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Abstract

This report documents efforts by civil society organizations (CSOs) in various countries, including Brazil, Ukraine and Thailand, to make Bedaquiline more accessible by using the flexibilities provided in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) – the safeguards in the intellectual property system that take into account public health needs. The case study was undertaken during 2023-2024.

Tuberculosis remains a major global health crisis, with drug-resistant forms requiring newer more effective treatments like Bedaquiline which offers shorter treatment times and fewer side effects than older regimens. The report offers an overview of global and country-specific efforts by CSOs to challenge patents held by Johnson & Johnson on the tuberculosis (TB) drug bedaquiline (BDQ) to improve patient access and affordability. CSOs primarily focused on opposing "evergreening" secondary patents that extend Johnson & Johnson's monopoly beyond the original patent expiration, arguing that these patents lack inventive merit and artificially inflate prices. Successful actions, such as patent rejections in India and Thailand and Johnson & Johnson's agreement not to enforce patents in 134 low- and middle-income countries (LMICs), are discussed alongside challenges, including judicial difficulties, insufficient political will, and the strategic importance of pursuing pre-grant patent oppositions.

Este informe documenta los esfuerzos realizados por organizaciones de la sociedad civil (OSC) en varios países, entre ellos Brasil, Ucrania y Tailandia, para hacer que la bedaquilina sea más accesible utilizando las flexibilidades previstas en el Acuerdo sobre los Aspectos de los Derechos de Propiedad Intelectual relacionados con el Comercio (ADPIC), las salvaguardias del sistema de propiedad intelectual que tienen en cuenta las necesidades de salud pública. El estudio de caso se llevó a cabo durante 2023-2024.

La tuberculosis sigue siendo una grave crisis sanitaria mundial, con formas resistentes a los medicamentos que requieren tratamientos más nuevos y eficaces, como la bedaquilina, que ofrece tiempos de tratamiento más cortos y menos efectos secundarios que los regímenes más antiguos. El informe ofrece una visión general de los esfuerzos globales y específicos de cada país realizados por las OSC para impugnar las patentes de Johnson & Johnson sobre el medicamento contra la tuberculosis (TB) bedaquilina (BDQ) con el fin de mejorar el acceso y la asequibilidad para los pacientes. Las OSC se centraron principalmente en oponerse a las patentes secundarias «perpetuas» que amplían el monopolio de Johnson & Johnson más allá de la expiración de la patente original, argumentando que estas patentes carecen de mérito inventivo e inflan artificialmente los precios. Se analizan las acciones exitosas, como el rechazo de patentes en la India y Tailandia y el acuerdo de Johnson & Johnson de no hacer valer las patentes en 134 países de ingresos bajos y medios (PIBM), junto con los retos, como las dificultades judiciales, la insuficiente voluntad política y la importancia estratégica de presentar oposiciones a las patentes antes de su concesión.

Ce rapport documente les efforts déployés par des organisations de la société civile dans divers pays, notamment au Brésil, en Ukraine et en Thaïlande, pour rendre la bédaquiline plus accessible en utilisant les flexibilités prévues dans l'Accord sur les aspects des droits de propriété intellectuelle qui touchent au commerce (ADPIC) – les garanties du système de propriété intellectuelle qui tiennent compte des besoins en matière de santé publique. L'étude de cas a été réalisée entre 2023 et 2024.

La tuberculose reste une crise sanitaire mondiale majeure, les formes résistantes aux médicaments nécessitant des traitements plus modernes et plus efficaces comme la bédaquiline, qui offre des durées de traitement plus courtes et moins d'effets secondaires que les anciens traitements. Le rapport présente un aperçu des efforts déployés à l'échelle mondiale et nationale par les organisations de la société civile pour contester les brevets détenus par Johnson & Johnson sur le médicament contre la tuberculose (TB) la bédaquiline (BDQ), afin d'améliorer l'accès et l'abordabilité pour les patients. Les organisations de la société civile se sont principalement concentrées sur l'opposition aux brevets secondaires « evergreening » qui prolongent le monopole de Johnson & Johnson au-delà de l'expiration du brevet initial, argumentant que ces brevets manquent de mérite inventif et gonflent artificiellement les prix. Des actions couronnées de succès, telles que le rejet de brevets en Inde et en Thaïlande et l'accord de Johnson & Johnson de ne pas faire valoir ses brevets dans 134 pays à revenu faible et intermédiaire (PRFI), sont examinées parallèlement aux défis à relever, notamment les difficultés judiciaires, le manque de volonté politique et l'importance stratégique de poursuivre les oppositions aux brevets avant leur délivrance.

