

# SUBMISSIONS TO THE KENYAN NATIONAL ASSEMBLY RELATING TO THE PROPOSED RATIFICATION OF THE KENYA/UNITED ARAB EMIRATES COMPREHENSIVE ECONOMIC PARTNERSHIP AGREEMENT

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## Submission to the Kenyan National Assembly on Some of the implications for Kenya of the Kenya-UAE CEPA

Thank you for the opportunity to submit a memorandum on the Kenya-United Arab Emirates (UAE) Comprehensive Economic Partnership Agreement (CEPA)<sup>1</sup> before the Kenyan National Assembly decides whether to ratify it.

#### Background on Impact of the CEPA to the Health Sector

Kenya already struggles with a heavy disease burden. The country already has problems accessing affordable medicines. By way of summary:

- **HIV/AIDS:** According to 2023 data<sup>a</sup>, over 1.4 million people live with HIV in Kenya. The country has about 18,000 annual HIV/AIDS related deaths (18,473 in 2022) and has about 1.2 million people on antiretroviral therapy accounting for about 86% of people living with HIV.
- <u>TUBERCULOSIS:</u> According to 2022 data<sup>b</sup>, Tuberculosis (TB) in Kenya is estimated at about 133,000 for all forms of TB cases annually. In 2022, the country reported 90,841 TB cases accounting for about 68% case detection. Drug-resistant TB cases are about 1,200 annually. The TB-HIV co-infection rate stands at 20% with that percentage of TB patients also being HIV-positive. The TB deaths in 2022 were about 12,000.
- <u>CANCER</u>: According to the Kenya National Cancer Registry<sup>c</sup>, the country has an estimated 42,000 new cancer cases every year. Annual deaths are 27,000. The leading cancers: include women: Breast (16%), Cervical (13%), Esophageal (7%) Men: Prostate (13%), Oesophageal (12%), Colorectal (6%). The five-year prevalence (people living with cancer) is about 100,000+.

The treatment for these diseases is not cheap. In the case of cancer, for example, the cost of Generic Chemotherapy Drugs\* (e.g., Doxorubicin, Cyclophosphamide, Paclitaxel) is estimated at KES 5,000 – 30,000 per dose\* (depending on the drug and dosage). In the case of Branded/Targeted Therapy Drugs such as Herceptin /Trastuzumab, Keytruda/Pembrolizumab, the cost is estimated at between KES 100,000 – 500,000 per dose (some can exceed KES 1 million for immunotherapy). For hormonal therapy\* (e.g., Tamoxifen, Letrozole): the cost is between KES 500 – 10,000 per month. Cancer patients also need pain management and supportive drugs (e.g., Morphine, Anti-nausea meds) whose cost is estimated at between KES 200 – 10,000 per month (depending on brand and dosage). These are heavy costs at a time when the economy is not doing well.

The Kenyan government has been subsidizing some of these drugs. This is being done at a time of a far-reaching fiscal consolidation program by the International Monetary Fund (IMF). This must also be viewed within the context of cancellation of the United States Presidential Emergency Plan for AIDS Relief (PEPFAR) under the USAID framework.<sup>d</sup> Getting funding

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<sup>&</sup>lt;sup>a</sup> See Kenya HIV Estimates Report 2023, NASCOP

<sup>&</sup>lt;sup>b</sup> WHO Global TB Report 2023

<sup>&</sup>lt;sup>c</sup> Kenya National Cancer Registry, Globocan 2022

d See generally Impact of USAID freeze on access to affordable medicines in Kenya. E.g. <a href="https://www.unaids.org/en/resources/presscentre/featurestories/2025/march/20250313\_Kenya\_fs">https://www.unaids.org/en/resources/presscentre/featurestories/2025/march/20250313\_Kenya\_fs</a> and <a href="https://www.unaids.org/en/resources/presscentre/featurestories/2025/april/20250401\_Kenya\_fs">https://www.unaids.org/en/resources/presscentre/featurestories/2025/april/20250401\_Kenya\_fs</a>. In Kenya approximately 41,000 doctors, nurses, technical and management staff and community workers were supported by the US government . Kenya and Rwanda are among the list of countries that have

to undertake a subsidy program in the health sector requires that Kenya does not get into trade deals that will make access to medicines a problem when the country is already facing debt sustainability challenges.

### Some comments on the implications of some of the intellectual property chapter provisions on timely access to affordable medicines

Kenya and the UAE are both Members of the World Trade Organization (WTO)<sup>2</sup> and so the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)<sup>3</sup> already applies to them. However since the USA has blocked the appointment of Appellate Body (AB) members, <sup>4</sup> there are none left, so the AB is no longer functioning.<sup>5</sup> ('The US stance of blocking the appointments at the Appellate Body has now reached the six-year mark and there is little likelihood that it will be restored at all, said people familiar with the development.'<sup>6</sup>). This means that if Kenya does not comply with TRIPS (e.g. it does not grant patents (20 year monopolies) on relevant vaccines or medicines during a pandemic) and it is sued at the WTO and loses, it can appeal ('into the void') and since the appeal cannot be heard, the decision cannot become final and Kenya cannot be penalised at the WTO for failing to comply with TRIPS.<sup>7</sup> Therefore since the intellectual property (IP) chapter of this CEPA is enforceable (see below), even incorporating any TRIPS provisions into it is effectively TRIPS+ (i.e. stronger than TRIPS currently) since TRIPS is currently unenforceable at the WTO.

The intellectual property (IP) chapter of the CEPA has a number of TRIPS+ provisions in it that go substantively beyond the TRIPS obligations (even when they were enforceable) which have a range of implications including on the ability to access affordable generic medicines as soon as possible in Kenya. This submission will touch on some of the main TRIPS+ provisions affecting timely access to affordable medicines.

#### Data Exclusivity and Linkage

We were shocked to see that this Kenya-UAE CEPA has:

- A hard obligation for market exclusivity for five years from the latest possible date for both the information in the dossier and the fact of the marketing approval. This means that even if there is no patent on a medicine (e.g. because it is insulin which is vital for diabetics but is not a new invention (it is 100 years old and is extracted from pigs and cattle) so is not eligible for patents) generic versions still cannot be approved by the medicine regulator as safe and effective and so reach Kenyan patients for 5 years.
- A hard linkage obligation<sup>10</sup> that prevents compulsory licences from being effective and requires the Kenyan government to be the patent police when even the USA's Food and Drug Administration does not have the capacity to do so (and the EU refuses to implement linkage).

Kenya currently does not have such data exclusivity or linkage, so this would be a significant change.

Medicines in Kenya are already unaffordable, and generic medicines are much cheaper than the innovator price:

As the Kenyan Ministry of Health noted in a 2004 report:

- A recent survey found that only about 30% of the population have access to essential medicines and the price of medicines is one of the barriers to access.
- 'the majority of Kenyans lack access to medicines as defined by World Health Organization, and that high price was a possible barrier hindering access to medicines. Other studies on the health sector have highlighted the high out-of-pocket health expenditures by households, and the high

reported that domestic resources are being mobilized to maintain priority HIV programmes previously funded by the US.

percentage of expenditures spent on medicines. Clearly, for an individual Kenyan, price often determines whether he or she receives a full treatment, an incomplete courts, or no medicine at all. At the national level, price can determine whether or not the Government of Kenya can offer treatment to the population for a particular disease.'11

- the public sector mostly uses generic medicines and 'many public health outlets offer medicines for free, specifically for the under-5-year-olds, pregnant mothers and treatments for malaria and PMCT of HIV.'
- the lowest paid Kenyan government worker would need:
  - 9-10 days' wages to purchase one month's dose of the recommended treatment for hypertension at the innovator price.
  - o 13-27.5 days' wages to buy one month's treatment for peptic ulcers at the innovator price.
- Increased use of generics could increase access to health services by low-income patients and even in the public sector the prices are still unaffordable for patients.
- The innovator brand of antimalarials can be 36 times more expensive than the generic version. And the innovator version of furosemide is 50 times more expensive than the generic version. 12
- 'Some essential medicines (including generic products) are unaffordable to the lowest-wage Kenya government workers and by extension more than half of the population, particularly if they had to purchase them from private retail pharmacies or mission facilities. Even though patient prices were found to be lower in the public sector, affordability was still a problem for some of the medicines, especially for chronic conditions and where more than one member of a family requires treatment.'

The UAE may be able to afford to comply with these TRIPS+ provisions on medicines since its GNI per capita is US\$49,020 (23 times larger than Kenya's),<sup>13</sup> but Kenya cannot for the reasons outlined above.

During the Trans-Pacific Partnership (TPP) negotiations with the USA, even developed countries such as Australia<sup>14</sup> and New Zealand opposed the TRIPS+ provisions on it since it did not suit them as net importers of intellectual property who needed to keep medicines affordable for their citizens. Even the original TPP did not have hard linkage (it only had soft linkage). Consequently, when the US refused to ratify the TPP, the remaining countries (including Australia and New Zealand) suspended most of the TRIPS+ provisions on medicines (including the market exclusivity provision on medicines which is similar to the one in the Kenya-UAE CEPA) in the renamed CPTPP. <sup>15</sup>

We note that the India-UAE Comprehensive Economic Partnership Agreement (CEPA)<sup>16</sup> which was signed in 2022<sup>17</sup> does not have the TRIPS+ provisions on medicines above (exclusivity and linkage) even though India's GNI per capita is higher than Kenya's.<sup>18</sup>

#### **Grace Period:**

The CEPA requires a grace period of at least 12 months which means that if the inventor/patent applicant etc disclosed the invention in the 12 months for filing the patent application, they are still eligible for a patent (when normally they would not be). See Appendix below for some implications of this grace period.

#### Overall:

We are puzzled as to why this CEPA has TRIPS+ provisions on medicines since neither Kenya nor the UAE are the homes of big pharmaceutical companies who have long sought these provisions in order to expand and extend their monopoly profits.<sup>19</sup>

In practice when countries implement these TRIPS+ provisions, they implement them with respect to applicants from the whole world. E.g. pharmaceutical companies from the US, EU, Switzerland, UK etc would also benefit from the exclusivity and linkage provisions above. This means they can free ride and Kenya loses potentially important bargaining chips in its upcoming built-in rendez-vous clause negotiations with the EU on intellectual property<sup>20</sup> and with the USA to remove the tariffs it announced on Kenya on 2 April 2025), see above. Kenya is not even getting any goods market access to the UAE in this CEPA in return for agreeing to these TRIPS+ provisions and the goods chapter is where

developing countries such as Kenya can usually benefit from an FTA (e.g. in the removal or reduction of the UAE's tariffs on Kenyan products).

