Date: July 11, 2023

To:
Mr. Joaquin Duato
Chief Executive Officer
Johnson & Johnson
New Brunswick, NJ, USA

Cc:
Mr. Sarthak Ranade
Managing Director
Janssen India
Mumbai, Maharashtra, India

Ms. Anna Caravaggio
Vice President, Global Public Health Franchises
Johnson & Johnson
New Brunswick, NJ, USA

Open Letter: Urgent action necessary for equitable access to bedaquiline in all countries with high burdens of TB, MDR-TB, and TB/HIV

Dear Mr. Duato,

We are writing as members of communities affected by tuberculosis (TB) and civil society to demand that Johnson & Johnson (J&J) publicly announce the company's commitment to not enforce its secondary patent on the fumarate salt formulation and any other versions of bedaquiline (Sirturo) and to withdraw any pending applications for the secondary patent so that all countries with high burdens of TB, MDR-TB, and TB/HIV can access generic, quality-assured bedaquiline after the primary patent expires on July 18, 2023.

J&J's commitment to non-enforcement of the secondary patent on bedaquiline is an urgent humanitarian and human rights concern. Each year, more than 450,000 people globally develop rifampicin resistant/multidrug-resistant TB (RR/MDR-TB), including many living with HIV.[1] RR/MDR-TB has been difficult to cure with older, longer regimens and has a high rate of mortality. Stellar medical developments in the form of newer drugs and regimens have the potential to bridge the unmet medical needs of people with drug resistant-TB (DR-TB); bedaquiline-based regimens, in particular, lead to faster cure and better treatment outcomes with fewer adverse effects. In addition to the bedaquiline-containing all-oral 9-month DR-TB regimen, the World Health Organization (WHO) has also recommended the shorter, safer 6-month regimen for DR-TB called BPaL[M], composed of bedaquiline, pretomanid, and linezolid, with or without moxifloxacin. Bedaquiline, the backbone of this regimen, makes up 35-70% of the cost of the regimen.[2]

In 2019, Sarthak Ranade, Managing Director of Janssen India, the pharmaceutical arm of J&J, was quoted in the The Hindu Business Line saying: "Composition of matter patent on Bedaquiline expires in July 2023. So, after that, any generic manufacturer is free to manufacture it."[3] Yet J&J has filed secondary patent applications on the non-innovative fumarate salt

formulation of bedaquiline, which were granted in 66 low- and middle-income countries (LMICs), including 34 countries with high burdens of TB, MDR-TB, and TB/HIV. If enforced, this secondary patent will delay access to affordable generic bedaquiline in these countries until 2027. This includes many countries currently undergoing other humanitarian crises such as the ongoing conflict in Ukraine, recovery from the recent cholera outbreak in Malawi, the legacy of Ebola in Sierra Leone, the deteriorating human rights situation and political crisis in Peru, the ongoing drought in Kenya, recent conflict and displacement in Mozambique and Burkina Faso, climate-driven scarcity in Cameroon, and the list goes on. Enforcing the secondary patent in these countries beyond the expiry of the primary patent in July would further exacerbate these humanitarian and human rights crises.

Because of J&J's secondary patent, 56% of the global market will not have access to generic bedaquiline until 2027. Based on data from MedsPaL and the WHO Global TB Report, the number of people with RR/MDR-TB in countries affected by the secondary patent amounts to approximately 349,421 people, about three quarters of the 450,000 people who develop RR/MDR-TB each year.[1,4] If the secondary patent is enforced, approximately 1,385,684 people with RR/MDR-TB would not have access to generic bedaquiline over the next four years. With the introduction of generic competition, researchers estimate that the price of bedaquiline will reduce by up to 80%, from the globally negotiated US$277 through the Global Drug Facility (and from US$324 in South Africa and US$1,650 in Russia) to as little as $48 for a 6-month treatment course.[5,6]

Non-enforcement of the secondary patent will save lives by allowing country programs to afford to put more people with RR/MDR-TB on treatment with the BPaL[M] regimen and any other WHO-recommended regimen containing bedaquiline. Access to generic bedaquiline will generate potential cost savings for LMICs up to US$80,017,409 each year and US$320,069,636 through 2027, when the secondary patent would otherwise expire.[1,4] These cost savings can be applied toward strengthening other areas of the TB response, including scaling up access to diagnosis and drug-susceptibility testing to ensure all people with RR/MDR-TB are able to access the life-saving treatment they need. Failure of J&J to commit to non-enforcement of the secondary patent will put the lives of many people with RR/MDR-TB at risk, decimate the health budgets of LMICs striving to scale up access to BPaL[M] and other bedaquiline-containing DR-TB regimens, and further set back progress in the fight to end TB by 2030.

