such use pursuant to sub-paragraphs (a), (b) or (c), the Party shall respect the provisions of Article 31 of TRIPS and Article 5A(4) of the Paris Convention. (U.S.-Jordan Art. 4.20)

On the flipside, the recently signed RCEP has fully embraced TRIPS Agreement flexibilities including compulsory licensing. The relevant texts for this include Article 11.8(2) and (3) which state as follows:

> 2. In recognition of the Parties' commitment to access to medicines and public health, this Chapter does not and should not prevent the effective utilization of the Article 31 bis of the TRIPS Agreement.
>
> 3. The Parties recognize the importance of contributing to the international efforts to implement Article 31 *bis* of the TRIPS Agreement, and the Annex and Appendix to the Annex to the TRIPS Agreement.

The above provision is a big departure from the U.S.-Jordan FTA and Kenya should be well advised to choose the RCEP approach accordingly.

It is important to note that Kenya already has compulsory licensing provisions under section 80, subsection 9 of its IPA, 2001. The law places no restriction in terms of supplying foreign markets since the provision states: "the exploitation of the invention pursuant to an order under this section shall be primarily for the supply of the market in Kenya." The above pro-public health standard should therefore be maintained even during the negotiations.

Pharmaceutical Data Protection

There is often a confusion between trade secrets and pharmaceutical data protection as enshrined under many FTAs. Cook provides three explanations to distinguish between regulatory data protection from confidential information protection or trade secrets. He observes that even though some argue that regulatory data can be protected under the law governing confidential information,

> "[t]rade secret law has proved inadequate for protecting data filed with regulatory authorities. First, the issue has not been about the disclosure of data but about its use (although freedom of information considerations today make a limited measure of disclosures inevitable, which can undermine its confidential nature.) Second, it is unclear whether regulatory authorities in fact do 'use' the data in a way that is subject to the law of confidential information, especially when officials merely rely on the existence of such data and do not actively refer to it. Third, even assuming that such reliance does constitute use, is there some 'public policy' or 'implied permission' defense that permits this use?" (Cook 2007)

Cook also explains why a patent alone is inadequate to protect innovation in all areas of pharmaceuticals and agrochemicals and therefore the need for data exclusivity as follows:

> "This objection (on another system or data exclusivity as opposed to patent), however, fails to recognize that proving safety and efficacy for regulatory authorities is a very different matter from demonstrating that an invention is patentable. From a regulatory perspective, much of the required expenditure of time and money is directed to R&D that rarely yields patentable inventions." (Cook 2007)

In other words, regulatory data protection is important to protect both data that is patentable and non-patentable and especially the latter. Indeed, depending on the patent system of a particular country,

> "patent protection for a product approved by regulatory authorities may be very weak or impossible to obtain, especially when the patent protection is not for a

> new chemical entity or other new active substance but is instead for a new physical form, new formulation, new synthetic process, or new use of an old substance. Such 'second generation' patents are at greater risk of successful attacks on their validity, because patent validity depends less on the work done to bring inventions to market, or to prove that inventions are safe and efficacious, than on the discovery of the invention in the first place. Such patent validity considerations are wholly unrelated to regulatory data protection, which may therefore provide the sole protection for a medicinal product." (Cook 2007)

In the U.S., drugs were approved for safety only before 1962 and this only changed as a result of the Thalidomide problem in children in which both safety and efficacy of a drug had to be proved before approval, in what is known as the 1962 amendments to the Federal Food and Drug, and Cosmetic Act (Mossinghoff 1999). Similarly, prior to 1962, generic medicines could be approved on the basis of "paper" new drug applications (NDA) and there was no requirement of data (Mossinghoff 1999). The Public Law 98-417 (Hatch-Waxman Act) enacted in 1984 imposes a five-year data exclusivity period for new molecular entities (NMEs) and a three-year data exclusivity period for supplements requiring clinical trials (Mossinghoff 1999).

At the international level, Article 39(3) of the TRIPS Agreement also provides for the protection of undisclosed information as follows:

> "Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use."