Even when countries are getting new goods market access from an FTA (which is not in this CEPA), the costs of these TRIPS+ provisions on medicines still far outweighs the gains from the goods chapter in terms of the other country in the FTA lowering their import tariffs:

- Research at the Australia Institute in Canberra has estimated that if provisions in the Australia-US FTA succeed in delaying by 24 months market entry of generic versions of just the top five Pharmaceutical Benefits Scheme (the 'PBS' is the Australian Government medicine reimbursement scheme) expenditure medicines due to come off patent, this could increase the cost of the PBS by \$1.5 billion over 2006-2009. The budgetary cost could easily swamp the \$53 million a year in economic gains from the agreement estimated by modelling work commissioned by a Senate Committee investigating the FTA.<sup>21</sup>
- After noting that patented medicines can be ten times the price of generic medicines and that the USA pushes for stronger intellectual property protection in its FTAs, economist Dr Dean Baker made it clear that the costs of agreeing to stronger intellectual property protection is greater than the possible gains from any lower tariffs in the FTA: 'There is no plausible set of tariffs and quotas that could be imposed by the United States on merchandise trade that would impose any remotely comparable burden on its trading partners. In short, U.S. trading partners stand to lose much more from accepting conditions on intellectual property as part of trade agreements than they do from increased protectionist barriers on merchandise trade.'22

The CEPA does not even have any goods market access, so the UAE will not be lowering its tariffs on any Kenyan products to offset the costs of these TRIPS+ provisions on medicines. Therefore, it is unclear how the benefits of this CEPA can outweigh the costs significant and deadly costs of these TRIPS+ provisions on medicines for Kenyan patients.

#### **Exceptions Chapter**

Although the CEPA has some exceptions, they are insufficient e.g.:

- The health and environment exception does not apply to the intellectual property chapter and it has been copied from the WTO where it is so difficult to use that governments only succeeded <u>twice in 48 attempts</u>.<sup>23</sup>
- The privacy exception has been copied from the WTO where it is self-cancelling so does not override problematic provisions in the CEPA
- The security exception is limited to the listed circumstances, so does not include cybersecurity in times of peace etc and it has been found at the WTO to not be self-judging.<sup>24</sup> There are many FTAs with better security exceptions, however these examples have not been followed by this CEPA.
- Other CEPA exceptions are often self-cancelling (they cannot be used to override problematic provisions) or irrelevant.

SOME COMMENTS ON THE IMPLICATIONS OF SOME OF THE INTELLECTUAL PROPERTY CHAPTER PROVISIONS ON TIMELY ACCESS TO AFFORDABLE MEDICINES

<sup>&</sup>lt;sup>e</sup> E.g. USFTAs since 2000 have considerably broadened the WTO's security exception to:

<sup>•</sup> remove the objective list of situations, just anything a Party considers necessary for its own essential security interests. And

<sup>•</sup> have a footnote in some recent USFTAs (<u>Colombia</u>, <u>South Korea</u>, <u>Panama and Peru</u>) as well which says the tribunal must find the security exception applies if a Party raises it. (E.g. 'For greater certainty, if a Party invokes Article 21.2 in an arbitral proceeding initiated under Chapter Ten (Investment) or Chapter Twenty (Dispute Settlement), the tribunal or panel hearing the matter shall find that the exception applies.').

The exceptions in the CEPA do not apply to the IP chapter (e.g. the difficult-to-use health exception in Article 15.1), are irrelevant (e.g. security exception in Article 15.2 and taxation exception in Article 15.3) or insufficient (e.g. the purported exceptions in the IP chapter which are self-cancelling etc). The CEPA IP chapter is enforceable because the CEPA dispute settlement chapter applies to the IP chapter<sup>25</sup> and if Kenya does not comply with the IP chapter and is sued by the UAE and loses, the UAE can suspend equivalent benefits until Kenya complies with this IP chapter.<sup>26</sup> Kenya current does not have such data exclusivity or linkage, so this would be a significant change. Article 21(2) of the Constitution requires the State to implement laws and policies to achieve progressive realisation of the right to health. This right will be greatly undermined by these CEPA provisions as can be seen above. The UAE may be able to afford to comply with these TRIPS+ provisions on medicines since its GNI per capita is US\$49,020 (23 times larger than Kenya's),27 but Kenya cannot for the reasons outlined above.

During the Trans-Pacific Partnership (TPP) negotiations with the USA, even developed countries such as Australia<sup>28</sup> and New Zealand opposed the TRIPS+ provisions on it since it did not suit them as net importers of intellectual property who needed to keep medicines affordable for their citizens. Even the original TPP did not have hard linkage (it only had soft linkage). Consequently, when the US refused to ratify the TPP, the remaining countries (including Australia and New Zealand) suspended most of the TRIPS+ provisions on medicines (including the market exclusivity provision on medicines which is similar to the one in the Kenya-UAE CEPA) in the renamed CPTPP.<sup>29</sup>

We are puzzled as to why this CEPA has TRIPS+ provisions on medicines since neither Kenya nor the UAE are the homes of big pharmaceutical companies who have long sought these provisions in order to expand and extend their monopoly profits.<sup>30</sup> This means these provisions benefit the US, EU, UK, Swiss etc big pharmaceutical multinationals, at the expense of Kenyans who need affordable medicines (see above).

In practice when countries implement these TRIPS+ provisions, they implement them with respect to applicants from the whole world. E.g. pharmaceutical companies from the US, EU, Switzerland, UK etc would also benefit from the exclusivity and linkage provisions above. This means they can free ride and Kenya loses a potentially important bargaining chip in its upcoming built-in rendezvous clause negotiations with the EU on intellectual property<sup>31</sup> and with the USA to remove its imminent reported additional tariffs. (The US government under President Trump is planning to introduce a reciprocal tariff later today (2 April 2025) which takes into account 'nontariff barriers' which is defined to include lack of intellectual property protection<sup>32</sup> which will reportedly apply to all countries in the world, including Kenya<sup>33</sup> in order to get concessions in return for removing these new US tariffs (that violate WTO rules)). Kenya is not even getting any goods market access to the UAE in this CEPA in return for agreeing to these TRIPS+ provisions and the goods chapter is where developing countries such as Kenya can usually benefit from an FTA (e.g. in the removal or reduction of the UAE's tariffs on Kenyan products).

We note that the India-UAE Comprehensive Economic Partnership Agreement (CEPA)<sup>34</sup> which was signed in 2022<sup>35</sup> does not have the TRIPS+ provisions on medicines above (exclusivity and linkage) even though India's GNI per capita is higher than Kenya's.<sup>36</sup>

### DATA/MARKET EXCLUSIVITY IMPACT ON MEDICINE PRICES - SOME EXAMPLES FROM AROUND THE WORLD

Data or market exclusivity is another monopoly which is often demanded by developed countries such as the USA and EU in their FTAs (even if there is no patent on the medicine). Colombia has had data exclusivity since  $2002^{37}$  and a 2012 study found that these data exclusivity requirements cost Colombia an additional US\$396million in additional expenses for its public health system from  $2003-2022.^{38}$ 

Another real life example of the impact of data/market exclusivity is when an old medicine to treat gout (colchicine) was given three years of market exclusivity in the USA as a new indication for this medicine and the company which received it sued to remove existing versions of colchicine from the market and then raised the price by more than 50 times adding \$50million per year to the cost of providing this medicine in the USA.<sup>39</sup> It was also given 7 years of market exclusivity for colchicine to treat a rare disease (familial Mediterranean fever), even though this was already a known use of the medicine.<sup>40</sup>

The USA provides an additional 6 months of market exclusivity for medicine manufacturers which do paediatric studies and a calculation of the impact of the additional 6 months of monopoly prices compared to the generic versions if they had been allowed found that: for just three medicine classes it cost the US Medicaid population US\$430million so the study concluded 'these results suggest that the costs to Medicaid and thus taxpayers are substantial.'<sup>41</sup>

It was recently estimated that eight years of data exclusivity alone in Canada would have added \$600 million to prescription medicine costs alone in the last five years.<sup>42</sup>

Another study found that data exclusivity would have prolonged monopolies in Canada by two years which would increase the cost by an additional C\$1,645million/year (13% of the total cost of patented medicines). An increase of two years of data exclusivity for biologics alone (e.g. vaccines etc) could cost up to \$305.8million in additional spending in Canada. Canada's Parliamentary Budget Office found that the two-year data exclusivity extension for biologics in the Canada-United States-Mexico Agreement (CUSMA/USMCA) could increase spending by at least \$169million in 2029 and increasing annually thereafter.