On March 23, 2023, the day before World TB Day, the Indian Patent Office acted in the interest of public health by rejecting J&J's secondary patent on bedaquiline.[7] The Indian Patent Office found this secondary patent to be unwarranted, non-innovative, and a clear case of evergreening. We know that two Indian generic manufacturers, Macleods and Lupin, will be able to market quality-assured bedaquiline after July 18, 2023 in India and export their bedaquiline products to any country where the secondary patent was not granted to J&J.[8] Several other generic manufacturers from LMICs are also preparing to manufacture generic bedaquiline, but any generic manufacturer in countries that granted the secondary patent will be blocked from entering this market, and Macleods and Lupin will be blocked from exporting to countries where the secondary patent was granted.

The enforcement of J&J's secondary patent is unjustifiable given the large public investment in the research and development of bedaquiline amounting to US$455–747 million compared to J&J's investments of just US$90–240 million.[9] Meanwhile, many people with RR/MDR-TB in countries affected by the secondary patent participated in key research generating evidence for the all-oral 9-month DR-TB regimen and in all three BPaL(M) trials – Nix-TB, ZeNix-TB, and TB-PRACTECAL – that ultimately helped change WHO guidelines to establish bedaquiline-based regimens as the standard of care for all forms of DR-TB globally. Bedaquiline should therefore be considered a public good and generic bedaquiline should be made available in all high-TB-burden countries after the expiry of J&J's primary patent on July 18, 2023. J&J should follow the positive example and precedent set by Sanofi in 2020 when it voluntarily withdrew all patent applications on combination forms of rifapentine-isoniazid, clearing the way for generic entry that expanded the supply and reduced the price of the rifapentine-based TB preventive treatment regimens.[10]

For all of the above reasons, the undersigned 83 organizations and 106 individuals representing affected communities and civil society demand that J&J take urgent action to commit to non-enforcement of the secondary patent on the fumarate salt formulation and any other versions of bedaquiline and withdrawal of all pending applications for the secondary patent. We call on J&J to formally make this announcement at or before the United Nations High Level Meeting on TB this September 22, 2023. Failure to do so will show the world that J&J cares more about extending its monopoly over bedaquiline than it does about the lives of people with RR/MDR-TB who need access to this drug at affordable prices.

We look forward to your response to our letter, and to the opportunity of meeting with you to further discuss the importance of global access to generic bedaquiline once the primary patent expires on July 18, 2023. Your response can be directed to david.branigan@treatmentactiongroup.org.

Sincerely,

Organizations:

1. Access Care Treatment and Support, Ghana
2. Advocacy Network Africa (AdNetA), Kenya
3. Advocates of Hope for Community (AHFCO), Kenya
4. Afrocab Treatment Access Partnership, Africa
5. Alma Partners, USA
6. Americas TB Coalition, Latin America and the Caribbean
7. Andhra Pradesh Drug Users Forum, India
8. APCASO, Thailand
9. ARK Foundation, India
10. Asia Pacific Network of People Living with HIV (APN+), Thailand
11. Assam Natok People (Vihaan Project), India

12. Assam Network of Positive People (ANP+), India
13. AVAC, USA
14. Blossom Trust, India
15. Bokk Yakaar, Senegal
16. Citizen News Service (CNS), India
17. Coalition for Health Promotion and Social Development (HEPS Uganda), Uganda
18. Coalition of Women Living with HIV and AIDS (COWLHA), Malawi
19. Community Forum (COFO), Malawi
20. Community Led Solutions CBO, Kenya
21. Community of Women Living with HIV, Lesotho
22. Dandora Community AIDS Support Association, Kenya
23. Delhi Drug Users Network, India
24. Delhi Network of Positive People (DNP+), India
25. Disability Peoples Forum, Uganda
26. Eastern Europe and Central Asia Community Advisory Board, Georgia
27. Global Alliance for Human Rights, India
28. Global Alliance for Human Rights - Women Wing, India
29. Global Coalition of TB Advocates (GCTA), Global
30. Global Network of People Living with HIV (GNP+), Netherlands, South Africa, Global
31. Global Tuberculosis Community Advisory Board (TB CAB), Global
32. Good Health Community Programmes, Kenya
33. Grupo de Trabalho sobre Propriedade Intelectual (GTPI), Brasil
34. Health GAP (Global Access Project), Global
35. Health Justice Initiative, South Africa
36. Indian Network for People Living with HIV/AIDS (INP+), India
37. Institute of Allergy and Clinical Immunology of Bangladesh (IACIB), Bangladesh
38. International Community of Women Living with HIV - Eastern Africa, Uganda
39. International Treatment Preparedness Coalition (ITPC), South Africa, Global
40. International Treatment Preparedness Coalition in EECA, Eastern Europe and Central Asia
41. Jointed Hands Welfare Organisation, Zimbabwe
42. Kitale HIV and AIDS Positive People Survival, Africa
43. League PLWHA, Republic of Moldova
44. Meghalaya State Network of Positive People, India
45. Misbah, India
46. Moldova National Association of Tuberculosis Patients “SMIT” (Society of Moldova against Tuberculosis), Republic of Moldova
47. Most At Risk Populations' Society in Uganda (MARPS), Uganda
48. MSF Access Campaign (Médecins Sans Frontières), Global
49. NAPUD, South & Southeast Asia
50. Nari Maitree, Bangladesh
51. Network of Naga People Living with HIV/AIDS, India
52. Network of TB Champions, Kenya
53. Network TB People, Georgia
54. NGO "INTILISH", Uzbekistan