本报告记录了包括巴西、乌克兰和泰国在内的**多国民**间社会组织（CSOs）为扩大贝达喹啉的可及性，利用《与贸易有关的知识产权协定》（TRIPS）**中提供的灵活性条款——即知**识产权制度中兼顾公共卫生需求的保障措施**——所作的努力。本案例研究于2023年至2024年期**间开展。

结核病仍是全球主要的公共卫生危机，其中耐药性结核病需要像贝达喹啉这样更新、更有效的治疗方案，该药物相比旧疗法具有疗程更短、副作用更少的优势。本报告概述了民间社会组织（CSOs）**在全球及各国**层面为挑战强生公司持有的结核病（TB）药物贝达喹啉（BDQ）专利所做的努力，旨在改善患者的可及性和可负担性。民间社会组织**主要致力于反**对通过"专利常青化"**策略申**请次级专利**——此**类专利将强生公司的垄断期延长至原始专利到期之后，并主张这些专利缺乏创造性，且人为抬高了药价。报告不仅探讨了印度和泰国专利驳回、强生公司同意不在**134个中低收入国家**（LMICs）**行使**专利权等成功案例，也分析了面临的挑战，包括司法障碍、政治意愿不足，以及开展专利授权前异议程序的战略重要性。

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I. Introduction

The 2023 annual report on Tuberculosis shows that more than 10 million people continue to fall ill with TB every year, according to WHO. In 2022, TB was the world's second leading cause of death from a single infectious agent, after the coronavirus disease (COVID-19), and caused almost twice as many deaths as HIV/AIDS. It is estimated that 1.3 million people died of TB in 2022.

Globally, an estimated 410 000 people developed multidrug-resistant or rifampicin resistant TB (MDR/RR-TB) in 2022. The number of people diagnosed and started on treatment was much lower —175 650 people in 2022—, equivalent to about two out of five of those in need of treatment and still below the pre-pandemic level of 181 533 people in 2019, as stated by the TB report in 2023.

The World Health Organization (WHO) uses five categories to classify cases of drug-resistant TB: isoniazid-resistant TB; RR-TB and MDR-TB; extensively drug-resistant TB (XDRTB); and pre-XDR-TB. Pre-XDR-TB is TB that is resistant to rifampicin and any fluoroquinolone (a class of second-line anti-TB drug). XDR-TB is TB that is resistant to rifampicin, plus any fluoroquinolone, plus at least one of either bedaquiline or linezolid.

Bedaquiline (BDQ) is a core component of an "all-oral" treatment regimen to multi-drug resistant TB (MDR-TB), recommended by the World Health Organization. Treatment time is significantly shorter compared to older, injectable treatments for MDR-TB. It takes around 9-12 months, compared to two years, and can be largely administered at home instead of in a hospital, with less side-effects such as hearing loss, which can be caused by an injectable treatment. Being forced to remain on outdated treatment reduces a patient's chances of recovery from TB.

Monopolies, obtained at country-level, on BDQ have prevented access to improved TB treatment. The prices set by the patent holder, Johnson & Johnson (J & J), are not fair prices, especially considering the large public investment in the drug development. Civil society is opposing J&J's unmerited patents on BDQ. Nine patent oppositions have been submitted so far, six of them by the Make Medicines Affordable campaign partners.

This case study tries to document efforts by CSOs in countries including Brazil, Ukraine, Thailand, to make Bedaquiline more accessible by using the flexibilities allowed by the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS)– the safeguards in the intellectual property system that take into account public health needs. The study benefited from interview of health activists in four countries (Brazil, Thailand, Ukraine and Belarus).

II. Background and Recent Developments

II.1 Pricing of Bedaquiline

In 2023, there were two key developments with respect to the access to Bedaquiline, on price and patents.

In August 2023, Johnson & Johnson that produces Bedaquiline reduced the price of the drug from US$272 to $130 per treatment course of six months for many low- and middle-income countries (LMICs). This was following a competitive tender by Global Drug Facility (GDF), an international pooled procurement mechanism of the Stop TB Partnership. (See more on this deal here.)

As per the terms of the GDF-J&J deal, countries with a high burden of the disease, including Russia, China, Belarus and Ukraine, were unable to access the lowest-priced generics in the longer term until the corporation's additional patents expired.

Studies have shown the significant public investments made for Bedaquiline which was launched in 2012, yet patenting strategies and high prices have affected access to the drug globally.