In Peru, 10 years of data exclusivity is calculated to lead to an increase of more than US\$300million in 2025 expenditure. A study found that market exclusivity for five years in Thailand would increase costs by between US\$146.3 million and US\$696.4 million per year and would increase medicine outlays by 9-45% in Thailand. Using WHO methodology, 5 years of data exclusivity was predicted to cost Thailand US\$3.7 billion over 15 years. The five years of data exclusivity applied in Mexico in 2012 due to its USFTA has resulted in US\$320million in lost cost savings to 2020 (US\$80million in 2018 alone). Using the generic than the generic

In Guatemala medicines with data exclusivity can cost 166%-846% more than the generic versions.<sup>51</sup>

When Jordan's medicines were at monopoly prices due to its data exclusivity they were up to 800% more expensive than in Egypt where there was generic competition because there was no data exclusivity or other TRIPS-plus rules.<sup>52</sup> For 81 medicines where there is no generic competitor because of data exclusivity in Jordan, spending was increased due to these TRIPS-plus monopolies by \$6.3million-\$22million from 2002-2006 (assuming generics are 30-80% of originator prices).<sup>53</sup> Data exclusivity also applies to biologics in some countries and even though biosimilars face higher regulatory hurdles and other barriers (e.g. often they cannot be

substituted for the original biologic by pharmacists, only by doctors) once the exclusivity expires and biosimilars (generic biologics) can enter the market:<sup>54</sup>

- Savings of around US\$1.5billion were likely in the early years of biosimilar competition to 2014 for the countries studied and this is likely to increase as biologics continue to increase as a proportion of pharmaceutical spending and more generic companies learn how to make biosimilars.
- Average market prices fall by about 3.5 percentage points per year after biosimilar entry (or 2.4 percentage points with each biosimilar entrant) but this was up to 7.8% annual price declines for some biologics

#### PATENT LINKAGE IMPACT – SOME EXAMPLES

Linkage prevents compulsory licences from being effective and requires the Kenyan government to be the patent police. It is so difficult to do that a US Congressional Report found that even the US Government's Food and Drug Administration does not have the capacity to do it because it 'does not have adequate expertise or resources to review the applicability of patents, and it has been unable to prevent abuses of the system by patentholders that have led to delays in the availability of generic drugs'. 55

The United Nations (UN) Special Rapporteur on the Right to Health (UNSRH) notes that the European Union does not implement linkage and linkage in the US has been abused by patent holders according to a US government study and the Canadian government recognises that linkage has been used to evergreen patents'. Evergreening means allowing patents on new uses of old medicines, new formulations and dosages etc. It is a TRIPS-plus provision that facilitates the extending of drugs monopoly by additional patents on existing medicines which delays the entry of cheaper generic versions.

For example, linkage means that the government becomes the enforcer of even weak patents (instead of the patent holder having to sue companies it thinks are violating the patents). Patents are often weak (found to be invalid when challenged by generic companies), e.g. in the USA in 73% of the cases where a decision was made on the substance, the patent was found to be invalid.<sup>57</sup> However the increase in litigation costs is a heavy burden especially for small to medium sized companies, impacting their ability to bring generics into the market.<sup>58</sup>

Linkage has delayed the entry of generics<sup>59</sup> and prolonged nominal patent terms60.

In Canada, linkage has also created a significant backlog in the Canadian Federal Court system. In 2008, there was a team of approximately 30 Federal Court judges devoting some or all of their time to about 350 separate drug patent cases and 'The Supreme Court of Canada has, on multiple occasions, held that the automatic stay issued to patentees under the NOC Regulations is an 'extraordinary' remedy, not available to patentees in any industry outside of the pharmaceutical industry.'<sup>61</sup>

A Malaysian study found that in the worst-case scenario linkage could cause medicine spending in 2026 to increase by RM334million.<sup>62</sup>

#### THE RIGHT TO HEALTH UNDER THE KENYAN CONSTITUTION

The 2010 Constitution has put in place fail-safe mechanism to protect against the abrogation of rights enshrined in the Bill of Rights. Article 21 of the Kenyan Constitution places a fundamental duty on the State and all its organs to ensure that the rights and fundamental freedoms enshrined in the Bill of Rights are upheld. This duty encompasses observing,

respecting, protecting, promoting, and fulfilling the rights and freedoms. Specifically, Article 21 includes the right to health within the scope of rights and freedoms that the State must uphold. The right to health, as recognized in the Kenyan Constitution, includes the right to the highest attainable standard of health, which encompasses access to healthcare services, including reproductive health care. The interpretation of this standard is laid out the General Comment No. 14 of the Convention on Economic, Social and Cultural Rights on the Right to Health specifically requiring access to medicines meet the threshold of "accessibility, availability, affordability and quality"

#### **CONCLUSION**

We therefore urge you not to ratify this CEPA in its current form because of the serious and unnecessary ways it will undermine access to affordable medicines in Kenya. An alternative is to use the revised Parliamentary Standing Orders on the ratification of treaties under 170A (4) (c) and (5) and approve the treaty with reservations on TRIPS Plus provisions. We look forward to the opportunity to discuss our concerns with you in more detail.

#### **GENERAL CONTEXT**

#### WTO rules are not currently enforceable at the WTO

The USA has been blocking<sup>63</sup> the appointment of members to the Appellate Body (AB) at the World Trade Organization (WTO), so it no longer functions,<sup>64</sup> so if Kenya does not comply with the services or intellectual property rules at the WTO and is sued and loses, it can appeal 'into the void' and since the appeal cannot be heard, no legal retaliation (of higher tariffs on Kenyan exports) is permitted under WTO rules. The USA was not expected<sup>65</sup> to allow the AB to come back to life before the new Trump tariffs (see below) and it presumably cannot allow it to resume work now since it would lose the many likely challenges to these tariffs.

Kenya has fortunately not joined the optional multi-party interim appeal arbitration arrangement (MPIA) to enable disputes to become final while the AB is not working (and neither has the USA). This means that if the CEPA includes any WTO rules, these are now newly enforceable commitments under the CEPA where the UAE can now sue Kenya via the CEPA's dispute settlement (see below) for failing to comply with WTO rules and legally retaliate (e.g. by suspending any benefits under the CEPA).

#### Trump's 2 April 2025 tariffs have changed the global context

The world has changed since this CEPA was signed on 14 January 2025<sup>67</sup>. On 2 April 2025, US President Trump announced new tariffs ('Trump tariffs') on nearly the whole world, including 10% tariffs on Kenya.<sup>68</sup> These Trump tariffs are illegal under World Trade Organization (WTO) rules. As Canada<sup>69</sup> and China<sup>70</sup> have already argued in their WTO cases challenging the tariffs that the Trump Administration imposed earlier this year, these tariffs violate the USA's bound tariff rates at the WTO (i.e. they go above the maximum tariff the USA is allowed to impose under WTO rules) and they violate the WTO's most-favoured nation (MFN) requirement (which requires the US to impose the same tariffs (e.g. on coffee) from all 165<sup>71</sup> other WTO Members). However because the WTO Appellate Body is no longer working (see above) this means that suing the USA at the WTO is not currently an effective way to get these Trump tariffs removed

This means that Kenya may need to make concessions to the USA to get these illegal and unfair Trump tariffs removed. It is unclear what concessions the USA will require, but some the Executive Order announcing these Trump tariffs highlighted the non-tariff barriers in the 2025 US National Trade Estimate (NTE) Report.<sup>72</sup> The Kenyan section of this Report includes:

• Kenya's failure to ratify the problematic and TRIPS+ World Intellectual Property Organization (WIPO) Internet Treaties, <sup>73</sup> which deal particularly with copyright and related rights in the digital environment. The Kenya-UAE CEPA requires Kenya to reaffirm their obligations in these WIPO Internet Treaties. <sup>74</sup> Therefore if Kenya ratifies or complies with these problematic WIPO Internet Treaties to comply with the UAE CEPA (in return for what seem to be no benefits from the UAE CEPA since it has no goods market access and no effective mode 4 market access for Kenya which are the two areas where developing countries can traditionally benefit from FTAs), it loses the ability to offer this to the USA in order to get these US tariffs removed.

In this NTE Report, it also complains about the lack of data/market exclusivity on medicines in other countries and the Kenya-UAE CEPA requires five years of market exclusivity on medicines<sup>f</sup> (in return for no apparent benefits from the UAE), so ratifying the UAE CEPA would mean Kenya loses that bargaining chip to get these US tariffs removed.

If Kenya wants to liberalise services, or have stronger intellectual property protection etc, it can always do this unilaterally instead of locking it in via this CEPA in return for no goods market access etc. If these changes are made unilaterally instead of via a free trade agreement (FTA), if it turns out to be problematic, Kenya can reverse it because it is not locked in by a trade agreement. Making these changes unilaterally also leaves Kenya with bargaining chips to offer in trying to get the Trump tariffs removed etc. The UAE CEPA does not appear to provide any enforceable aid and in fact may result in less Kenyan government revenue, see below.

#### Initial Provisions and General Definitions Chapter

The CEPA general definitions include a broad and non-exhaustive definition of 'measure' which includes laws, regulations, rules, procedures, decisions, practices, administrative actions etc, <sup>75</sup> so obligations with 'measure' in it in the CEPA are very broad. E.g. Kenya is required to take such reasonable 'measures' as may be available to it to make subnational governments comply with the whole CEPA. This chapter is enforceable via the CEPA's dispute settlement chapter, see below.

#### **GOODS CHAPTERS**

The CEPA does not currently contain goods market access (those negotiations will be done via the East African Community structures<sup>77</sup>). In a free trade agreement (FTA) with a more developed country (e.g. the UAE's GNI/capita is 23 times larger than Kenya's), the goods chapter is generally the chapter where the poorer country can benefit since it lowers the import tariffs on the poorer country's cheaper agricultural or manufactured products. However, since there is no goods market access in the CEPA, it is unclear what the economic benefits are for Kenya from the CEPA to offset the costs of the other CEPA chapters below.

#### TRADE FACILITATION CHAPTER

Context: The WTO concluded new rules on trade facilitation (the Trade Facilitation Agreement (TFA)) in 2013 and they came into force in 2017<sup>78</sup> and both Kenya and the UAE are bound by it<sup>79</sup>. These TFA rules are already difficult and expensive to comply with for many developing countries and so the TFA includes special and differential treatment where developing countries have transition periods (including until after they have received assistance and capacity building for TFA provisions they have designated as 'Category C'). <sup>80</sup> The UAE has already been able to implement 100% of the TFA rules but Kenya has only been able to implement 43.7% of the TFA rules so far. <sup>82</sup> This is not surprising because it is very expensive to buy, maintain and update the equipment requirement to implement the TFA provisions as well as pay the salaries of the extra staff etc and UAE's GNI/capita is 23 times larger

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<sup>&</sup>lt;sup>f</sup> Which in practice would be given to big pharmaceutical companies from the whole world including the USA since it is too difficult to implement the law only with respect to UAE pharmaceutical companies given the use of subsidiaries etc

than Kenya's. <sup>83</sup> E.g. Kenya scheduled 70.2% of its TFA commitments as Category C (to be implemented once sufficient technical assistance and capacity building has been provided).

