Available online at www.sciencedirect.com

Public Health

journal homepage: www.elsevier.com/puhe

Short Communication

Public health–oriented intellectual property and trade policies in Africa and the regional mechanism under Trade-Related Aspects of Intellectual Property Rights amendment

T.A. Adekola

School of Law, City University of Hong Kong, Hong Kong

ARTICLE INFO

Article history:
Received 18 February 2019
Received in revised form
15 April 2019
Accepted 27 April 2019
Available online 13 June 2019

Keywords:
Public health
TRIPS agreement
Access to medicines
Regional mechanism

ABSTRACT

Objective: The short communication is prompted by the debate relating to the effect of pharmaceutical patents on access to affordable medicines, particularly in Africa. A recent amendment made to the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement creates a policy space for the regional alliance of low-income countries for the collective procurement and local production of drugs under compulsory licensing. This article examines the extent to which the regional mechanism can deliver access to pharmaceuticals. The article examines the regional mechanism in the light of the recent regional trade agreements and pharmaceutical plans of some regional economic blocs in Africa as well as the newly signed African Continental Free Trade Agreement (AfCFTA).

Study design: This short communication adopts a descriptive approach in linking the regional mechanism in the TRIPS amendment to the regional trade agreements of African countries at the subregional and continental levels.

Methods: To ascertain the extent to which TRIPS Agreements regional model can deliver access to medicines in Africa, the article adopts a desk review approach by examining the relevant provisions of TRIPS Agreement, particularly the newly added Article 31bis, and the provisions of the relevant regional and continental free trade agreements in Africa.

Results: The article finds that although the regional model has great prospects in supporting the wider effort to deliver access to medicine, the limitations to its operative utilization may weaken its potency in addressing the urgent public health needs of the continent.

Conclusion: The article concludes by stressing the inevitability of Africa's integration in tackling the deficiency of access to generic medicines in Africa. It was noted that even though there could be some potential challenges, the regional mechanism is indeed the way to go for low-income countries.

E-mail address: atadekola2-c@my.cityu.edu.hk.

https://doi.org/10.1016/j.puhe.2019.04.019

The director general of the World Health Organization (WHO) in a 2018 report titled *Addressing the global shortage of, and access to, medicines and vaccine* decried the global challenge of access to medicines, vaccines, and medical technologies in less-developed countries.[1] The challenge is seen as a threat to the attainment of the Sustainable Development Goals and the universal health suffrage.[1] The report pinpoints the World Trade Organization's (WTO) Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS) as having far-reaching implications on the deficiency in access to generic medicines in low-income countries. The rising price of medicines coupled with the continuing challenge of scarcities and stock-outs of essential medicines in most developing countries undoubtedly poses a great threat to public health.[2] The TRIPS Agreement places legal restraints on the global trade of patented pharmaceuticals to encourage innovation and allow pharmaceutical patent holders recoup the investments put into their intellectual properties. The monopoly rights enjoyed by patent holders result in the high prices and scarcity of pharmaceuticals. This intersection between trade and public health therefore has a significant impact on the ability of developing countries to respond to public health emergencies.[3] While the TRIPS Agreement has been argued not to be the only cause of lack of access to medicines in developing countries, the agreement has been argued to have exacerbated public health crises.[4] To ameliorate the effect of pharmaceutical patent protection on public health, the TRIPS Agreement contains some built-in flexibilities aimed at striking the right balance between trade policies and public health. Some of these flexibilities are compulsory licensing, parallel importation, and transition periods. The WHO and public health activists have complained the low utilization of these flexibilities by less-developed countries.[5] The key reasons why these flexibilities have not been fully used to drive access to generic drugs have been ascribed to the low purchasing power and weak economies of less-developed countries. To address the concerns, an amendment was made to the TRIPS Agreement which came into force on 23 January 2017. The amendment, in its Article 31bis(4), creates a policy space for a regional collective effort, which allows less-developed countries to harness their economies of scale and purchasing power for collective procurement of medicines and joint effective use of TRIPS flexibilities. The essence of the regional mechanism is to ensure that low-income countries stand strong together to tackle their shared public health concerns as opposed to when an individual country makes a seemingly futile effort to do the same alone. For the regional agreement to be effective, however, a free trade or single market policy is required within the regional alliance to facilitate the free flow of pharmaceuticals. This article will examine through the lens of the regional mechanism in the TRIPS Agreement the prospects and challenges of some regional trade efforts geared toward tackling the access to medicine conundrum on the African continent.