The TRIPS Agreement provision therefore does not specify the manner and timelines for such protection, thereby allowing member countries the discretion to decide.

The USMCA, Article 20.48(1)(a) provides that

> "[i]f a Party requires, as a condition for granting marketing approvals for a new pharmaceutical product, the submission of undisclosed test or other data concerning the safety and efficacy of the product, that Party shall not permit third persons, without the consent of the person that previously submitted that information, to market the same of a similar product on the basis of:
>
> (i) that information, or
>
> (ii) the marketing approval granted to the person that submitted that information,
>
> For at least five years from the date of marketing approval of the new pharmaceutical product in the territory of the Party."

What is provided for under the USMCA is therefore marketing exclusivity for five years. There is no specific provision on data exclusivity. The five years' exclusivity period is consistent with the U.S. Hatch-Waxman Act provision.[6]

[6] As is now clearly the trend, Article 18.50 of the CPTPP providing for the same was suspended according to Article 7(e), CPTPP Annex including footnotes 50-57.

In Kenya, there is no similar provision in the Pharmacy and Poisons Act relating to either data exclusivity or marketing exclusivity, which are both forms of regulatory exclusivity.

The U.S.-Kenya FTA may therefore seek to introduce such provisions into the Kenyan legal system.

Biologics Exclusivity

Related to pharmaceutical regulatory data protection is the protection of biologic data or biologic exclusivity.

It is important to note that there is no specific provision on biologic exclusivity under the TRIPS Agreement. Therefore, any provision on this is TRIPS-plus and represents no international obligation(s) for countries. Some countries like the U.S. however, have specific provisions addressing the same.

In the U.S., the term biologics and biosimilar are defined under section 262(i)(1) of the Price Competition and Innovation Act (BPCIA) as follows:

> "The term 'biological product' means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative or arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human being" (USCODE 2010).

It should be noted that the BPCIA under the same section 262(i)(7)(A) and (B) provides for a 12 year effective date of biosimilar application approval or marketing exclusivity and a 4 year filing period data exclusivity period. The U.S. therefore has both a data exclusivity and marketing exclusivity period of 12 and 4 years respectively in relation to biologics (AJMC 2019).

Biologic exclusivity became a prominent issue during the negotiations leading up to the adoption of the USMCA. NAFTA Chapter 17 on intellectual property and specifically Article 1711 did not directly address biologics and but this changed with the introduction of Article 20.49.1 of the USMCA, which has a biologic product marketing exclusivity provision and not a data exclusivity. The section provides as follows:

> With regards to protecting new biologics, a Party shall with respect to the first marketing approval in a Party of a new pharmaceutical product that is, or contains, a biologic, provide effective market protection through the implementation of Article 20.48.1 (Protection of Undisclosed Test or Other Data) and Article 20.48.3 (Protection of Undisclosed Test or Other Data), *mutatis mutandis,* for a period of at least ten years from the date of first marketing approval of that product in that Party.

The new provision is expected to strengthen the previous standard, and specifically NAFTA's Article 1711(6) on trade secrets and specifically marketing exclusivity for pharmaceutical products (not biologics) which interpreted "reasonable period" to mean "not less than five years from the date which the Party granted approval to the person that produced the data for approval to market its product…."

Also, the ten year period is indeed an enhancement of the eight year period proposed under the CPTPP but now remains suspended.

Another important consideration in relation to biologics is that "[i]t has been argued that the USMCA would expand the scope of products subject to the BPCIA's exclusivity provisions. The definition of 'biologic product' under the BPCIA specifically excludes 'chemically synthesized polypeptides,' and therefore such drugs are not subject to the BPCIA's exclusivity provision. The USMCA provision does

not include this exception and arguably would require an expansion to the scope of products currently eligible for exclusivity under the BPCIA" (AJMC 2019).

Further, "[t]he USMCA would require stronger marketing exclusivity protections for reference biologic products in Canada and Mexico. Canada's Food and Drug Regulations currently provide only 6 years of data exclusivity and 8 years of marketing exclusivity. Mexico's Industrial Property Law does not provide for a specific period of regulatory exclusivity, except to state that information regarding safety and efficacy of pharmaceutical products 'shall be protected under the terms of the international treaties to which Mexico is party'" (AJMC 2019).