If the CEPA trade facilitation (TF) provisions are the same as the TFA, this is already a substantive new obligation because:

- It makes it enforceable via the CEPA's dispute settlement (see below) when WTO rules (including the TFA) are not currently enforceable at the WTO since its Appellate Body is not functioning (see above).
- There is none of the TFA's special and differential treatment/transition periods in the CEPA trade facilitation chapter so there are no transition periods for Kenya (even though Kenya still has not been able to comply with the TFA).
- Since the UAE has already complied with 100% of the TFA provisions, this would not require the UAE to do anything but would entail onerous efforts by and significant new legal liability for Kenya, without any assistance or capacity building from the UAE.

If the CEPA trade facilitation chapter has obligations which go beyond the TFA, that is even more difficult for Kenya (since Kenya has not even been able to comply with the TFA so far, unlike the UAE) and the CEPA TF chapter does not have any enforceable technical assistance or capacity building or transition periods etc. This TF chapter is enforceable via the CEPA's dispute settlement chapter, see below.

What are the benefits for Kenya of this CEPA trade facilitation chapter? Since the UAE has already completely implemented the WTO's TFA, Kenyan exports to the UAE already benefit from this. Are there still serious obstacles to Kenyan exports which are addressed by this CEPA chapter? Or is it only new and enforceable obligations that will be expensive and difficult for Kenya to implement?

#### SERVICES CHAPTER

While Kenya and the UAE are both bound by the services rules in the WTO (the General Agreement on Trade in Services (GATS)), it is not currently enforceable at the WTO, see above. Therefore the various GATS rules (and those of Kenya's GATS services liberalisation commitments) which have been copied/incorporated into the CEPA exposes Kenya to new legal liability, especially if Kenya's GATS commitments are problematic or have mistakes, see below.

Like the GATS, the CEPA services chapter applies to measures by Parties affecting trade in services<sup>84</sup> (which is defined the same broad way<sup>85</sup>) which is defined to include the same Modes 1-4<sup>g,86</sup> While it is good that the CEPA excludes subsidies, grants, government procurement and public services from the scope of the services chapter,<sup>87</sup> the definition of public services is too narrow to be effective, see below.

This scope provision also excludes employment, residence, citizenship and visas from the scope of the services chapter, so even if the UAE gives Mode 4 market access to Kenyans on paper, it can still refuse to issue visas to Kenyans and so any such Mode 4 market access would be ineffective. (Furthermore, there is nothing in the CEPA services chapter that requires the UAE to recognise Kenyan qualifications (e.g. as doctors, lawyers, engineers etc.), see below).

The CEPA includes a most-favoured nation (MFN) provision<sup>88</sup> which specifies that if Kenya enters into a services agreement with another country (e.g. the USA) after the CEPA comes into force, then Kenya must consider a request by the UAE to incorporate the same benefits that Kenya gave the USA into the UAE CEPA.

Mode 3 is foreign direct investment (e.g. a UAE hotel opens in Kenya)

Mode 4 is where the human being who supplies the service works abroad e.g. a Kenyan going to work in the

UAE, https://www.wto.org/english/thewto\_e/20y\_e/services\_brochure2015\_e.pdf

g Mode 1 is where the service supplier and consumer are in different countries e.g. call centres

Mode 2 is where the consumer travels abroad (e.g. tourism).

The Kenya-UAE CEPA services chapter requires Kenya to liberalise in many more service sectors than it has at the WTO. E.g. Kenya did not liberalise these services sectors in the WTO but has in the UAE CEPA:

- some business services,
- some construction services,
- all retail services (except: Mode 4 and sale of motorbikes and their parts),
- some environmental services.
- some health services (including all hospital services except Mode 4),
- some maritime transport services,
- some groundhandling<sup>h</sup> and airport management services,
- some rail transport services.

#### This is very surprising given:

- the implications this has for various Kenyan laws (see below for some examples)
- the lessons learned from the COVID pandemic in terms of lockdowns etc, see below.
- the way it increases legal liability under the existing Kenya-UAE Bilateral Investment Agreement (BIA), see below

We were surprised to see that Kenya has completely liberalised hospital services (except for Mode 4) in the CEPA. Hospitals services are a very sensitive sector and liberalising it means they are subject to the restrictions on regulation in the CEPA including that Kenya cannot cap foreign equity, cannot require hospitals to be non-profit (e.g. as they are in Japan<sup>89</sup>). If Kenya wanted more foreign direct investment (FDI) in hospitals, it could always unilaterally liberalise it and then close it again if it turns out to be a problem.

Even though Kenya has liberalised many more service sectors in the CEPA (including sensitive sectors such as hospital services) than it has in GATS, the CEPA still includes a built-in obligation to negotiate additional liberalisation in successive rounds of negotiations starting within a year of the CEPA coming into force.

Some examples of Kenyan laws and regulations etc which may have to be changed to comply with the CEPA services chapter

There may be many Kenyan measures (laws, regulations etc) which need to be changed at national and subnational level to comply with the CEPA services chapter. A comprehensive study needs to be done. Some examples are below.

#### Mineral dealerships:

Kenya's distribution services liberalisation (all wholesale, retail, on commission and franchising except sale of motorbikes and mode 4) appears to mean it has liberalised mineral dealerships. However according to the US government 'Mineral dealership licenses are only issued to Kenyan citizens or to corporations where at least 60 percent shareholding is held by Kenyan citizens. This requirement appears to be no longer possible with respect to UAE companies (they have to be allowed to have 100% shareholding in mineral dealership licences), so:

- Kenya would have to change the Mining Act which requires 60% shareholding by Kenyan citizens for mineral dealership licences.
- in practice it is difficult for developing countries to differentiate where companies come from since they can incorporate in many places etc, so Kenya may liberalise the distribution sector with respect to the whole world, including the USA who has listed this as a restriction<sup>92</sup> (which Kenya could use as a bargaining chip to get rid of the US tariffs, but not if it is already doing so with respect to the whole world because of this UAE CEPA).

<sup>&</sup>lt;sup>h</sup> Defined in Article 9.1 to include passenger and baggage handling, catering, ramp services, air cargo and mail handling, aircraft: fuelling, cleaning and servicing etc.

#### Insurance Sector

The US government notes these restrictions on foreign investment in Kenya: 'The Kenya Insurance Act of 2010 limits foreign capital investment in insurance companies to two-thirds, with no single person holding more than a 25 percent ownership share.'93

- If these Kenya Insurance Act requirements apply to both life and non-life insurance, the non-life insurance requirements will need to be removed due to the CEPA. This is because Kenya's services schedule in the CEPA only has an exception to allow the requirement for one-third of the paid-up capital to be held by Kenyans for **life** insurance. There is no equivalent limitation to national treatment and market access for **non-life** insurance in Kenya's CEPA services schedule.
- Kenya's 25% cap on how many shares an individual can own in an insurance company is a market access limitation which needed to be listed in Kenya's services schedule where it has committed the insurance sector to be saved. Because Kenya did not include an exception for this in its CEPA services schedule where it liberalised the insurance sector,<sup>94</sup> it will need to remove this requirement to comply with the CEPA.

#### Foreigners being able to buy land in Kenya

Kenya's UAE CEPA schedule also appears allows UAE companies to buy land in Kenya (which presumably violates Art 65 of the Kenyan 2010 Constitution). This is because Kenya has made full Mode 3 commitments in hotels in both GATS and the UAE CEPA and although Kenya's services schedule in the UAE CEPA has a horizontal limitation/exception to national treatment that a foreign service supplier cannot own land on a freehold basis (only lease it), footnote 3 on page 2 of Annex 9B says this does not apply to sectors already committed under GATS. (In GATS, Kenya's services schedule does not have an exception to prevent foreign hotels from being able to buy land in Kenya<sup>95</sup>). So, the exception is good, but because it does not apply to Kenya's GATS commitments (e.g. in the hotel sector) which have been incorporated into Kenya's CEPA schedule, UAE hotel companies can still buy land in Kenya.

This was a common mistake in GATS schedules e.g. Fiji's GATS schedule. <sup>96</sup> However the GATS schedule of other countries like Timor Leste have avoided this mistake by having a horizontal exception/limitation that allows them to keep their restriction on foreigners owning land. <sup>97</sup>

Since GATS is not currently enforceable because the WTO Appellate Body is not working (see above), that means Kenya cannot currently be penalised at the WTO for failing to allow foreign hotel owners to buy land. Therefore, it is a significant commitment to reiterate the GATS commitment (without the domestic land ownership exception applying to it) in this enforceable CEPA provision.

#### Some Implications for Pandemic Lockdowns

During the COVID pandemic, some countries prevented bars and luxury shops from opening to curb the spread of the disease or specified that restaurants could only provide takeaway services. These kinds of restrictions in a future pandemic would violate services market access commitments under the CEPA and it is not clear the health exception would be sufficient, see below. This is because Article 9.7 CEPA specifies that in the service sectors liberalised, Kenya cannot impose on the whole country of a 'regional subdivision', lockdowns on services companies the UAE. This is because Article 9.7.2a) and c) is equivalent to Art XVI.2a) and c) of the General Agreement on Trade in Services (GATS) at the World Trade Organization (WTO) where the WTO's Appellate Body found that a US ban on gambling violated Art XVI.2a) (restriction on the number of companies that can supply the service) and c) (restriction on the quantity of output) in GATS.

<sup>&</sup>lt;sup>i</sup> See mode 3) limitation on market access on page 20 of Annex 9B which is listed for life insurance (this limitation applies to both market access and national treatment according to Article 9.5.3), but not for non-life insurance (on page 21 of Annex 9B).

<sup>&</sup>lt;sup>j</sup> 'regional subdivision' is not defined in the CEPA. It may have been agreed in the CEPA negotiating history whether regional subdivision means county and/or municipality etc.

#### **Public Services Exception**

The public services exception in the CEPA<sup>99</sup> is the same as in the GATS which has been heavily criticised for being too narrow because it only applies to services which are 'supplied neither on a commercial basis, nor in competition with one or more service suppliers.' A 'commercial basis' could include full market price, not-for-profit cost recovery or even a partial user charge. In most countries there is a private school or hospital which competes with public schools/hospitals etc, so these would not be public services under this definition. In some countries there may even be private fire-fighting services (e.g. in airports or large factories), so then even the fire department may not be a public service under this definition.