55. NGO AFI, Republic of Moldova
56. Nyabende Support Programmes CBO, East Africa
57. Partners In Health, Global
58. Princess of Africa Foundation, South Africa
59. Public Association for Support of Social Protection and Integration of Persons with Disabilities, Azerbaijan
60. Rekat Peduli Indonesia, Indonesia
61. Results International, Australia
62. RESULTS UK, UK
63. Saglamliga Khidmat Public Union, Azerbaijan
64. Sankalp Rehabilitation Trust, India
65. Sikkim Drug Users Forum, India
66. SMLS Trust, India
67. Stop TB Canada, Canada
68. Stop TB USA, USA
69. Tashtriya Manav Vikas Samiti, India
70. TB Europe Coalition, WHO Europe Region
71. TB Proof, South Africa
72. TBPPM Learning Network, Canada
73. The Sentinel Project on Pediatric Drug-Resistant Tuberculosis, USA
74. The Union for Equity and Health, Republic of Moldova
75. TransNoah Alliance, Uganda
76. Treatment Action Group, USA
77. Tuberculosis Research Unit Foundation of Barcelona, Spain
78. UK Academics & Professionals to End TB (UKAPTB), UK
79. Vietnam Network of People Living with HIV, Vietnam
80. We Are TB, New Jersey, USA
81. Women Initiatives for Development PA, Azerbaijan
82. Wote Youth Development Projects CBO, Kenya
83. Zimbabwe National Network of People Living with HIV, Zimbabwe

Individuals:

1. Adhithya Raj P.K., India
2. Adriana Jarrett, USA
3. Agui Daimie, India
4. Aiyana Masla, USA
5. Aman Shukla, India
6. Anandi Yuvaraj, India
7. Andrew Codlin, Viet Nam
8. Anupama Srinivasan, India
9. Anussha Murali, India
10. Arya Kalathilparampil Babu, Germany
11. Ashique Ahmed, India

12. Avinash Kumar, India
13. Badri Singh, India
14. Barry Kharmalki, India
15. Bharatesh Shetty, India
16. Biswa Bikash Chetia, India
17. Brian Citro, USA
18. Caren Wambui Kiarie, Kenya
19. Carole Mitnick, USA
20. Charity Wambui, Kenya
21. David Branigan, USA
22. David Moskowitz, USA
23. Diana Mailosi, Zimbabwe
24. Diptendu Bhattacharya, India
25. Dr Aditi Krishnamurthy, India
26. Dr Ankita Jain, India
27. Dr Jessica Potter, UK
28. Dr Kavyashree M, India
29. Dr Marlise Richter, South Africa
30. Dr Rajabhau Yeole, India
31. Dr Shivangi Shankar, India
32. Dr Swathi SB, India
33. Elizabeth Reyes, USA
34. Fatima Hassan, HJI Director, South Africa
35. Francis Joseph, Thailand
36. Ganesh Acharya, 2 times TB survivor, India
37. Godfrey Mbulelo Tabata, South Africa
38. Hari Shanker Singh, India
39. Harry Prabowo, Thailand
40. Henry Zohmingthanga, India
41. Jahnabi Goswami, India
42. Jimmy H. Galarza Castillo, Peru
43. Josephine R. Pitasari, USA
44. Juan Carlos Raxach, Brasil
45. Jyotsna Singh, India
46. Kanika Chauhan, India
47. Karthi Krishnan, India
48. Kate O'Brien, USA
49. Ketho Angami, India
50. Laia Ruiz Mingote, Spain
51. Lalruat Feli, India
52. Liang Yan, China
53. Mageto Dennis, Kenya
54. Maja Kiselinova, Belgium
55. Manitosh Ghildiyal, India

