

Strategic patent benchmark actions against Tuberculosis

Ações estratégicas de referência de patentes contra a Tuberculose

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ABSTRACT

Tuberculosis (TB) is the second cause of death lead by infectious disease worldwide and with a growing incidence and death rates by 2022. United Nations preventive and treatment targets to fight TB were unmet and the upcoming TB patent portfolio is vulnerable what jeopardize global progress against TB. Funding for TB research is limited and strategical initiatives through intellectual property could be applied to optimize public and private efforts to fight TB epidemic. To stimulate the research and drug market aspects related with TB technologies, it was synthetized through searches in technological databases 15 strategic actions to enhance development and access of TB assets at regional, national and international level.

Keywords: intellectual property, patent protection, neglected diseases, public policies, tb burden.

RESUMO

A tuberculose (TB) é a segunda causa de morte liderada por doenças infecciosas em todo o mundo e com incidência e taxas de mortalidade crescentes até 2022. As metas preventivas e de tratamento das Nações Unidas para combater a TB não foram atingidas e o portfólio de patentes de TB é vulnerável, o que compromete o progresso global contra TB. O financiamento para a pesquisa da tuberculose é limitado e iniciativas estratégicas por meio da propriedade intelectual podem ser aplicadas para aperfeiçoar os esforços públicos e privados para combater a epidemia de tuberculose. Para estimular a pesquisa e os aspectos do mercado de medicamentos relacionados às tecnologias de combate a TB, no presente trabalho foram sintetizadas por meio de pesquisa em bancos de dados tecnológicos 15 ações estratégicas com recomendações para potencializar o desenvolvimento e o acesso aos ativos da TB em nível regional, nacional e internacional.

Palavras-chave: propriedade intelectual, proteção de patente, doenças negligenciadas, políticas públicas, tuberculose.

1 INTRODUCTION

Tuberculosis (TB) is a communicable disease caused by the bacteria *Mycobacterium tuberculosis* and the second (first is COVID-19) cause of death lead by an infectious globally¹. Approximately 10 million people worldwide were infected by tuberculosis by 2020, with roughly 1.5 million of the cases progressed to death. With the COVID-19 pandemic, the rate of people infection and drug-resistant TB increased by 4.5% and 3% respectively, with a concomitant decline in diagnosis and treatment globally².

The global patent scenario against tuberculosis is vulnerable and lacks immediate dedicated public policies to increase health technologies to fight TB³. Most of the preventive and treatment targets established by the UN were not met until 2022. This include the funding targets for TB research and universal access to TB prevention, diagnosis, treatment, and care^{2,4,5}. Strategical actions trough intellectual protection could be applied by public and private actor to favor development and access of anti-TB assets. To advance in this field, we developed a benchmark of strategic actions and initiatives for the development and access of anti-TB technologies globally and nationally.