It is particularly concerning that this inadequate public services exception has been copied into the CEPA when Kenya has made services liberalisation commitments in sensitive sectors such as hospitals and other health services which it had not liberalised in the GATS.

#### **Domestic Regulation Disciplines**

Where the CEPA incorporates GATS services domestic regulation disciplines (SDRD),<sup>102</sup> it now applies to more sectors since Kenya has liberalised more services sectors in the CEPA than it has at the WTO. (In addition to making incorporated GATS SDRD enforceable when they are not currently enforceable at the WTO, see above).

Kenya has not joined the problematic optional plurilateral Joint Initiative on Services Domestic Regulation (JISDR)<sup>103</sup> which restricts the ability to regulate services,<sup>104</sup> presumably because it thought the costs outweighed the benefits to it. Therefore we were surprised to see that the CEPA includes some even stronger requirements than the JISDR. E.g.:

- Article 9.11.4b) of the CEPA is stronger than its equivalent JISDR provision<sup>105</sup> because:
  - o the JISDR is only 'to the extent practicable' which is not in the CEPA
  - o the JISDR has a safeguard that deadlines do not need to be extended which is missing in the CEPA
  - o the CEPA requires Kenya to identify 'all' the additional information required, something that is not required by the JSIDR
- Article 9.11.4d) of the CEPA is stronger than its equivalent JISDR provision 106 including because:
  - The CEPA requires the applicant to be informed **in writing** (whereas the JISDR allows it to be done orally)
  - The CEPA requires it to be done 'without delay', whereas the JISDR does not specify a timeframe
  - The JISDR has safeguards that the CEPA is missing:
    - another application only needs to be allowed 'solely on the basis of a previously rejected application'
    - governments can require the application's content to be revised.
- These CEPA domestic regulation provisions apply to all the services sectors that Kenya has committed in the CEPA and will increase the burdens on Kenyan regulators and may require additional government spending to pay for any extra civil servants needed to provide all this assistance to applicants for licences (e.g. for hotels, banks etc).

While Article 9.11.1 of the CEPA does say that 'Each Party may regulate and introduce new regulations on services and services suppliers within its territory in order to meet national policy objectives':

• this is only an exception for 'regulations' whereas the obligations in Article 9.11 often apply to 'measures' which is defined broadly and non-exhaustively to include laws, regulations, procedures etc. see above.

• this apparent exception is cancelled out by the rest of the sentence: 'in so far as such regulations do not impair any rights and obligations arising from this Agreement.' This means that this exception cannot be used to override any problematic obligations, so it cancels itself out.

Furthermore, the CEPA does not even include the minimal transition periods (up to 7 years for developing countries)<sup>107</sup> and encouragement to provide technical assistance and capacity building<sup>108</sup> which are in the JISDR.

#### The CEPA does not require recognition of Kenyan qualifications

If Kenyan qualifications are not recognised in the UAE, Kenyan professionals (e.g. doctors, nurses, engineers and lawyers) cannot effectively work in their professions in the UAE, even if the UAE provides Mode 4 market access in the CEPA on paper. However, the CEPA does not require the UAE to recognise Kenyan qualifications. Article 9.12 of the CEPA leaves it up to the UAE whether it recognises Kenyan qualifications e.g. medical/engineering/legal etc qualifications. If the UAE recognises qualifications from another country (e.g. the USA), it merely has to offer Kenya the opportunity to: negotiate equivalent recognition or demonstrate that Kenyan qualifications should also be recognised. The UAE also only has to encourage where possible its professional bodies to explore the possibility of recognition and pursue mutually acceptable standards and criteria.

The main area where developing countries can benefit from services liberalisation is if there is effective Mode 4 market access allowing their citizens to work in the other country in the FTA with visas and recognition of their qualifications (e.g. their medical/law/accounting/engineering etc degrees). However, this is not in the CEPA as can be seen above.

#### Overall

This services chapter is enforceable via the CEPA's dispute settlement chapter (see below) and has no special and differential treatment (e.g. transition periods etc) for Kenya.

#### **INVESTMENT CHAPTER**

There is already a UAE-Kenya Bilateral Investment Agreement (BIA) which already has extensive protections for UAE investors in Kenya including a broad non-exhaustive definition of 'investment', fair and equitable treatment (the most successful basis for investor-to-state dispute settlement (ISDS) cases<sup>109</sup>), national treatment, most-favoured nation (MFN) treatment, expropriation, free movement of capital, ISDS etc.

CEPA investment chapter includes an agreement to review this existing UAE-Kenya BIA to make it more comprehensive in coverage. Presumably this could be by adding additional problematic provisions like restrictions on performance requirements etc. But this is going against the trend where governments are realising the problems with these investment treaties e.g. there are 18 known ISDS cases where investors have been awarded at least US\$1billion each. It E.g.:

- the EU<sup>112</sup> and UK<sup>113</sup> are withdrawing from the Energy Charter Treaty because it restricts their ability to take climate change measures.
- The Trump<sup>114</sup> and Biden<sup>115</sup> Administrations are against ISDS.
- The Australian<sup>116</sup> and New Zealand<sup>117</sup> governments are against ISDS etc.
- South Africa, Indonesia, India, Ecuador, Bolivia etc have been withdrawing from their bilateral investment treaties (BITs). 118

The CEPA services chapter is likely to increase liability under this UAE BIA if UAE investors are able to invest in more sectors in Kenya (e.g. in construction services) because of the services chapter liberalisation (which includes Mode 3, i.e. foreign direct investment (FDI), see above). UAE investors

are known to have sued in 12 ISDS cases already, 119 and there have been 30 known ISDS cases about construction in the past which investors have won and many more pending, <sup>120</sup> so it is not an idle threat.

Fortunately, the CEPA investment chapter is not subject to dispute settlement, but the services liberalisation in the CEPA services chapter still increases Kenya's legal liability under the existing UAE BIA's dispute settlement mechanisms including ISDS.

#### DIGITAL TRADE CHAPTER

This chapter appears to contain a number of provisions demanded by US big tech companies such as Google, Amazon, Facebook, Twitter etc. 121 Since the US is not in this CEPA and these companies are not Kenyan or UAE companies, it is unclear why a Kenya-UAE CEPA includes the wish list of US big tech companies so they can benefit from the CEPA provisions for free. Especially at a time when Kenya may need bargaining chips to get Trump's tariffs removed and some of these CEPA digital trade chapter provisions are what the US has been seeking. 122

The CEPA digital trade chapter includes:

- A ban on customs duties on downloading: movies, music, video games, computer software, eBooks etc from 'a person of a Party' (which is not defined) for as long as there is a WTO decision on this. 123 E.g. Amazon.com has an office in the UAE, so is unclear if the CEPA bans tariffs on buying ebooks etc from Amazon.com. The WTO decisions banning customs duties on downloads are not enforceable, but this CEPA digital trade chapter is. The temporary multilateral version of this ban on customs duties on downloading movies and music etc is calculated to have cost Nigeria US\$1.2billion in 2020 alone<sup>124</sup> and this is likely to have increased as more is digitised (instead of paper copies of books, music CDs and films on DVDs etc coming across the border and paying tariffs). It would be useful to know how much potential tariff revenue Kenya is giving up by including this provision in the CEPA.
- A provision requiring digital products from the UAE to be treated as well as those from Kenya (national treatment) or another country (most-favoured nation treatment. 125 This provision can prevent laws which:<sup>126</sup>
  - o require platforms such as Facebook and Google to share their advertising revenue with newspapers the way that Australia etc require.<sup>1</sup>

<sup>&</sup>lt;sup>k</sup> The multilateral moratorium on customs duties on electronic transmissions is scheduled to expire in March 2026 (unless it is renewed) and these temporary moratoria are anyway not enforceable via the WTO's dispute settlement mechanism.

Kenya is still in the optional plurilateral JSI ecommerce agreement at the WTO which also has this provision. (Of the 91 countries who were negotiating the JSI ecommerce, these 20 countries (including the USA) dropped out of the final JSI ecommerce text because it was so problematic: Brazil, Cameroon, Colombia, Côte d'Ivoire, Ecuador, El Salvador, Guatemala, Honduras, Indonesia, Mexico, Nicaragua, Nigeria, Panama, Philippines, Russian Federation, Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu, Thailand, Türkiye, United States, Uruguay. Countries like South Africa and India were never in it). But the JSI ecommerce provisions have been blocked from being added to the WTO rulebook (by India, Indonesia, South Africa, Turkey etc) and even if they were, the WTO Appellate Body is not working (and the US will not allow it to come back to life for the foreseeable future, especially now that Trump is wholesale defying WTO rules with his 2 April 2025 tariffs), so they would still not be ultimately enforceable at the WTO.

<sup>&</sup>lt;sup>1</sup> Since local newspapers and broadcasters are losing revenue to big tech companies, Australia, Canada, Indonesia etc have implemented laws to require big tech platforms like Facebook and Google to share revenue with newspapers etc when they use their content. E.g. it resulted in almost A\$250million per year from big tech to newspapers etc and allowed newspapers to increase their staff by 50%. also https://www.bbc.co.uk/mediaaction/insight-and-impact/insightblog/indonesia/regulation-and-big-tech https://www.abc.net.au/news/2025-04-02/media-bargaining-code-tariffs-trump/105124278.

- o restrict (as Korea's law does) the ability of platforms such as Google and Apple to force videogame companies to use their payment systems (where they can charge a 30% commission on sales etc) etc,
- o are pro-competition (e.g. various EU laws).

Even though this provision was pushed by the USA in its FTAs (e.g. it is in the Trump Administration's 2020 negotiating objectives for its Kenya-USFTA<sup>127</sup>), the Biden Administration withdrew its proposal of this provision from the JSI ecommerce negotiations in October 2023<sup>128</sup>. This provision is also not in the final JSI ecommerce text, yet it is still in this CEPA.

