

Compulsory Licensing in the Age a Pandemic

By John Syekei and Sidharth Shah

Introduction

As the COVID-19 pandemic continues to spread rapidly across the globe and claim numerous lives, health care systems of countries are coming under severe pressure. Governments globally, including Kenya, are taking measures to combat the effects of the COVID-19 pandemic and some, in liaison with pharmaceutical companies and research groups in the private sector, are continuously ramping up efforts to find a cure or vaccine; likely to be protected through patents.

In light of the race to develop and patent a vaccine, the question that arises concerning affordable and universal access is whether the Kenyan government can secure affordable access to a vaccine when one becomes available?

There is real danger that access to a vaccine may be restricted by factors such as the need to meet local demand (for a country producing the vaccine), price, fragmented supply lines and patent protection. However, it is possible to overcome these restrictions through governmental co-operation and creation systems to facilitate easy access of the COVID-19 vaccine. For example, low and middle class countries may access an affordable vaccine that is currently on trial, as a result of an access project led by Geneva based Vaccine Alliance (**GAVI**). Kenya may be 1 of 92 countries benefitting from the GAVI project.

In the absence of any global solution or cooperation, countries like Kenya which are party to the Agreement on Trade Related Aspects of Intellectual Property Rights, 1995, (**TRIPS**) and the Doha Declaration on the TRIPS Agreement and Public Health, 2001 (the **Doha Declaration**), may rely on compulsory licensing provisions contained in these treaties and local laws, to tackle concerns around patent rules limiting Kenyans' access to affordable medication.

Compulsory Licensing

Compulsory licensing enables a government to override a patentee's power to control the manufacture, supply and licensing of patented inventions. The Doha Declaration affirms that member nations may take measures to protect public health, including the right to grant and determine the grounds upon which compulsory licences are granted. Kenya has domesticated the provisions of the Doha Declaration in the Industrial Property Act of 2001, providing that a patentees' rights are amenable to limitation through compulsory licensing, where there is public interest, interdependence of patents or where the government desires to exploit the patented invention.

The Cabinet Secretary for Industry, Trade and Cooperatives (the **CS**) may authorise the exploitation of a patented invention, where public interest so requires. Relevant **public interest emanates from health** or national security concerns or anything significant affecting the development of any other vital interest of

Kenya. A compulsory licence may also be granted where the CS determines that a patent is not being exploited in a competitive manner.

Given that the World Health Organization declared the COVID-19 pandemic a health emergency of international concern, any action to fight and prevent its spread and effects qualifies as a public health reason and thereby, a ground to grant a compulsory licence.

The Tribunal

If the CS fails to take action, an interested party may make an application to the Industrial Property Tribunal, for a compulsory licence. The Tribunal may grant a compulsory licence where there has been a **failure to put the patent to use or there is a clear interdependence of patents.**

Additionally, the applicant must establish that they have attempted but failed to reach an agreement with the patentee for a contractual licence on reasonable commercial terms. However, where the compulsory licence is required to address a national emergency or other extreme emergency (like the COVID-19 pandemic) the Act waives this requirement. That said, the applicant must also furnish the Tribunal with sufficient guarantees that they will put the patent to use.

It is clear that the grant of a compulsory licence washes away protection against unauthorized use, rendering a patent somewhat useless, as a patentee cannot derive any commercial benefit on its own terms. This may discourage innovators from investing in research and development going against the very nature of intellectual property rights protection, which is to incentivize invention. The Kenyan regulatory framework is aware of this fact and accordingly, the Act limits the ways in which the patented invention may be exploited, including for example, limiting the scope and duration of the licence. Notably, it is mandatory for the patentee to be compensated for exploitation of the patent.

Kenya has never issued a compulsory licence, however it is likely that the COVID- 19 pandemic may present an opportunity for these provisions to be tested.

Right to Life

Courts in Kenya have determined that the government has a duty to ensure that Kenyans have access to affordable health care and that no steps are undertaken to jeopardise access to health care. Bearing this in mind, Kenyan courts have concluded that the right to health takes precedence over the intellectual property rights of a patentee. Moreover, where provisions of the law pose a danger to Kenyans right to health, in that the patients may not access cheaper generic drugs required to sustain life, then the right of the patentee is unlikely to be protected through enforcement of the intellectual property laws.

It will be interesting to see if the government adopts a similar approach to ensure that Kenyans' right to access an affordable vaccine for the COVID-19 pandemic, as and when one becomes available, trumps the commercial interests of pharmaceutical companies and research groups.

Conclusion

To satisfy its duty to ensure Kenyans have access to affordable health care, it is mandatory for the Kenyan government to take appropriate action and facilitate access to a vaccine for the COVID-19. This is achievable through cooperation with the international community, like participating in access projects led by institutions such as GAVI; or by invoking the provisions of the compulsory licensing laws.