Suffice to note the RCEP has no provision on biologics exclusivity and this is a significant indicator that Kenya should also avoid such provisions on biologics altogether. Kenya's IP law likewise has no similar provision on biologics exclusivity and this will therefore be a major development in the IP landscape in the country and beyond.

Judging from the above analysis, the protection of biologics exclusivity has undergone rapid development and it is also possible that the U.S. may use Kenya as a test-case for developing further its biologics sector for health and other reasons.

Patent Linkage

Patent linkage is provided for under USMCA Article 20.51 under measures relating to the marketing of certain pharmaceutical products.

Patent linkage is definitely a TRIPS-plus measure because it "ties the granting of marketing approval by regulatory agencies to the status of a patent" and is considered "one of the most regressive provisions in terms of access to medicines given that it tilts the market in favor of originator companies at the expense of generics" (Jorge 2019). Accordingly, the USMCA Agreement provides two alternatives to patent linkage as follows: "1) no mandatory linkage, but requiring countries to provide a fair court system to ensure the timely resolution of patent disputes; or 2) mandatory linkage." Jorge notes that the first option goes beyond what is available under the U.S. law because:

> "Option 1 follows the New Trade Policy or May 10th Agreement which was a renegotiation of the Agreement the U.S. negotiated with Colombia, Peru and Panama under which linkage was no longer mandatory. However, this provision includes a notification requirement that goes beyond the notification required under U.S. law where notification is required only in certain circumstances under the Hatch-Waxman Act and only a small molecule drugs (it does not extend to biologics). In general, it applies only to *product and methods of use patents listed in FDA's Orange Book*" (emphasis in original). (Jorge 2019)

The second option is clearly beyond the U.S. law and would therefore be the most broad linkage ever because the U.S. has mandatory patent linkage in only three types of patents as follows: "for patents that claim the drug substance (active ingredient), drug product (formulation and composition), or method(s) of use, and only a small molecule drugs, it does not extend to biologics" (Jorge 2019).

Unlike other TRIPS-plus provisions discussed above that have been suspended, similar provisions have not been suspended and still remains in force under Article 18.53 of the CPTPP.

RCEP has no provisions on patent linkage and as such this represents the best practice.

Kenya currently has no patent linkage provisions in its patent law and as such this would be a new addition through the U.S.-Kenya FTA judging from the emerging consensus reflected above.

OTHER IMPORTANT PROVISIONS, WHICH SHOULD BE INCLUDED

Another area that Kenya should pay keen attention to during the negotiations is the introduction of provisions to provide for *Bolar* exceptions, patent opposition as well as the ISDS mechanism.

Bolar Exceptions

The *Bolar* exception is one of the flexibilities available under the TRIPS Agreement Article 30, which provides as follows:

> Members may provide limited exceptions to the exclusive rights conferred by a patent, 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 into account of the legitimate interest of third parties.

Bolar exception flexibility is normally used by many countries to advance science and technology by allowing researchers utilization of "patented invention for research, in order to understand the invention more fully" (WTO n.d.). Some countries allow for the generic drug industry to exploit patents for purposes of market approval so that their entry into the market is expedited as soon as the patent expires (WTO n.d.).

Both the USMCA and CPTPP have no provisions allowing for this flexibility but the RCEP expressly includes the same in its articles, specifically Article 11.40, which provides that "...each Party shall provide that any person may do an act that would otherwise infringe a patent if the act is done for experimental purposes relating to the subject matter of a patented invention."

In Kenya, a *Bolar* exception is provided for under section 58(1) which provides that "[t]he rights under the patent shall extend only to acts done for industrial or commercial purposes and in particular *not to acts done for scientific research*." (author's emphasis)

It would therefore be crucial for Kenya to provide for the same in the U.S.-Kenya FTA and avoid any situation that may jeopardize this flexibility.