- Deregulation of the security of electronic transactions (with an exception for one category of transactions).<sup>129</sup> This CEPA provisions means it must be left to consumers and businesses how secure and/or interoperable their systems are.
  - Because of market failures, many governments in both developed (e.g. USA and EU) and developing countries (e.g. Kenya, Mauritius, Nigeria, Malaysia and India) regulate electronic authentication methods e.g. to prevent credit card/identify theft, ensure the security of online banking, ensure the cybersecurity of critical infrastructure such as oil/gas pipelines, ensure interoperability and efficiency of transactions (e.g. between hospitals and health insurance companies etc). 130
    - o E.g. in Kenya: 'Microfinance institutions guideline: Institutions shall ensure that agents: i) Identify customers with at least two factor authentication while performing any transaction requiring identification'. <sup>131</sup>
    - O Since the CEPA only allows one category of transactions, if it is used to preserve this Kenyan microfinance institutions guideline, Kenya cannot have other regulations e.g. to ensure the cybersecurity of online banking/credit cards/oil and gas pipelines etc.
    - While the CEPA has a security exception, it is insufficient for cybersecurity requirements in times of peace etc, see below.

#### MSME AND COOPERATION CHAPTERS

There are micro, small and medium-sized enterprise (MSME) and cooperation chapters in the CEPA. However, they only have vague provisions on cooperation (e.g. via seminars), require the CEPA text etc to be put on a website, have a committee to discuss the issues and any resources must be agreed by both the UAE and Kenya. In addition, both these chapters are unenforceable (they are excluded from the scope of the CEPA dispute settlement chapter. I.e. these chapters do not require the UAE to provide US\$Xmillion in aid to Kenya each year. The provisions in these chapters apply equally to Kenya and the UAE so Kenya is also supposed to aid the UAE, even though the UAE's GNI per capita is 23 times larger than Kenya's<sup>132</sup>.

#### DISPUTE SETTLEMENT CHAPTER

The CEPA chapters discussed above (except the MSMEs and cooperation chapter) are enforceable because the CEPA dispute settlement chapter applies to all CEPA chapters unless otherwise specified. <sup>133</sup> If Kenya does not comply with the CEPA (e.g. the IP chapter) and is sued by the UAE and loses, the UAE can suspend equivalent benefits until Kenya complies with the IP chapter. <sup>134</sup>

#### **GENERALLY**

We note that the CEPA text released still has a number of typos in it (e.g. 'Article XX.14' is presumably supposed to be 'Article 16.14' and 'GPA' is defined in Article 1.3 but then not used in the text). So this text presumably still needs to at least be legally scrubbed to fix such errors There appears to be no special and differential treatment/transition periods for Kenya (even though the UAE's GNI/capita is 23 times larger than Kenya's<sup>135</sup>), except for some transition periods in Kenya's services schedule (which

the UAE also has). Even US FTAs e.g. the Trans-Pacific Partnership (TPP) included transition periods, including for the TRIPS+ provisions on medicines such as market exclusivity. <sup>136</sup>

#### **CONCLUSION**

We therefore urge you to remove all TRIPS+ provisions before ratification of the CEPA if at all it needs to be ratified because costs significantly outweigh any benefits, as outlined above. We look forward to the opportunity to discuss our concerns with you in more detail.

#### Appendix: Grace period - some preliminary implications

#### **Executive summary**

While a few inventors may benefit from a grace period (and these benefits can be obtained in other ways), there are costs for consumers, other inventors and producers, patent examiners etc. According to the European Patent Office's Economic and Scientific Advisory Board, the costs of a grace period include: 137

- Increased legal uncertainty
- Complicating the patent system (including reduced efficiency in patent examination and processing)
- Increased costs of advisory opinions and litigation
- Delaying entry into the public domain
- Increased risk of unintentional infringement by competitors

#### Introduction

#### What is a grace period?

The grace period is a period before a patent application is filed when disclosure of the invention can be done without losing novelty.

The benefits of a grace period are:

- To reduce the risk of accidental disclosure by the inventor which means it is not novel anymore and so cannot be patented
- To allow earlier dissemination of research to increase knowledge spillovers.

Ie that this helps inventors disclose the invention eg to funders (eg via an exhibition) so they can invest in producing the invention etc. However there are a number of problems caused by the grace period, some of which are outlined in this note.

The USA and Japan have been pressuring countries to agree to grace periods. 138

#### Length and breadth of grace periods

#### Length:

Some countries have a grace period eg of 6 or 12 months.<sup>139</sup> Of the countries in WIPO wanting a grace period as of 2006, 37 wanted it for 6 months, 22 wanted it for 12 months.<sup>140</sup> (The longer the grace period, the more additional inventions which will be patented, see below).

#### What grace period is available for:

Some countries only allow grace periods for novelty or inventive step. E.g. the European Patent Convention only allows grace periods for novelty (not for inventive step).<sup>141</sup>

#### Situations where grace period is available:

Some grace periods are broader than others. Eg some may only allow grace periods for displaying the invention at a recognised exhibition. The European Patent Office (EPO) only recognized two

exhibitions in 2016.<sup>142</sup> This meant there is more legal certainty because it is easier to check whether there were any relevant disclosures at this limited number of exhibitions.<sup>m</sup>

Even if Kenya already has a grace period, including it in the CEPA:

- a) locks it in. Therefore if it turns out to be difficult to administer or causes too much to be patented, the country cannot repeal the grace period the way it can if it is merely in its law.
- b) May lengthen it (e.g. if the Kenya only has a grace period for 6 months since the CEPA grace period is for 12 months).
- c) May broaden it e.g. if Kenya only allows a grace period for:
  - a. certain limited disclosures (e.g. in exhibitions), since CEPA broadens it to any public disclosure
  - b. novelty or inventive step, since the CEPA grace period appears to apply to both
  - c. disclosures by the inventor, since the CEPA applies to disclosures by the inventor, patent application or anyone who obtained the information from the inventor/applicant whether inside/outside Kenya.

#### Some concerns about grace periods

Some of the problems caused by grace periods are outlined below.

#### **Implications for consumers**

Grace periods can have implications for purchasers of patent products/their generic versions, e.g. patients needing generic medicines, or farmers/manufacturers needing inputs or governments needing to buy generic environmental technology/subsidise medicines etc.

Professor Carlos Correa notes that the impact of the grace period is that more (e.g. medicines) will be patented because the grace period 'expands the scope for patenting, as inventions disclosed during that period would be eligible for protection, notwithstanding that they would have been deemed in the prior art in accordance with the general rule on novelty'. 143

A grace period can also delay the entry of generic medicines and other products because it causes 'Postponement of the moment at which the invention will fall into the public domain. Important patents which are maintained for the full patent term are likely to fall in the public domain later for graced patents than would be the case if no grace period were available.' 144

The Nobel Prize winning<sup>145</sup> humanitarian organisation Doctors Without Borders therefore recommends the rejection of the grace period proposed in the Regional Comprehensive Economic Partnership (RCEP).<sup>146</sup> RCEP includes countries which are more and less developed than Kenya.<sup>147</sup>

#### **Implications for third parties**

Third parties such as generic companies and other inventors need to be able to tell if an invention is patented so that they can make/import generic versions or invent around it: The 'grace period would also mean that, for others working in the same area of medicines or medical technology, there would be additional uncertainty as to whether they can work on or produce a particular medicine or medical technology disclosed by any person for fear that a patent application may be filed 12 months later.' 148

#### A grace period would decrease legal certainty

A grace period increases legal uncertainty both before and after the patent on the invention concerned is granted according to the European Patent Office's Economic and Scientific Advisory Board. <sup>149</sup> This is because:

• 'it would take longer before third parties could know whether an application has been filed for the subject matter or whether the invention is and shall remain in the public domain'

<sup>m</sup> As the industry association representing 90% of the chemical industry in Germany noted: 'where third-party patents are traced the rules of the German and European patent law enable the identification of an objective reference date (priority date) and of objective reference content (the description in writing of the invention as submitted). This results in a maximum of legal certainty and security of investments', <a href="https://www.vci.de/vci/downloads-vci/firstspirit-1413809313891vci-position-on-grace-periode-140714-en.pdf">https://www.vci.de/vci/downloads-vci/firstspirit-1413809313891vci-position-on-grace-periode-140714-en.pdf</a>. This reduces costs for inventors, see below.

• 'there would also be legal uncertainty post-grant, related to difficulties of determining the status of items of potential prior art for the assessment of the validity of granted patents.' A grace period would 'Increase in the costs of obtaining freedom to operate opinions and in litigation costs. Post-grant, the assessment of the prior art and thus of the validity of granted patents would be more difficult than in the absence of a grace period. This may lead to an increase in the costs of litigation and in the costs of obtaining freedom to operate opinions. Moreover, the fact that an invention is put into the public domain prior to filing may cause an increase in disputes over entitlement, contributing to litigation costs.'

German law and the European Patent Convention (EPC) specify that the only disclosure of patent subject-matter within 6 months prior to patent filing which has no prejudicial effect is if that disclosure took place within a presentation of the invention at an official or officially recognised exhibition or is due to an evident abuse of law to the detriment of the patent applicant. According to the industry association representing 90% of the chemical industry in Germany (VCI) (which categorises the current German law and EPC as not having a grace period):<sup>150</sup>

'In the existing legal situation in Germany and in Europe, the reader of a (scientific) publication within the above-described "freedom-to-operate" analysis can assume that he/she may freely use the information given in this publication if 18 months after the scientific publication no relevant patent applications of an earlier priority date can be found: because the patent filing for an invention and the technical teaching in that application are usually disclosed 18 months after the filing date. In the existing legal situation, the companies can fully resort to all of the published non-patent literature, use it if they wish and possibly make further developments by way of improvements to existing inventions.

With the immense and constantly rising numbers of scientific publications that come out every year and are generally accessible, the "freedom-to-operate" analysis is a great challenge to the companies already under existing law. The experiences of companies in countries with grace periods show that introducing a grace period in Germany or Europe would once more significantly increase the amount of research necessary: because after 18 months it can be no longer assumed automatically that the published scientific findings may be used freely, since it would need to be expected – at any time and as a matter of principle – that a grace period is claimed for a patent application.