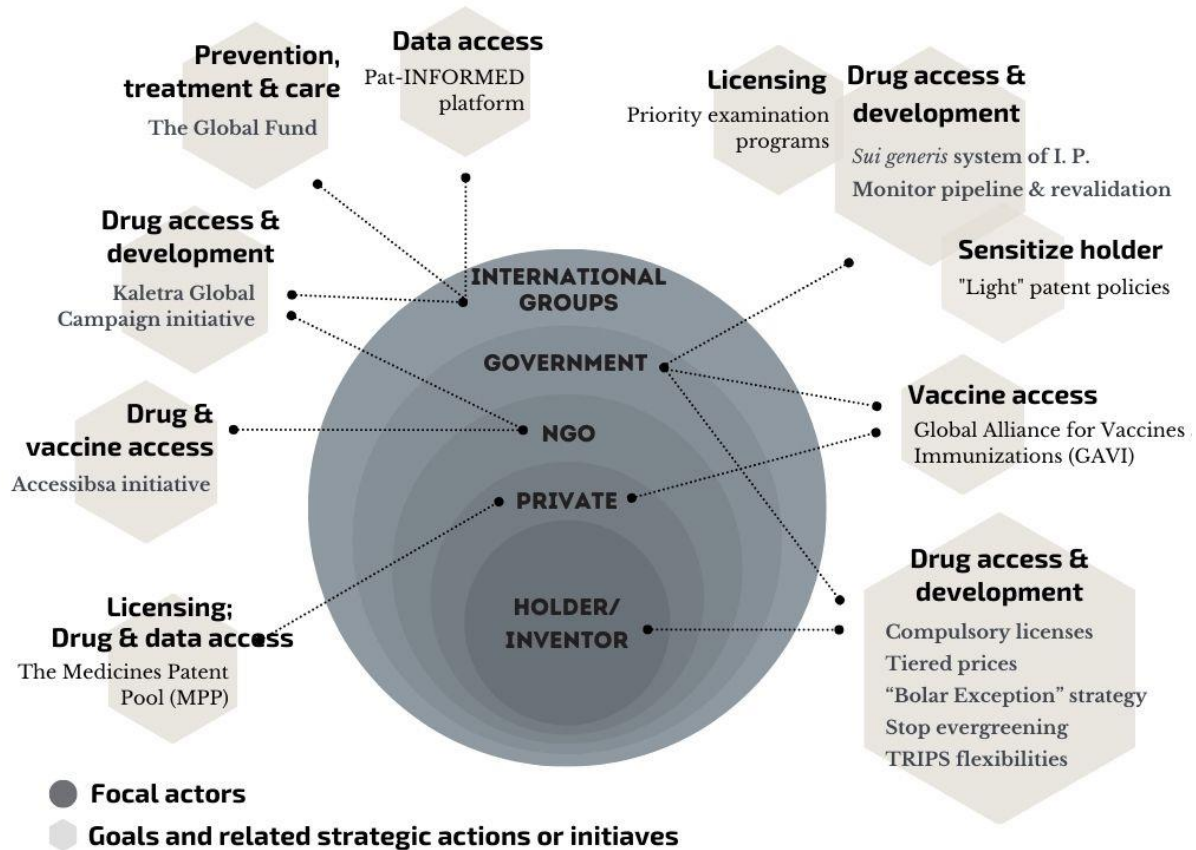
2 METHODS

A search in technological databases complemented with our personal knowledge was conducted to identify actions and market strategies that could be applied by multiple-level actors (international, national, and local/holder level) to fight TB. Information about product development intelligence of TB technologies was ordered to the Coherent Market Insights⁶ and Value Network for Business Intelligence⁷. With the last, we also ordered the prospection of information about TB technologies in the news. Searches were conducted between 2017 to 2018 and updated by august 2022.

3 FINDINGS

We identified 15 strategies to be applied by multiple-level actors to fight TB worldwide (Figure 1):

Figure 1 - Benchmark of strategic actions and goals to enhance the development and accessibility of TB-related technologies by local, national, and global actors.



Apply priority examination programs for patent applications: Is a strategy to facilitate the process of patent licensing. For example, in Brazil the Federal Law n° 9279⁸ in consonance with the INPI Resolution n° 237⁹ were formulated to synergistically promote privileges to increase the number of patents granted to nationals and decrease the average time for granting patents, thus increase "Brazilian priority" in the patent portfolio.

Employ compulsory licenses: Use of jurisprudence by the inventor or government to provide mechanisms for use of anti-TB patents without a voluntary authorization by the right holder^{ix}.

Tiered prices strategy: Is the practice of holders and governments of selling essential drugs to low- and middle-income countries at lower prices than in rich countries thus improving medicine accessibility¹⁰.

"Bolar Exception" strategy: Governments or inventors/holders allow the research and development of a drug before its patent expired to stimulate manufacture of generic drugs to be commercialized as soon as the patent expire. This strategy is inspired by the Hatch-Waxman

Act (Law nº 98-417) that allowed research and development of a drug before its patent expires in the USA¹¹.

Global Alliance for Vaccines and Immunizations (GAVI) initiative: Is a Swiss public-private partnership that facilitates access to vaccines in low-income countries¹². Could establish anti-TB partnerships.

Stop evergreening: Prohibition by governments that holders practice the successive renewal of monopoly without, for example, any therapeutic innovation to maintain high drug prices (Evergreening)¹³.

Adopt a sui generis system of intellectual property: Is a well-established policy (in USA and EU) to guarantee protection of pharmaceutical innovations by the implementation of a system (such as the Supplementary Protection Certificate) to increase the patent term only for the drug approved for marketing (e.g. Marketing Exclusivity), not the complete patent. Or some temporal protection of the test results submitted by thirties to register a new drug (Data Exclusivity) on drug regulatory agencies, with simultaneous validity with a patent or not¹⁴.

Monitor pipeline patents and patents revalidation: Is a retroactive protection of technologies coming from other countries which are already in the public domain or are outside the unionist priority period (12 months from the filing date) in the lack of the patent exploration in the destination country¹⁵.

TRIPS flexibilities: Holders and governments can evoke the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities for public health reasons and other provisions (Articles 1, 6, 7, 8, 31 bis, 40 and 44) to assure access to anti-TB medicines¹⁶.

Implement "light" patent policies: Creation of a task force by governments to stimulate holders of anti-TB pharmaceutical patents to reformulate their "policy of writing a board of patent claims". Moreover, ban the "writing strategy" that makes patents subjective and difficult to interpret to delay or block manufacturers from entering the market³.

Medicines Patent Pool (MPP): Private initiative to promote access of anti-TB drugs in low- and middle-income countries through voluntary licensing and patent pooling. The MedsPaL database provides information of intellectual property of drugs¹⁷.

Accessibsa initiative: The Innovation and Access to Medicines in India, Brazil and South Africa is a tri-continental task force promoted by the Shuttleworth Foundation to expand the access to drugs by vulnerable socioeconomic populations through intellectual property systems, public health, and pharmaceutical innovation¹⁸.

Pat-INFORMED platform: The Patent Information Initiative for Medicines is an open access database developed to facilitate patent data access through directly consulting biopharmaceuticals companies holding drugs patents by WIPO, the platform host¹⁹.

Kaletra Global Campaign: Originally, was a worldwide campaign against monopolistic holders of anti-HIV/AIDS medicines to instigate competition with generic drugs in 2011. Through subsidies for technical examinations or compulsory licensing reduced prices of anti-HIV/AIDS drugs. Could be reapplied to fight TB in a jointed effort between governments' representatives and NGO²⁰.

The Global Fund: Is an international organization of multiple actors to raise and invest in health programs to fight TB, AIDS and malaria and the biggest international financier against TB²¹.

4 CONCLUSIONS

Our benchmark shows several strategies and initiatives that can be applied by multiple-level actors to enhance the development and accessibility of TB-related technologies. It could be used as a reference guide for holder/inventors, private companies, international groups, governments, and public institutions in the elaboration of strategies and initiatives to develop pharmaceutical and non-pharmaceutical technologies to fight TB. For this, we encourage a combined effort of public and private actors for more effective policies and actions against TB through intellectual protection. Specially in low-income countries with low market competitiveness and high number of vulnerable populations.

CONFLICT OF INTEREST

The authors report no conflict of interest.

FOUNDING

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