

The Patent Landscape and Access Issues for TMC207: A Case Study

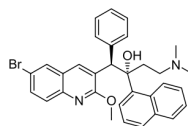
Tahir Amin

42nd Union World Conference on Lung Health
29 October, 2011
Lille



- The role of intellectual property rights (IPRs) in shaping access to TMC207
- Options for overcoming potential IP barriers for accessing TMC207

Background to TMC207



- Discovered by Janssen Pharmaceutica in 2002 while screening for compounds to kill mycobacterium smegmatis
- Class of compound - diarylquinolines (DARQS)/substituted quinoline derivatives
- Offers new mechanism of anti-tuberculosis over fluoroquinolones and other quinoline classes by specifically inhibiting mycobacterial adenosine triphosphate (ATP) synthase.
- In Phase III clinical trials - potential to inhibit DS-TB, MDR-TB and latent TB.
- June 2009 - Tibotech announces collaboration with TB Alliance to develop TMC207 and royalty free license for world wide development and access to TMC207 in field of DS-TB. Tibotech to maintain IPRs in the collaboration

The Role of Intellectual Property in Access to TMC207 - The Patent Landscape

Substituted quinoline derivative compounds - including the free base, enantiomers and isomers of TMC207	Use of substituted quinoline derivative compounds for the treatment of drug resistant mycobacterial diseases.	Use of quinoline derivative compounds, including TMC207, for the treatment of latent tuberculosis.	Process for preparing the enantiomer form of TMC207	Fumarate Salt of TMC207 and the enantiomer of TMC207
<p><i>International Patent Pub. No. WO 2004/011436</i></p> <p>Filed in all the key high burden and middle-income countries. Granted in:</p> <p>China, India, Azerbaijan, Belarus, Bulgaria, Kyrgyzstan, Moldova, Tajikistan, Turkmenistan, Ukraine and the African Organization of Industrial Property (OAPI) (covering Benin, Burkina Faso, Cameroon, Central African Rep. Chad, Congo, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Ivory Coast, Mali, Mauritania, Niger, Senegal and Togo.</p>	<p><i>International Patent Pub. No. WO 2005/117875</i></p> <p>Filed in all the key high burden and middle-income countries. Granted in:</p> <p>Azerbaijan, Belarus, Bulgaria, Kyrgyzstan, Moldova, Serbia, Tajikistan, Turkmenistan, Philippines and the African Regional Intellectual Property Organization (ARIPO) (covering Botswana, Gambia, Ghana, Kenya, Lesotho, Malawi, Mozambique, Namibia, Sierra Leone, Sudan, Swaziland, Tanzania, Uganda, Zambia and Zimbabwe.</p>	<p><i>International Patent Pub. No. WO2006/067048</i></p> <p>Filed in all the key high burden and middle-income countries. Granted in:</p> <p>Azerbaijan, Belarus, Bulgaria, Kyrgyzstan, Kazakhstan, Moldova, Tajikistan, and Turkmenistan.</p>	<p><i>International Patent Pub. No. WO2006/125769</i></p> <p>Filed in all the key high burden and middle-income countries.</p> <p>Information available shows patents have yet to be granted.</p>	<p><i>International Patent Pub. No. WO2008/068231</i></p> <p>Filed in all the key high burden and middle-income countries.</p> <p>Information available shows patents have yet to be granted.</p>

Options for overcoming potential IP barriers for accessing TMC207

- Tibotech and TB Alliance royalty free license to access TMC207 for:
 - DS-TB and/or MDR-TB?
 - Worldwide access or segmentation of markets for DS-TB and/or MDR-TB?
- Tibotech to develop and establish an access programme for TMC 207 - worldwide access or market segmentation?
- Generic competition/voluntary licenses - patent quality issues in India and other territories?
- Compulsory licenses
- Advocacy by civil society and public health bodies

THANK YOU

Contact Information:

Initiative for Medicines, Access & Knowledge (I-MAK)

tahir@i-mak.org