56. Manjappa Koder, India
57. Manmohan Mitruka, India
58. Marina Magalhães, Brazil
59. Matanat Garakhanova, Azerbaijan
60. Meera Yadav, India
61. Mihir Kulkarni, India
62. Milind Vishnu Rajwade, India
63. Monica Shandal, USA
64. Mundrika Gahlot, India
65. Nandita Venkatesan, India
66. Narayan Dass, India
67. Nicole Linda Gadon, USA
68. NK Lian Guite, India
69. Nonna Turusbekova, Kyrgyzstan
70. Noor Sabha, USA
71. Novia Rachmayanti, Indonesia
72. Oxana Ibragimova, Kazakhstan
73. Pallavi Sharma, India
74. Paran Sarimita Winarni, Indonesia
75. Pere-Joan Cardona, Catalonia
76. Peter Owiti, Kenya
77. Pradeep Kumar Maurya, India
78. Preenie Gill, USA
79. Puniteswar Upreti, India
80. Rajkumar E, India
81. Rebecca Balogh, USA
82. Robyn Waite, Canada
83. Romella Osmanli, Azerbaijan
84. Runjun Dutta, Lawyer, Treatment Activist, India
85. Sachin S Hiremath, India
86. Sahera Ramzan, UK
87. Samir Kumar Sahu, India
88. Shamim M Mannan, India
89. Sharonann Lynch, Associate Director, GHPP, O'Neill Institute, USA
90. Simon W Beddoe, India
91. Sona Hajiyeva, Azerbaijan
92. Steven Callens, Belgium
93. Sumitha TS, India
94. Suraj Madoori, USA
95. Surjeet Singh, India
96. Sushil Khatri, Nepal
97. Tekhe Pradia, India
98. Timothy Barlow Muwanga, Uganda
99. Tobias Ogola, Kenya

100. Tom Rogers Muyunga-Mukasa, Kenya
101. Trisasi Lestari, Indonesia
102. Vaishnavi Mangal, India
103. Vlada Rabinova, Ukraine
104. Wiwit Khuntari, Indonesia
105. Yoma Kristiani Tarukbua, Indonesia
106. Yuliya Chorna, Ukraine

References

[1] World Health Organization. Global tuberculosis report 2022. Geneva: World Health Organization; 2022; https://www.who.int/teams/global-tuberculosis-programme/tb-reports

[2] Gotham D, Fortunak J, Pozniak A, Khoo S, Cooke G, Nytko F, Hill A. Estimated generic prices for novel treatments for drug-resistant tuberculosis. Journal of Antimicrobial Chemotherapy. 2017; Volume 72, Issue 4, Pages 1243–1252. https://doi.org/10.1093/jac/dkw522

[3] Maitri Porercha, Meenakshi Verman & Ambwanim Somasekar, Come 2023, generic companies will be able to manufacture anti-tuberculosis drug Bedaquiline: Janssen India Managing Director, The Hindu Businessline (Nov. 16, 2019). https://www.thehindubusinessline.com/companies/come-2023-generic-companies-willbe-able-to-manufacture-anti-tuberculosis-drug-bedaquiline-jansssen-india-managingdirector/article29899749.ece

[4] MedsPaL. The medicines patents and licenses database [Internet]. (Cited 2023 June 27). https://www.medspal.org/

[5] Stop TB Partnership Global Drug Facility. Medicines catalog. March 2023. https://www.stoptb.org/sites/default/files/gdf_medicines_catalog.pdf

[6] Access Campaign Médecins Sans Frontières. DR-TB Drugs Under the Microscope 8th Edition: Pricing and patent landscape of medicines for adults and children. 2022; https://msfaccess.org/dr-tb-drugs-under-microscope-8th-edition

[7] Patent Opposition Database. Bedaquiline Decision. 2023 March 23. https://www.patentoppositions.org/en/drugs/bedaquiline/patent_office_decisions/641c1136d2708f00050ab275

[8] The Global Fund. List Of Tuberculosis Pharmaceutical Products classified according to the Global Fund Quality Assurance Policy. 2023 March 31. https://www.theglobalfund.org/media/4757/psm_productstb_list_en.pdf

[9] Gotham D, McKenna L, Frick M, Lessem E. Public investments in the clinical development of bedaquiline. PLoS ONE. 2020; 15(9): e0239118. https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0239118

[10] Treatment Action Group, Observatoire de la transparence dans les politiques du médicaments (OTMeds). Patents WO2015011161/WO2015011162 and access to treatments to prevent tuberculosis worldwide. 3 August 2022; https://www.treatmentactiongroup.org/wpcontent/uploads/2020/08/TAG_OTMeds_letter_sanofi_patent_withdrawals_8_3_20.pdf