Patent Term Opposition

The TRIPS Agreement Article 62(5) contemplates patent term opposition but does not distinguish whether its pre or post-grant opposition. This provision is however lacking in both the USMCA and CPTPP and included under the RCEP. RCEP Article 11.41(2)(c)(i) allows for the patent system to provide for an opportunity to "file an opposition against the patent application[.]"

Kenya's patent law implements a revocation as opposed to an opposition procedure under its section 103(2), which provides that "[a]n interested person may, within a period of nine months from the date of publication of the grant of a patent...request the Tribunal to revoke or invalidate the patent...."

ISDS Mechanism

Unlike the CPTPP,[7] the USMCA has a much more constrained ISDS mechanism.

Chapter 9 of the CPTPP deals with investment, and under section B of the Agreement the ISDS mechanism has been proposed. Article 9.18 of the Agreement provides that "[i]n the event of an

[7] This Agreement between Canada and 10 other countries in the Asia-Pacific including Australia, Chile, Brunei, Japan, Mexico, Malaysia, Mexico, New Zealand, Peru, Singapore and Vietnam.

investment dispute, the claimant and the respondent should initially seek to resolve the dispute through consultations and negotiation, which may include the use of non-binding, third-party procedures, such as good offices, conciliation or mediation."

Consequently, it appears that consultation and negotiation is the preferred mode of dispute resolution. However, if the dispute remains unresolved within six months then a claim may be submitted by a claimant under Article 9.19. Article 9.19(4) of the CPTPP provides for submission of such claims under one of the following alternatives:

> (a) The ICSID Convention and the ICSID *Rules of Procedure for Arbitration Proceedings,* provided that both the respondent and the party of the claimants are parties to the ICSID Convention;
>
> (b) The ICSID Additional Facility Rules, provided that either the respondent or the Party of the claimant is a party to the ICSID Convention;
>
> (c) The UNCITRAL Arbitration Rules; or
>
> (d) If the claimant and respondent agree, any other arbitral institution or any other arbitration rules.

The above effectively means that the ISDS mechanism is available to all parties in relation to dispute resolution.

In contrast, the ISDS mechanism seems to be conspicuously missing in the USMCA FTA. Chapter 14.2(4) dealing with the scope provides as follows:

> "For greater certainty, an investor may only submit a claim to arbitration under this Chapter as provided under Annex 14-C (Legacy Investment Claims and Pending Claims), Annex 14-D (Mexico-United States Investment Disputes), or Annex 14-E (Mexico-United States Investment Disputes Related to Covered Government Contracts)."

There seems to be no mention of Canada in all these. According to Gleeson, the "USMCA only provides for the ISDS between the U.S. and Mexico and grounds for a claim are significantly narrowed (would not apply to pharmaceuticals)" (Palmedo 2019).

Seeing that the U.S. may not be keen on promoting the ISDS mechanism, Kenya should prepare to propose the mechanism for introduction in the agreement. Failure to do so may lead to its exclusion as well going by the trends set under USMCA.

Suffice to note RCEP chapter 11 on dispute resolution also does not include an ISDS mechanism in its provisions.

CONCLUSION

The analysis above shows that apart from patent linkage, the other TRIPS-plus provisions that appear most likely to be introduced do not enjoy broad consensus. It seems the renegotiated USMCA signed in 2018 appears to have brought back many provisions that were hitherto suspended under the CPTPP. It appears that the U.S. is determined to promote these provisions all over the world through FTAs despite the mounting evidence that there is strong opposition. Apart from the CPTPP the biggest FTA recently signed, RCEP, does not provide for the same agenda being pursued by the U.S. and instead focuses strongly on the protection of public health and access to medicines by safeguarding

some important TRIPS flexibilities as enshrined under the Doha Declaration on the TRIPS Agreement and Public Health. Kenya should therefore negotiate the IP chapter by making reference to RCEP which is more progressive than the CPTPP. The USMCA model is definitely out of question in this regard because it contains harmful TRIPS-Plus provisions.

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The views expressed in this Working Paper are strictly those of the author(s) and do not represent the position of Boston University, or the Global Development Policy Center.

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