In this connection, further points of legal uncertainty would ensue and render it even more difficult to assess the patent situation. For example, introducing a grace period would give rise to several questions of whether a pre-publication of a potentially relevant third-party patent takes into account the state-of-the art or not and, consequently, whether a third-party patent constitutes a problem or not. Concretely, the following questions would need to be asked by way of example:

- In the first place: does the third-party patent owner claim the grace period?
- Does the pre-publication really go back to the inventor of the third-party patent?
- What is the course of action with several inventors or joint patent applications (e.g. two companies) if the pre-publication constituting a bar as to novelty was made by only one inventor alone?
- To what extent does the pre-publication need to be taken into consideration as the state-of-the art for the third-party patent?
- How to proceed with verbal disclosures or a general public display?
- In cases of dispute: how long does it take to reach a decision? Must development/production stops of several years be feared?

... there is the risk of a general increase in legal disputes in connection with the grace period, leading to clearly higher financial burdens for the companies and longer disruptions of

development/and or production with an uncertain outcome. These aspects are a major danger to competitiveness, especially for SMEs.'

#### *Grace period makes it more difficult for inventors*

According to the industry association representing 90% of the chemical industry in Germany (VCI), the increased legal uncertainty due to a grace period (see above) is problematic: 151

'In innovative industries like the chemical industry, companies need to be able to assess the patent situation as reliably as possible before investing in research and development (R&D). For example, this is important in the strategic assessment of fields of technology or of concrete R&D projects – and within this assessment it needs to be found out whether third-party patents stand in the way of own developments or prevent a return on the necessary investment. In professional R&D processes this is done by way of so-called "Freedom-to-Operate" analyses which constitute legal assessments of relevant third-party patents. If uncertain legal points emerge in the assessment of thirdparty patents, this can delay the development process or development projects might even be given up entirely. At the very least, it becomes necessary to invest in a deeper assessment of patent law aspects, channelling these funds away from the actual innovation process. This risk increases considerably due to a multitude of open questions in an introduction of a grace period. . . As described above, a grace period would cause a high level of legal uncertainty and thus be detrimental to innovation.'

#### Do universities need grace periods?

The members of the German chemical industry association (VCI) frequently collaborate with universities and other researchers and finds they are aware of the implications of disclosure before patenting and have patent exploitation agencies to advise them, so the lack of a grace period has not been a problem for them:<sup>152</sup>

'The proponents of a grace period frequently emphasise an alleged need by universities and other research facilities. Their argument is an alleged conflict at universities and research institutes between the necessity of early publication of scientific findings on the one hand and the prejudicial effect of pre-publication on inventions/novelties on the other, holding that this conflict cannot be resolved due to the lack of a grace period. In their numerous cooperation activities with the above-named partners, the VCI member companies have not encountered any such problems. Rather, the companies of the chemical-pharmaceutical industry note that the recent years have seen a strong professionalization of science in IP management, especially in patent law. This is also reflected in the setting up of many patent exploitation agencies. From the VCI's viewpoint, these cooperation partners of the member companies are proficient in handling the German and European patent systems. No cases are known of pre-publications with a prejudicial effect on patents having been made by scientific cooperation partners. . . 'Unlike from what some of the stakeholders might expect, introducing a grace period would not make IP management any easier for SMEs and universities or research institutes.'

#### Grace period makes it more difficult for SMEs

'Unlike from what some of the stakeholders might expect, introducing a grace period would not make IP management any easier for SMEs and universities or research institutes.' 153

For example, if there is a grace period, SMEs 'would need to gather their data for all of their publications and ensure that the grace period has not expired before filing the relevant patent applications. In this context, it is frequently forgotten that a grace period is no general "free ticket" for the disclosure of an

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<sup>&</sup>quot;VCI categorises the German and European Patent Convention systems as not allowing a grace period (even though they specify 'disclosure of a patent subject-matter within 6 months prior to patent filing has no prejudicial effect if that disclosure took place within a presentation of the invention at an official or officially recognised exhibition or is due to an evident abuse of law to the detriment of the patent applicant or his/her legal predecessor. Such protection of exhibitions and reasons of equity should not be confounded with a grace period', <a href="https://www.vci.de/vci/downloads-vci/firstspirit-1413809313891vci-position-on-grace-periode-140714-en.pdf">https://www.vci.de/vci/downloads-vci/firstspirit-1413809313891vci-position-on-grace-periode-140714-en.pdf</a>).

invention prior to patent filing. Also with a grace period, deadlines need to be observed, checked and complied with. Needless to say that such deadlines can be missed too.

Moreover, early publication can lead to a loss of legal protection in other countries which have no grace period or where grace periods are shaped differently. . .

Furthermore, the proponents of a grace period entirely overlook that – based on the publication by an inventor – third parties could file their own patent application with an even earlier priority date than that of the patent filing by the inventor him/herself, barring the commercialisation of the invention. Those who are calling for a grace period in order to possibly use it systematically are running high risks. The existing system provides a meaningful incentive – also commercially – to first of all protect innovations under patent law instead of presenting them to third parties practically free-of-charge and "in the comfort of their homes". It is the latter scenario that could bring about a situation where the commercial use of research results is no longer possible or at least no longer attractive.' <sup>154</sup>

'the VCI acknowledges that – especially among some SMEs – isolated problems might arise which the impacted parties attribute to the lack of a grace period. However, the VCI takes the view that these problems are not primarily due to this lack of a grace period and cannot be solved by introducing one. Quite the contrary, a considerable amount of legal uncertainty would be the price to be paid by SMEs and all other users of the patent system for an introduction of a grace period'. <sup>155</sup>

'the main policy objection invoked in Europe against the adoption of a grace period is that it creates legal uncertainty for third parties, which may find it difficult to ascertain the state of the art in regard to the application or patent of a competitor, if pre-filing publications which would be novelty-destroying are later found to be graced. The simplicity and legal certainty offered by the EPC in terms of the definition of prior art is considered by European users to be one of the most attractive aspects of the European patent system.' 156

#### German chemical industry opposes grace periods

VCI is the industry association which represents 90% of the chemical industry in Germany, (including German subsidiaries of foreign businesses) and it notes that:<sup>157</sup>

- 'A grace period would bring a large degree of legal uncertainty and, consequently, impair innovation. . . A high level of legal certainty and clear-cut legal rules are central to creating attractive framework conditions and security of investments'
- 'Introducing a grace period would make IP management more difficult, especially for small and mid-sized enterprises (SMEs) and universities/research institutes'
- 'grace periods are used only in rare exceptional cases in the relevant countries. Those exceptional cases cannot be the reason for far-reaching legislative changes, such as introducing a grace period' (See Annex below for details).
  - 'Exceptional sector- or technology-specific cases of pre-disclosure prejudicial to innovation or regarding the use of grace periods are not representative. Therefore, they should not give rise to calls for a grace period, and they should not be decisive for legal changes of such far-reaching impact.'
  - Even if rules increasing transparency about clinical trial data (eg so dangerous side effects are not hidden by patent owners) are introduced, there is still no need to introduce a grace period. This is because an application on a patent for a medicine is usually filed as soon as the medicine is found to work in a test tube, long before any clinical trials which may disclose the medicine begin: 'Generally, patents in the field of pharmaceutical products are filed a long time before the underlying clinical trials are finalised and comprehensive transparency rules are to apply only at the end of these trials. Consequently, a grace period is likely to be used only marginally in such cases. Therefore, this sector-specific feature should not be taken as the reason for a change in patent law that would affect all sectors and industries.'
- Therefore 'the companies represented by the VCI see no need to introduce a grace period.'

There were 59 British respondents to a 2002 UK consultation on grace period (individual inventors, SMEs, patent agents, academics and large companies) and they were mostly happy with model E or if a grace period had to be introduced, for it to be for a maximum of 6 months.<sup>158</sup>

#### **Implications for patent examiners**

'A grace period also makes the work of patent offices more complicated, which, in times of backlogs and work-sharing, implies policy issues of systemic relevance. At the EPO, given the extremely narrow range of declarations filed in relation to Art. 55 EPC, the application of the novelty requirement for searchable prior art is simple: where the date of publication of a document is prior to the filing or priority date of the application, inclusion into the state of the art may be ascertained from the face of the document. Where a grace period exists, other issues may become pertinent, such as the origin of the disclosure, or whether the invention thus disclosed is that of the subsequent applicant's. These may require additional office actions, which impact on the duration and efficiency of the procedure.' 159

The European Patent Office's Economic and Scientific Advisory Board also noted that a grace period would could result in 'a systemic negative impact on the functioning of the patent system because introducing a grace period may complicate the process of identifying the applicable prior art. Single items of potential prior art would require investigation as to the origin and circumstances before they could be identified as such. Pre-grant, this may result in a lengthening of the granting procedure, a loss of operational efficiency and an increase in patenting costs due to the potential need for additional communications between the examiner and the applicant.' 160

#### Who benefits from a grace period?

Inventor A who accidentally discloses the invention A during the grace period benefits from a grace period for invention A. However, as noted above, if there is a grace period, other inventors who want to invent around the product A then have to spend more time and effort figuring out whether product A is patented etc.

Furthermore, since all RCEP countries (with enough data) except Japan are net intellectual property (IP) importers, they do not have many inventors who can benefit from a grace period.

US companies benefit if CEPA includes a grace period (since countries generally implement it with respect to applicants from the whole world, not just from the UAE, since it is too difficult to determine whether a company is from the UAE given subsidiaries etc). 'Patents originally filed in the US but subsequently filed in countries without a 12 month grace period cannot benefit from the grace period exception in the US. This disfavours US companies and is the reason why the US pushes trading partners to adopt grace periods. All US trade agreements, including the proposed TPP Agreement, require 12 month grace periods.' <sup>161</sup>

In European discussions, 'The FR delegation stated unequivocally that inventors should be advised to patent their inventions before disclosing them in any way.' 162

As can be seen from the German chemical industries above, even some inventors do not want grace periods.