The significance of TRIPS amendment to public health in Africa

When compared with the rest of the world, Africa bears the greatest burden of diseases.[6] The continent relies majorly on the importation of pharmaceutical products in meeting the health needs of its population. It has been reported that 90% of citizens of developing countries, particularly in Africa, lack access to affordable medicines, thereby making drugs 'the largest family expenditure after food'.[1] Reports from the WHO Africa show that there are 20.7% chances of persons aged between 30 and 70 years dying of non-communicable diseases.[1] With the chronic nature of non-communicable diseases, affected persons may have to rely on life-sustaining medicines for their lifetime. However, the continued reliance of most African countries on China and India for drug importation has been threatened in recent time by the obligation imposed on these countries by the TRIPS Agreement to enforce protectionist intellectual property frameworks.[7] This development impedes the continued access of African countries to the procurement of generic versions of on-patent medicines. Furthermore, the threat of antimicrobial resistance has given rise to the production of newer effective drugs which are protected by patent laws. In the light of these critical developments, the regional mechanism in the TRIPS amendment remains a viable pathway for African countries to procure or produce generic versions of patented drugs within the rules of the WTO multilateral trading system.

Regional mechanism and the African Continental Free Trade Agreement model

Article 31bis(4) of the TRIPS Agreement stipulates three conditions that must be satisfied before a regional trade agreement can use the regional mechanism:

1. Half of the current membership of the regional agreement must be ranked as least developed countries (LDCs).
2. Members of the regional trade agreement must share similarities in disease burden.
3. The regional agreement must comply with the requirements of the WTO.

A critical look at the regional mechanism shows that African regional groupings are the targeted beneficiaries. This is because the continent has the highest concentration of LDCs in the world (United Nations Office of the High Representative for the Least Developed Countries).

The East African community has the most comprehensive pharmaceutical plan among the four economic communities in Africa. The community comprises six members, of which five are categorized as LDCs. The regional community is now driving the 2nd East Africa Community regional manufacturing plan of action 2017–2027. The Economic Community of West African States (ECOWAS) also has the ECOWAS Regional Pharmaceutical Plan (ERPP) developed by the West African Health Organization, Bobo-Dioulasso, Burkina Faso, in 2014. The ECOWAS also fits into the regional model of the TRIPS amendment because more than half of its members are categorized as LDCs. Little or nothing has been achieved by the EAC and ECOWAS because of the weak economic strength of the regions and lack of political will, skills, and expertise.

Furthermore, on 21 March 2018, 44 countries signed the African Continental Free Trade Agreement (AfCFTA) in Kigali, Rwanda. The free trade agreement is targeted at creating a single market for goods and services across the 54 African countries. As of December 2018, the agreement has been signed by 49 African countries.

The AfCFTA also matches the regional model envisaged in Article 31bis of the TRIPS Agreement for the following reasons: first, of the 55 African countries, 33 are ranked LDCs by the United Nations; second, the continent shares similarities in disease burden, particularly malaria, tuberculosis, HIV/AIDS, and other non-communicable diseases; and third, the AfCFTA provides that the WTO shall be duly notified of the regional trade agreement.

Prospects and limitations

The signing of the AfCFTA and the subregional effort of the EAC and ECOWAS are indeed a commendable feat for African countries. The regional drive will provide the platform to jointly tackle the manifold socio-economic challenges of the regions, particularly that of access to medicines. The African continent can leverage on the regional mechanism by combining its economies of scale and purchasing power for the bulk importation of patented drugs under compulsory licensing. It is important to note that the regional mechanism expands the scope of pharmaceuticals under the system to include active ingredients and diagnostic kits. The regional mechanism can also utilize the benefits of regional patents, patent pools, voluntary licensing, collective price negotiation with patent holder, and collective production and/or procurement of generic drugs to make medicines more affordable and accessible to its poor population.

Furthermore, the TRIPS amendment stresses the imperative of building jointly owned local manufacturing capacity for the regional alliance as an enduring solution to the access to medicine conundrum (newly added Annex to the TRIPS agreement Paragraphs 5 and 6). To achieve this, the TRIPS amendment emphasizes undertaking of developed countries under the TRIPS Agreement to assist in technical cooperation and technology transfer.

In addition, by the decisions of the TRIPS Council, LDCs are to enjoy a transition period until July, 2021 and January 2033 for the substantive provision of the TRIPS Agreement and pharmaceutical patents, respectively (See WTO document Nos IP/C/64 and IP/C/73). The TRIPS Agreement also makes provision for the possibility of further extension upon satisfactory request by LDCs (See Article 66 of TRIPS). The rationale behind these transitional waivers is to afford LDCs sufficient time to build viable technological base and local pharmaceutical manufacturing capacity before full compliance with TRIPS obligations. The implication of these flexibilities on the regional mechanism under TRIPS reforms is that members of the 'qualified' regional alliance can collectively appropriate the gains of the transitional waivers enjoyed by its LDC members to facilitate the combined local production and onward distribution of generic versions of patented pharmaceuticals within the economic coalition without fear of falling foul of TRIPS obligations. If the waivers are fully harnessed by Africa's continental and regional economic blocs, LDC members can become the 'pharmacy shop' where generic drugs can be legally sourced for the collective utilization of all.