The company used a tiered pricing model and set $3,000 per treatment course of 6 months in middle-income countries, and $900 in low-income countries in 2014. This was followed by a donation programme for a few years brokered by Janssen, the patent holder of Bedaquiline and the United States Agency for International Development (USAID).

Subsequently, in 2018, South Africa struck a deal with J&J and brought the price down to $400 per treatment course.

In 2020, the GDF brought the price down to $272 per treatment course. Activists had called this a market-driven deal with GDF. This is because the deal allows some LMIC to access affordable generic versions of BDQ – but it excludes some of the countries with the most urgent need for this drug. Overall, 9 of the 11 countries excluded from the new GDF/J&J deal are among the world's 30 nations with the highest burdens of DR-TB. In 2021, these excluded countries were home to at least 112,100 people living with DR-TB, but barely 50 percent (57,408) were able to access treatment, according to WHO data.

Studies have shown that estimated generic prices were US$8–$17 *per month* for bedaquiline. Scholars point out that "competitive large-scale generic manufacture could allow supplies of treatment for 5–10 times more MDR-TB cases within current procurement budgets." Pricing is linked to the patent status of the drug.

II.2 Patents on Bedaquiline

The primary patent on BDQ expired in July of 2023, bringing hope that affordable generic versions would become available in LMIC, since experts have estimated that generic

BDQ could be profitably mass-produced for only $48 – $102 per treatment course of six months.

But J&J has been filing secondary patents on BDQ, a practice known as evergreening, which allows pharmaceutical companies to extend the life span of their patent monopolies and retain revenues by patenting new forms (salts, polymorphs, etc.) of known substances and claiming that known treatment methods are inventive (oral administration, administering BDQ with a meal, combining a known medicine with other medicines). Activists have been demanding that J&J withdraw all patent applications for BDQ and that they agree not to enforce secondary patents or pursue any action against generics manufacturers.

II.3 High Prices Protected by Patents

It is understood that the company has extended its monopoly until at least 2027 in many countries, including at least 35 out of 43 countries with a high burden of TB, DR-TB, and TB/HIV, through an aggressive patenting strategy consisting of patent term extensions and secondary patents.

In March 2023, the Indian Patent Office rejected an attempt by J&J to secure a secondary patent in the country that would have extended its monopoly for four more years, until 2027. Activists say that "The system to review patent applications that can extend a corporation's monopoly beyond the internationally accepted term of 20 years does not exist in a majority of countries with a high burden of TB. However, many countries have now started to realize the impact of secondary patents on the accessibility and scalability of this medicine that is urgently needed for all people with DR-TB."

Under sustained pressure from civil society groups and massive public pressure, Johnson & Johnson announced in September 2023 that it will not enforce patents for BDQ used for MDR-TB treatment in 134 Low- and Middle-Income Countries.

It is estimated that unrestricted access to Bedaquiline could make access possible for 500,000 people who are newly affected by DR-TB every year. This will pave the way for generic competition and ensure access for everyone who needs it. J&J must now withdraw all existing patents and pending patent applications related to Bedaquiline to ensure legal assurance for manufacturers exporting generic versions of this drug from or to countries where patents still exist.

II.4 Patent Oppositions

Excluded LMICs can oppose the secondary patents on BDQ on grounds of lack of novelty or lack of inventive step, or grant a compulsory license (CL), which would allow them to produce or import generic BDQ. Community-led organizations in the Make Medicines Affordable (MMA) campaign have been working to improve access to BDQ by filing 15 oppositions against J&J's evergreening patents on BDQ, in Belarus, Brazil, India, Kazakhstan, Kyrgyzstan, Moldova, Thailand, Ukraine, and Vietnam. In October 2020, the Brazilian patent office rejected the evergreening patent application on BDQ, and in June

2023, Thailand's patent office rejected two of four pending evergreening patent applications.

In Thailand and in the Eastern European region, for example, the company submitted applications for a paediatric version of BDQ. This is simply a soluble version of the adult version. It lacks "inventive step" and is "obvious to any expert in that sphere", which means it fails to achieve any grounds for patenting, activists say.

Thailand had also challenged patents on the paediatric formulation – nearly 1.2 million children fall ill with TB annually around the world.

