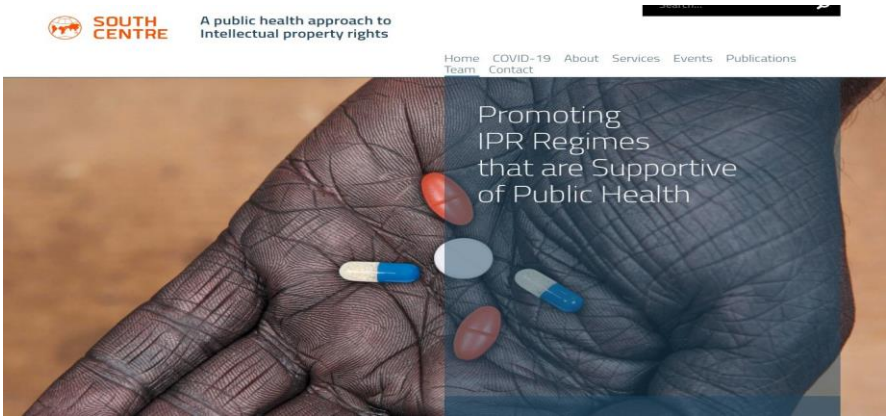
A Public Health Perspective on Pharmaceutical Patents: Patent Examination and Policy Coherence

SOUTH CENTRE

IP VIET NAM



Workshop for Patent Examiners

Background

Pursuant to the WTO TRIPS Agreement (1994), many developing countries had to amend their patent laws to implement patent protection for pharmaceutical products for a minimum term of 20 years. This has impacted the freedom to operate for the pharmaceutical industries in developing countries which predominantly manufacture generic medicines which are significantly more affordable for patients than patented medicines. However, the flexibilities in the TRIPS Agreement, reaffirmed by the WTO Doha Ministerial Declaration on TRIPS and Public Health (2001), provide the necessary policy space for governments to adopt measures to advance public policy modulated according to national needs and priorities. One of the most important fields for the application of patent related TRIPS flexibilities is public health, particularly with regard to efforts to guarantee access to medicines and thus realize the human right to health.

Given the substantial effects that patents can have on competition and, hence, prices of medicines, vaccines and diagnostic kits the criteria that are applied to examine and grant pharmaceutical patents are extremely relevant for public health policies, and not only a matter of concern for patent and industrial policy. The report of the UN Secretary-General's High-Level Panel on Access to Medicines has specifically recommended to strengthen the capacity of patent examiners at both national and regional levels to apply rigorous public health sensitive standards of patentability taking into account public health needs.

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Implementation of the TRIPS flexibilities also depends on multi-sectoral and multi-institutional policy interventions, including the national patent office, Ministry of Health, Ministry of Trade and Industry, Ministry of Foreign Affairs, Ministry of Justice, Ministry of Higher Education and Scientific Research, members of civil society, industry and academia, among others. Ensuring policy coherence between different departments of the government and awareness in other sectors is essential for the effective utilisation of the TRIPS flexibilities for access to medicines.

In this context, the South Centre and the Intellectual Property Office of Viet Nam (IP Viet Nam) are organizing this national workshop on advancing a public health perspective related to the examination of pharmaceutical patent applications in Viet Nam.

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The workshop will focus on exchange of experiences on the application of rigorous patentability criteria for the examination of pharmaceutical patents. The objective of the workshop is to present analysis of international experiences and exchange of information on examination policies and practices concerning pharmaceutical patent applications, from a public health perspective. The workshop will respond to growing concerns about the proliferation of patents that protect minor, and in some cases obvious, variants of existing drugs or processes (such as changes in the drug formulation, salts, esters, ethers, isomers, polymorphs of known molecules, combinations of a known drug with other known drugs).

To that end, the sessions will first, briefly discuss the scope allowed to WTO member countries by the TRIPS Agreement to determine the standards under which the novelty and inventive step of claimed inventions are assessed. Second, it will discuss some guidelines with examples of different categories of patent claims for pharmaceutical products, indicating the practice of some patent offices, and including recommendations for each category of claims. The proposed recommendations will suggest elements for the development of public health-sensitive guidelines for the evaluation and review of pharmaceuticals patents at the national level. Finally, the last segment will address some of the mechanisms that may be adopted to incorporate public health perspectives into procedures for the granting and review of pharmaceutical patents.