

**Patents for Pharmaceuticals and Access to Affordable Medicines:
Towards an All-Encompassing Access Paradigm for Africa**

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Declaration of Originality

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Abstract

The connection between patents for pharmaceuticals and access to affordable medicines has elicited considerable attention and highly stimulating debates since the emergence of the World Trade Organisation (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (the TRIPS Agreement) as part of the Marrakesh Agreement Establishing WTO in 1994. The TRIPS Agreement is the first international convention to make it mandatory for all countries to make patents available in all fields of technology provided the invention to be patented meets the criteria for patentability. Consequently, countries like India, Brazil, China and Thailand that used to refuse to grant patents for pharmaceuticals were constrained to amend their patents laws to bring them in line with the WTO standard. Many developing countries did not even have legislation for a number of the intellectual property rights areas covered by the agreement at the time it was adopted. The TRIPS Agreement has been criticised as being a significant part of the global access to medicines problem and strong arguments have been raised for having more flexible standards for the protection of patents particularly in relation to pharmaceuticals.

This thesis examines the WTO regime for patent protection in the context of pharmaceuticals and the existing flexibilities in the TRIPS Agreement that countries seeking access to affordable patented pharmaceutical products might adopt. The effectiveness of the TRIPS compulsory licensing regime is examined, with particular focus on the limitations resulting from the TRIPS requirements for test data protection. The concepts of parallel importation and exhaustion of intellectual property (IP) rights are also examined with a view to ascertaining the extent to which they may serve as legal stratagems for developing countries seeking access to affordable medicines. The thesis argues that the existing frameworks for the right to health and the right to development in international law may provide a strong justification for the broad interpretation of the existing flexibilities in the TRIPS Agreement without the need for going through the very rigorous process of amending it.

The thesis considers the patents and access to medicines problem in the context of the special and highly complex challenges people in Sub-Sahara Africa are currently encountering. It recommends the establishment of an African Free Trade Area to make it easier for Africa as a continent to make better use of the TRIPS flexibilities. The thesis argues that more than ever before, the time has come for Africa to harness her resources to address her access to

medicines problem through the use of all the available options in international economic law and international human rights law.

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