Of the growing number oppositions, 10 have been submitted by Make Medicines Affordable partners (as of 2021). The filed oppositions include the following[1]:

Thailand

Opposition filed by: AIDS Access Foundation & TNP+
Patent application scope: Bedaquiline to treat MDR-TB and/or combinations with other antimycobacterial agents (eq. to WO2005117875)

Opposition filed by: AIDS Access Foundation & TNP+
Patent application scope: Bedaquiline fumarate salt (eq. to WO2008068231)

Opposition filed by: AIDS Access Foundation
Patent application scope: Bedaquiline to treat latent TB (eq. to WO2006067048)

Third party observation filed by: AIDS Access Foundation
Patent application scope: Bedaquiline Paediatric Formulation (1701004168)

Brazil

Opposition filed by: ABIA/GTPI
Patent application scope: Bedaquiline fumarate salt (eq. to WO2008068231)

Ukraine

Opposition filed by: 100% LIFE
Patent application scope: Bedaquiline Paediatric Formulation (eq. to WO2016120258)

India

Opposition filed by: DNP+
Patent application scope: BPaL – Bedaquiline/Pretomanid/linezolid (optionally pyrazinamide) compositions and their use in TB, (eq. WO2017066053)

[1] More information on the global picture is available here.

Kyrgyzstan

Opposition filed by: Partnership Network Association
Eurasian patent scope: 017091, bedaquiline fumarate salt (eq. to WO2008068231)

Kazakhstan

Opposition filed by: Answer Public Foundation
Eurasian patent scope: 017091, bedaquiline fumarate salt (eq. to WO2008068231)

Belarus

Opposition filed by: People Plus Public Organization
Eurasian patent scope: 017091, bedaquiline fumarate salt (eq. to WO2008068231)

III. Successes

There are different kinds of barriers to access to medicines including those related to patents, production, treatment literacy and political environment. Interviewed activists were of the view that technical knowledge and tools can be successfully deployed to deal with these barriers including on pricing and production. They also believe that working closely with patient communities is useful during campaigns.

Some activists suggested that filing pre-grant oppositions was more beneficial than filing post-grant oppositions. They believe that going fast track with the pre-grants is more efficient. However, it is not always possible to file pre-grant oppositions on time. By the time it is determined that a new drug is effective, the deadline for filing a pre-grant opposition may have been missed. In this case post-grant and judicial proceedings will then be needed, activists said. It is harder to question when a patent has already been granted.

In some countries, higher protection to ensure the legal standing of CSOs will be important in patent-related judicial proceedings, activists pointed out.

Considering the difficulties of the judicial procedures, they believe it would be more effective to switch to pre-grant opposition. Pre-grant opposition is a more effective use of resources, of donor resources, of human and time resources in general, they said.

Among the other successes in the world-wide campaign on Bedaquiline, activists said it was helpful to work across regions to challenge the abuse of the patent system on this drug.

The situation in five of the studied countries can be summarized as follows:

- **Brazil:** The Brazilian patent office rejected an evergreening patent application on BDQ in October 2020. Subsequently, activists filed a pre-grant opposition related to the fumarate salt patent application and received a partial rejection (preliminary opinion) from the Patent Officer. A post-grant opposition related to the paediatric formulation is still pending a final decision.

- **India:** The Indian Patent Office successfully rejected J&J’s attempt to secure a secondary patent in March 2023. This outcome was noted as a key factor contributing to J&J’s subsequent non-enforcement statement.

- **Thailand:** Thailand’s patent office rejected two of four pending evergreening patent applications in June 2023. These two rejected applications concerned the use of bedaquiline for MDR-TB treatment and latent TB treatment, which are considered non-patentable "methods of treatment" under Thai law. J&J filed appeals against these rejections in September 2023.

- **Ukraine:** Following a lawsuit and negotiations with activists, J&J's legal representatives provided an agreement to officially revoke patents related to

bedaquiline (specifically patents for fumarate salts, compositions, and Bedaquiline to treat drug-resistant TB) in Ukraine.

- **Belarus:** Although the status of the formal patent opposition on the fumarate salt is not explicitly finalized, activists in Belarus noted that the campaign against the patent was successful, contributing to a price reduction.

IV. Challenges

Activists interviewed for this case study indicated a difficult political environment in some countries and a decreasing interest of some governments in prioritising public health over commercial industry interests. A democratic political environment is critical to address the possibility of using the TRIPS flexibilities to improve access to medicines, activists said.

As people's and societal participation in the public policies is diminishing, it becomes more difficult to address the issue of access to treatment by governments. There is also insufficient political will to use TRIPS flexibilities, activists said.

In some cases, voluntary licensing deals have worsened access, activists say. Signing the GDF/J&J voluntary license could lock down generic manufacturers, by preventing them from supplying affordable versions of bedaquiline to excluded countries even in the absence of patents. In these excluded countries, accessing affordable generic BDQ may be difficult – even if they issue a compulsory license or oppose evergreening patents.