Despite the prospects of the regional mechanism for tackling the conundrum of access to medicines in Africa, there are some factors that may inhibit its effective use.

First, it has been argued that the challenge of access to medicine in Africa is not only caused by the TRIPS Agreement.[8] The challenges posed by non-TRIPS factors such as lack of good roads, inadequate power supply, poor logistics, inadequate medical personnel, etc. will render the regional mechanism of little or no effect, if left unsolved.

Second, there is the lack of coherence in the intellectual property domestic laws of African countries. For the regional mechanism to be effectively used, some specific provisions must be uniformly incorporated in the domestic legislation of individual countries. To achieve this, legal expertise and a strong political willpower, which is not readily available in most African countries, will be needed.

Third, the trend by developed countries to incorporate higher standards of intellectual property protection (TRIPS-plus) into bilateral and free trade agreements could reduce the potency of the regional mechanism.[9] TRIPS-plus provisions elongate the life span of patented drugs beyond the statutory period. The fact that some African countries are signatories to TRIPS-plus Agreements will have a distressing effect on the regional collective drive for access to life-saving drugs in Africa.

Conclusion

The need for African countries to jointly address the challenge of access to medicine has become inevitable. As discussed, the signing of the AfCFTA and the efforts of the EAC and ECOWAS present a great opportunity for the continent to take advantage of the policy space made available for parties to regional trade agreements under the amended TRIPS Agreement. Even though there are several challenges that threaten the effective use of the system, the pooled effort of African countries holds a lot of promises in surmounting the challenges. When, for instance, an African country within the regional alliance has shortcomings, other countries possessing a complementary condition could help in alleviating the inadequacies. Hence, regional collective effort is indeed the way to go.

Author statements

Acknowledgments

The author wishes to appreciate the contribution of Associate Professor Wenwei Guan of the School of Law, City University of Hong Kong, for helping with the initial draft of this manuscript.

Ethical approval

Not required given the nature of the article.

Funding

No funding.

Competing interests

None declared.

REFERENCES

1. World Health Organization. Addressing the global shortage of, and access to, medicines and vaccines Report by the Director-general background [Internet] *World Health Assembly* 2018;**EB142/13**:50. Available from: http://apps.who.int/gb/ebwha/pdf_files/EB142/B142_13-en.pdf%0Ahttp://apps.who.int/gb/ebwha/pdf_files/WHA70/A70_20-en.pdf.
2. Guan W. IPRs, public health, and international trade: an international law perspective on the TRIPS amendment. *Leiden J Int Law* 2016;**29**(2):411–40.
3. Liberman J. Implications of international law for the treatment of cancer: the single convention on narcotic drugs and the TRIPS agreement. *Public Health [Internet]* 2011;**125**(12):840–6. Available from: https://doi.org/10.1016/j.puhe.2011.09.032.
4. Abbott FM, Reichman JH. The Doha round's public health legacy: strategies for the production and diffusion of patented medicines under the amended TRIPS provisions. *J Int Econ Law* 2007;**10**(4):921–87.
5. Nicol D, Owoeye O. Using TRIPS flexibilities to facilitate access to medicines. *Bull World Health Organ [Internet]* 2013;**91**(7):533–9. Available from: http://www.who.int/entity/bulletin/volumes/91/7/12-115865.pdf.
6. African Development Bank Group. *Revitalizing Africa's pharmaceutical industry - African development bank* [Internet] [cited 2018 Nov 13]. Available from: https://www.afdb.org/en/news-and-events/revitalizing-africas-pharmaceutical-industry-13289/; 2014.
7. Owoeye OA. *Compulsory patent licensing and local drug manufacturing capacity in Africa* [Internet]. Bull World Health Organ; 2014. p. 92 (November 2013):214–9. Available from: https://doi.org/10.2471/BLT.13.128413.
8. Soyeju O, Wabwire J. The WTO–TRIPS flexibilities on public health: a critical Appraisal of the East African community regional framework [Internet] *World Trade Rev* 2018;**17**(01):145–68. Available from: https://www.cambridge.org/core/product/identifier/S1474745617000143/type/journal_article.
9. Owoeye O, Olatunji O, Faturoti B. Patents and the Trans-Pacific Partnership: how TPP-style intellectual property standards may exacerbate the access to medicines problem in the East African Community [Internet] *Int Trade J* 2017:1–22. 00(00) Available from: https://doi.org/10.1080/08853908.2017.1386143.