There are other ways to obtain the benefits of a grace period which have fewer costs, for example:

Benefit of grace period (GP)	Alternative
Reduced risk of accidental novelty-destroying disclosure <sup>163</sup>	Since the GP only protects against accidental disclosure during the GP (eg 12 months), it is not a total solution because the GP does not protect against accidental disclosures at any time. The French government instead suggests educating inventors (eg via offices with patent expertise in universities and research institutions) not to disclose their invention without patenting it.
Earlier research dissemination <sup>164</sup>	This can also be achieved by filing an earlier patent application

For inventions which cannot be tested in secret, a grace period may allow such inventions to be improved or their effectiveness to be more accurately assessed prior to filing a patent application. <sup>165</sup>	Based on the Annex below, this is likely to be rare and a patent application could still be filed first.
Disclosure to potential funders	This can also be achieved by filing an earlier patent application

#### Implications when combined with other TRIPS+ provisions

According to the EPO's Economic and Scientific Advisory Board, a grace period can result in 'Increased risk of unintentional infringement by competitors. There might be a higher risk of unintentional infringements by third parties using a disclosed invention unaware of the fact that the invention might eventually be patented. These parties then would become infringers.' <sup>166</sup>

Therefore the implications of a grace period also need to be considered in combination with any other TRIPS+ provisions which may be proposed in a free trade agreement (FTA) such as the CEPA. For example if the CEPA has TRIPS+ enforcement, then a generic company which unintentionally infringes a patent (by using a disclosed invention which can eventually be patented due to a grace period) could face a much higher penalty. This can discourage generic producers of medicines, environmental and other technology etc from producing.

#### Conclusion

Careful cost-benefit analyses need to be carried out of the implications of agreeing to a grace period. These should include consideration of the implications for: consumers (eg if more medicines are patented due to the grace period), generic companies and other inventors who want to avoid infringing the patent, patent examiners etc. 'The advantages that a grace period would bring for a very small number of users must not be paid at the price of disadvantages for the vast majority of applicants and for the functioning of the patent system overall.' This is because as the German chemical industry noted (see above), grace periods would decrease legal certainty, which increases costs for many inventors and SMEs, for a provision which is rarely used (see Annex) and which is to solve a problem (disclosure before filing the patent application) which can be solved in other ways: eg as the French government said: by educating inventors (for example universities often have an office that advises them on patents) to apply for patents before disclosing their inventions.

Even British companies said that if a grace period had to be introduced, it should be for a maximum of six months. If even German chemical companies (including large companies such as subsidiaries of multinationals) are only able to cope with a very short and narrow grace period (6 months and only for officially recognised exhibitions (of which there are about two per year) or abuse that harms the applicant), then the SMEs in Kenya are likely to find it difficult even to implement such a limited grace period. Grace periods should be left to each country to introduce and adapt in accordance with their level of development and the capacity of their SMEs etc to be able to cope with any grace period.

It does not make sense for net IP importers to lock-in a grace period in a free trade agreement (FTA) like the CEPA.

#### Annex: extent of use of grace period<sup>168</sup>

'In 2013 the patent offices of the USA (USPTO), Japan (JPO), Germany (DPMA), Great Britain, France and Denmark as well as the European Patent Office (EPO) carried out a consultation on the international harmonisation of patent law ("Tegernsee survey").

<sup>&</sup>lt;sup>o</sup> Unless there are effective exceptions for prior use rights

Within this consultation it was enquired, inter alia, about the real use of grace periods by patent applicants in those countries were grace periods were in place.

The results available from this consultation show that patent applicants really use grace periods only in rare exceptional cases:

In Japan over 80% of the respondent SMEs stated to have relied on the grace period in maximally 1% of all patent applications. Roughly a further 10% stated to have used the grace period in maximally 10% of applications. Nearly 100% of the research institutes answered that they resorted to the grace period in maximally 10% of applications. Around 30% of research institutes added that they used the grace period merely in maximally 1% of applications. Finally, over 95% of large companies stated to have used the grace period in maximally 1% of applications.

In Europe 21.6% of the survey participants stated to have needed a grace period less than once per 1000 patent applications (< 0.1%). Another 27% replied that they used a grace period in 0.1% of applications. 43% of the respondents relied on the grace period merely in 1% of applications. The EPO summed up the survey results as follows: "... for 63% of respondents, the grace period has either never been relied upon or has been a factor in an infinitesimally small number of cases."

Moreover, 61.5% of the respondents in Germany opposed the introduction of a grace period. Among those who had resorted to the grace period provisions in other countries, only well over half (55%) spoke for introducing a grace period in Europe.

In their answers to the USPTO, 82% of respondents originating in Europe stated to have never relied on a grace period.'

'Furthermore. . . the mere fact that a grace period was claimed should not lead to the deduction that an unintended disclosure had to be circumvented; we find this deduction per se misleading. The instrument of a grace period might have been used deliberately even though it might have been possible to patent the invention also without the grace period option.'

 $\frac{03/Memorandum\%20to\%20the\%20National\%2025-}{03/Memorandum\%20to\%20the\%20National\%20Assembly\%20to\%20Commence\%20the\%20Ratification\%20Process\%20of\%20\%20the\%20Kenya\%20-$ 

<u>United%20Arab%20Emirates%20Comprehensive%20Economic%20Partnership%20Agreement%20-1.pdf</u>

<sup>&</sup>lt;sup>1</sup> http://www.parliament.go.ke/sites/default/files/2025-

https://www.wto.org/english/thewto\_e/whatis\_e/tif\_e/org6\_e.htm https://www.wto.org/english/docs\_e/legal\_e/27-trips\_01\_e.htm

<sup>4</sup> https://www.twn.my/title2/wto.info/2025/ti250315.htm

<sup>&</sup>lt;sup>5</sup> https://www.wto.org/english/tratop\_e/dispu\_e/appellate\_body\_e.htm

<sup>6</sup> https://www.twn.my/title2/wto.info/2025/ti250315.htm

<sup>&</sup>lt;sup>7</sup> Because Kenya has not joined the optional Multi-Party Interim Appeal Arbitration Arrangement (MPIA) that enables decisions to become final while the AB is not working, https://wtoplurilaterals.info/plural initiative/thempia/

<sup>&</sup>lt;sup>8</sup> Article 13.33.1

<sup>&</sup>lt;sup>9</sup> E.g. see https://www.npr.org/sections/health-shots/2015/03/19/393856788/why-is-u-s-insulin-so-expensive

<sup>&</sup>lt;sup>10</sup> Article 13.33.2

<sup>11</sup> https://haiweb.org/storage/2015/07/Kenya-Report-Pricing-Surveys.pdf

<sup>12</sup> https://haiweb.org/wp-content/uploads/2015/07/Kenya-Summary-Report-Pricing-Surveys.pdf

<sup>13</sup> https://data.worldbank.org/indicator/NY.GNP.PCAP.CD

<sup>&</sup>lt;sup>14</sup> E.g. see https://wikileaks.org/tpp-ip2/tpp-ip2-chapter.pdf

<sup>15</sup> https://www.mfat.govt.nz/en/trade/free-trade-agreements/free-trade-agreements-in-

force/cptpp/comprehensive-and-progressive-agreement-for-trans-pacific-partnership-text-and-resources

<sup>16</sup> https://www.commerce.gov.in/international-trade/trade-agreements/comprehensive-economic-partnershipagreement-between-the-government-of-the-republic-of-india-and-the-government-of-the-united-arab-emiratesuae/

<sup>17</sup> https://rtais.wto.org/UI/PublicShowMemberRTAIDCard.aspx?rtaid=1198

<sup>&</sup>lt;sup>18</sup> India's is US\$2,540 and Kenya's is US\$2,110, <a href="https://data.worldbank.org/indicator/NY.GNP.PCAP.CD">https://data.worldbank.org/indicator/NY.GNP.PCAP.CD</a>

<sup>&</sup>lt;sup>19</sup> E.g. see https://phrma.org/resources/phrma-special-301-submission-2025

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- <sup>24</sup> E.g. https://www.wto.org/english/tratop\_e/dispu\_e/cases\_e/ds512\_e.htm and https://www.wto.org/english/tratop\_e/dispu\_e/cases\_e/ds567\_e.htm
- <sup>25</sup> Article 16.4
- <sup>26</sup> Article 16.25
- <sup>27</sup> https://data.worldbank.org/indicator/NY.GNP.PCAP.CD
- <sup>28</sup> E.g. see <a href="https://wikileaks.org/tpp-ip2/tpp-ip2-chapter.pdf">https://wikileaks.org/tpp-ip2/tpp-ip2-chapter.pdf</a>
- <sup>29</sup> https://www.mfat.govt.nz/en/trade/free-trade-agreements/free-trade-agreements-in-

force/cptpp/comprehensive-and-progressive-agreement-for-trans-pacific-partnership-text-and-resources

- <sup>30</sup> E.g. see https://phrma.org/resources/phrma-special-301-submission-2025
- 31 https://policy.trade.ec.europa.eu/eu-trade-relationships-country-and-region/countries-and-regions/east-africancommunity-eac/eu-kenya-agreement en
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- <sup>36</sup> India's is US\$2,540 and Kenya's is US\$2,110, https://data.worldbank.org/indicator/NY.GNP.PCAP.CD
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- <sup>50</sup> https://igbamedicines.org/doc/IQVIA-
- IGBA Impact%20of%20FTAs%20on%20generic%20and%20biosimilar%20markets Final%20Deck%20-%20October%202020.pdf
- <sup>51</sup> See Exhibit 3 of <a href="https://cpath.org/sitebuildercontent/sitebuilderfiles/GuateCpathhaonline8-25-09.pdf">https://cpath.org/sitebuildercontent/sitebuilderfiles/GuateCpathhaonline8-25-09.pdf</a>
- <sup>52</sup> https://policy-practice.oxfam.org/resources/all-costs-no-benefits-how-trips-plus-intellectual-property-rules-inthe-us-jord-114080/
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https://dash.harvard.edu/bitstream/handle/1/41292244/scottmorton%2cstern%2cstern biosimilars WP.pdf?sequ ence=1&isAllowed=v

<sup>55</sup> And see footnote 44 in the same document,

https://www.twn.my/title2/FTAs/Intellectual Property/IP and Access to Medicines/TradeAgreementsandAcc esstoMedicationsUnderTheBushAdmini.pdf

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<sup>63</sup> E.g. see https://www.twn.my/title2/wto.info/2025/ti250315.htm
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#### **ENDORSED BY THE FOLLOWING ORGANIZATIONS**

- 1. Econews Africa
- 2. Action Aid International Kenya
- 3. The Kenya Legal & Ethical Issues Network on HIV and AIDS (KELIN)
- 4. Cancer Must Bow
- 5. Wote Youth and Development Projects
- 6. Network of Tuberculosis Champions Kenya