In the specific case of this drug, advocacy was difficult given that TB continues to be a neglected disease in many countries.

V. Conclusion

CSOs successfully deployed several strategies to improve access to Bedaquiline: these included filing patent oppositions and collecting data on national and international prices, which were successfully used to deal with challenges related to pricing and production. Many activists concluded that pre-grant oppositions are generally more beneficial, efficient, cheaper, faster, and a more effective use of resources compared to post-grant oppositions or judicial proceedings. Cross-regional collaboration was also identified as a success in order to challenge the abuse of the patent system on BDQ. The success of local campaigns was often attributed to being part of a larger global movement.

The interviewed activists noted several systemic and political hurdles that complicated their work including evergreening patent strategies, a difficult political environment and a lack of political will in some cases. Threats to democracy and participation in some countries also impinged on activism, they said. Limitations of voluntary licensing deals, difficulties with post-grant opposition, also made access to medicines activism more difficult.

References

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   - https://msfaccess.org/dr-tb-drugs-under-microscope-8th-edition
   - https://makemedicinesaffordable.org/jj-urged-to-reduce-the-price-of-breakthrough-tb-drug-bedaquiline/
   - https://globaltbcab.org/statement/tb-cab-access-considerations-statement-regarding-johnson-johnson-announcement-of-bedaquiline-price-reduction/ - TB CAB statement on J&J price reduction on BDQ
2. Research conducted by Gotham et al. on the estimated cost of manufacturing was important in terms of increasing transparency and showed that estimated cost of manufacturing were far lower of what J&J was charging - https://academic.oup.com/jac/article/72/4/1243/2884272
3. Another groundbreaking study on public investments in R&D of this drug showed that governments/philanthropists invested more than J&J in development of bedaquiline - https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7500616/
4. Eventually, as J&J was not responding to demands of civil society, CSOs filed 18 patent oppositions against secondary patents on bedaquiline in Brazil, Moldova, Ukraine, Belarus, Kazakhstan, Kyrgyzstan, Thailand, India, Indonesia, Vietnam:
   - https://makemedicinesaffordable.org/brazil-and-thailand-activists-oppose-more-tb-patents-during-covid-19-pandemic/ - BR, TH opposition
   - https://makemedicinesaffordable.org/civil-society-files-lawsuit-against-thai-department-of-intellectual-property-as-failure-to-reject-tb-patent-is-unlawful/ - BDQ lawsuit, TH
   - https://makemedicinesaffordable.org/ukraine-100-life-opposes-patent-on-tb-drug-for-children/ - Ukraine paediatric formulation opposition
   - https://makemedicinesaffordable.org/tb-9-oppositions-against-jjs-overpriced-drugs/ - 9 oppositions filed
   - https://makemedicinesaffordable.org/thailand-submits-patent-opposition-on-tb-drug-for-children/ - TH paediatric formulation opposition
   - https://makemedicinesaffordable.org/moldovan-patients-and-csos-stood-against-the-patent-monopoly-on-bedaquiline/ - Moldova invalidation lawsuit of BDQ secondary patents
   - https://makemedicinesaffordable.org/activists-across-the-world-demand-urgent-action-to-improve-access-to-lifesaving-tuberculosis-tb-medicine-bedaquiline/ - another call to reduce the price in 2022
5. On 13 July GDF announced an agreement with J&J that will enable them to sell generic bedaquiline to a majority of low and middle income countries.
6. For 44 low- and middle-income countries, but it seems 9 EECA countries are excluded, and South Africa is excluded as well.
   - https://www.forbes.com/sites/willskipworth/2023/07/13/johnson--johnson-letting-nonprofit-distribute-life-saving-generic-tuberculosis-drug-greatly-expanding-access-in-poorer-countries/?sh=21a6ccd53dcd
   - https://makemedicinesaffordable.org/j-js-deal-with-the-global-drug-facility-disguises-the-continued-issue-with-access-to-bedaquiline-to-treat-drug-resistant-tuberculosis/

7. On Aug 30th, GDF publicly shared the result of the bedaquiline tender – the link to the announcement: https://www.stoptb.org/news/stop-tbs-global-drug-facility-announces-historic-price-reductions-to-55-bedaquiline-life-saving
8. Guardian article: https://www.theguardian.com/global-development/2023/aug/31/cost-of-tuberculosis-treatment-halved-in-deal-to-permit-generic-versions
9. Johnson & Johnson's Patenting & Pricing Strategy for TB Medicine Bedaquiline: A Cautionary Tale for New TB Medicines: Geneva Health Files, October 2023

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