Overcoming intellectual property monopolies in the COVID-19 pandemic

Médecins Sans Frontières (MSF) is responding to the global COVID-19 pandemic, providing treatment and care for people with COVID-19, protecting people living in vulnerable conditions, and ensuring uninterrupted essential health services for people suffering from other diseases.[1] Having universal access to existing and future tools for treatment, diagnosis and prevention is critical.

MSF has repeatedly witnessed how exclusive rights and monopolies granted to pharmaceutical corporations, resulting in high prices and blocking generic competition, have had a negative impact on our medical actions in different countries.[2] For example, in the past, high prices for patented medicines have undermined the capacity of countries to provide access to treatment for HIV/AIDS, tuberculosis (TB), hepatitis C and cancer to all patients who need them. However, the impact of intellectual property (IP) monopolies is not limited to drugs. The availability of more affordable pneumococcal conjugate vaccine and human papillomavirus vaccine in low- and middle-income countries has been delayed due to unmerited patents on key technologies blocking follow-on producers.[3]

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While several of the drugs being trialled as COVID-19 treatments are now off patent, patented drugs and experimental drugs are also being trialled, and some of which are under patent protection in many developing countries.[4] With control over the market as a result of patents or other exclusive rights, pharmaceutical companies could determine how global production and supply chain are organised, who ultimately has access, who can produce medicines and where they can be supplied. Furthermore, lack of access to know-how, data and IP can impact technology dissemination and delay of scale-up of more affordable generic and biosimilar products.

Patent term extension and "evergreening"

Companies often apply for secondary patents on known medicines to seek new monopolies or prolong current market control. This business strategy is known as "patent evergreening". In some countries, patents could also be granted on second medical use of a repurposed medicine. Given that many of candidate therapeutics for COVID-19 are repurposed medicines, it is in the public interest of all countries to refrain from allowing "patent evergreening" by restricting the grant of secondary patents on known medicines and excluding from patentability second medical uses as being mere methods of medical treatment.

Issues of voluntary licensing

The terms and conditions of licensing agreements between pharmaceutical companies are often negotiated confidentially and kept secret. These agreements may allow only a few generic companies to supply to a limited number of low- and middle-income countries.[5] For example, pharmaceutical corporation Gilead Sciences, after ignoring demands calling for non-enforcement of its patents on COVID-19 candidate drug remdesivir,[6] proceeded to secretly sign voluntary licensing agreements with only a few manufacturers of its choosing from India, Pakistan and Egypt. The voluntary licensing agreements excluded nearly half of the world's population, including most South American countries and many countries with manufacturing capacity, some of which have supported COVID-19 treatment clinical trials.[7] Currently suffering from some of the highest infectious rates in the world, thousands of patients in the 10 South American countries excluded from the license territory could potentially benefit from remdesivir-based treatment. This dangerous precedent must alert governments that voluntary actions of companies are not reliable.

Data and market exclusivity

Data exclusivity [8] prohibits regulatory agencies, within a fixed period of time, from registering generic or biosimilar products even if they do not directly rely on the test data submitted by the originator company. Moreover, some countries allow for data exclusivity for a new medical indication for an old repurposed medicine. Market exclusivity associated with orphan drug status and other designations prevent any alternative producers from supplying the concerned medicine for a certain period of time. Both data exclusivity and market exclusivity provide additional monopoly power alongside already granted patents and can thus represent a barrier for access to and scale-up of COVID-19 treatment.

Policy and legal actions to overcome patent barriers

To overcome these barriers of market dominance and access patented health technologies and products needed for COVID- 19 treatment, diagnosis and prevention, countries can make use of a range of public health safeguards. In particular, flexibilities are contained in the Agreements on Trade-related Intellectual Property Rights (TRIPS) and the Doha Declaration on TRIPS and Public Health. Already some countries have taken a lead in recognising COVID-19 as a public health emergency and have taken measures to overcome any future IP barriers.

Measures that can be adapted at national, regional and international levels include but are not limited to:

- Suspending the application and enforcement of patents and other IP on essential health technologies, materials and products concerning COVID-19.
- Issuing compulsory licenses and government-use licenses to allow production, supply, importation and exportation of patented products, materials and technologies, including exploring a regional approach and adopting expedited procedures to allow fast-track compulsory licenses for all COVID-19 related technologies.
- Applying strict patentability criteria by excluding from patentability second medical uses as being methods of medical treatment and new forms and derivatives of known medicines.
- Suspending the application of data exclusivity, other market exclusivities and patent linkage (or providing waivers if existing in national or regional regulations), to enable rapid regulatory approval of generic and biosimilar products.
- Applying a 'Bolar exemption'[9] that allows alternate manufacturers to undertake development and seek marketing and regulatory approval of generic and biosimilar versions of patented medicines even during the patent term.
- Suspending certain obligations under bilateral or regional trade and investment agreements that may constrain a country's ability to issue a compulsory license, undermine strict patent examination criteria, and facilitate data or other exclusivities on medicines.
- Stop all free trade agreement (FTA) negotiations during the pandemic.[10] If FTAs are negotiated, restrictive IP provisions that could hinder timely and affordable access to medical technologies must be excluded. Before engaging in bilateral FTA negotiations, it is important to assess the impact of the restrictive IP provisions that are likely to be tabled on access to affordable medicines including for COVID-19 treatment.

The global impact of the COVID-19 pandemic also presents challenges and limitations of relying only on national strategies to ensure an effective global response. In this regard, countries should explore effective international collaborations and binding agreements to facilitate open sharing and the right to use of technologies, know-how, data, and global non-exclusive rights to use and produce COVID-19 medicines. In the event of the need to pool technologies, data and intellectual property, mandatory measures and essential considerations including non-exclusive and worldwide coverage should be adopted.[11]

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