United Nations Development Programme

Guidelines for the examination of patent applications relating to pharmaceuticals

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Guidelines for Pharmaceutical Patent Examination:

Examining Pharmaceutical Patents from a Public Health Perspective

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Empowered lives. Resilient nations.

Acronyms and Abbreviations

5ASA	5-aminosalicylic acid
5-FU	5-fluorouracil
AIDS	Acquired immune deficiency syndrome
AZT	Zidovudine
DAT	Dementia of the Alzheimer type
DCL	Descarboethoxyloratadine
EPO	European Patent Office
HIV	Human immunodeficiency virus
ICTSD	International Centre for Trade and Sustainable Development
IR	Infrared absorption spectrum
NIF	Neutrophil inhibitory factor
NMDA	N-methyl-D-aspartate
NMR	Nuclear magnetic resonance
NOS	Nitric oxide synthase
NRTIs	Nucleotide analogue reverse transcriptase inhibitors
R&D	Research & Development
SDG	Sustainable Development Goal
TRIPS	Trade-related Aspects of Intellectual Property Rights
UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Programme
USPTO	US Patent and Trademark Office
WHO	World Health Organization
WTO	World Trade Organization

Contents

Acknowledgements

The *Guidelines for the Examination of Patent Applications relating to Pharmaceuticals* was written by Carlos Correa.

This document represents a follow-up to an earlier document, *Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective,* which was published in 2007 as a working paper by the International Centre for Trade and Sustainable Development (ICTSD), the United Nations Conference on Trade and Development (UNCTAD) and the World Health Organization (WHO).

The present document takes into account developments since the publication of the ICTSD-UNCTAD-WHO working paper in 2007. It includes new examples of patent applications and/or grants, and analysis of and references to the initiatives of a number of countries that have adopted laws and/or policies that seek to factor in public health considerations in the examination of patent applications.

With this document, the aim is to provide guidance for the development or revision of guidelines on patent examination processes in developing countries in response to concerns about the rise of patent numbers in the pharmaceutical sector. For this purpose, a number of recommendations are made with regard to the examination of the patentability of applications relating to pharmaceutical products and processes.

The draft of this document was also reviewed by policy and technical experts from China, Indonesia, Malaysia, Thailand and Viet Nam during the Regional Consultation on Integrating Public Health Considerations in Pharmaceutical Patenting in Low- and Middle-Income Countries, held in Bangkok, Thailand, on 6–7 May 2015.

This document has had the benefit of an expert review process and comments and inputs from a number of experts in the field. They include Susana Piatti (Consultant, Argentina); Suchart Chongprasert (Food and Drug Authority, Thailand); Barbara Milani (Consultant, Geneva); and Srividya Ravi (Consultant, India). In addition, Cecilia Oh (UNDP) and Kazuyuki Uji (UNDP) reviewed and commented on the drafts of the document, with Les Ong (UNDP) providing coordinating support. All of their contributions are gratefully acknowledged.

Foreword

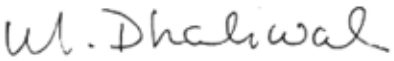
One important lesson of the global AIDS response is that efforts to stimulate innovation and R&D for lifesaving treatments must be accompanied by measures to ensure timely and affordable access to such treatments.

The 2030 Agenda for Sustainable Development has embraced this lesson. In aspiring to ensure health and well-being for all, Sustainable Development Goal (SDG) 3 includes the target of ending epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases by 2030. In so doing, it recognizes that support for research and development is essential to achieving this target but that such support must be linked to affordable access.

SDG 3 further highlights the relationship between patents and access, specifying that access should be provided in accordance with the *"the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all …"* This is a reflection of the growing consensus that an appropriate balance should be maintained between protecting the rights of inventors and incentivizing innovation, on the one hand, and promoting accessibility and affordability of treatments, on the other.

Recognizing the key role that patent offices and patent examiners play in safeguarding this balance, some countries have taken steps to provide guidance for how public health considerations may be factored into the examination of patent applications. This document examines initiatives in countries, such as Argentina, Ecuador, India and the Philippines, to integrate public health considerations into the procedures for the granting of patents on pharmaceuticals. It proposes a number of recommendations on guidelines that can be adopted as criteria for the examination of patent applications. Adoption of a clear criteria will ensure the public health perspective is properly integrated in the process of patent examination.

It is hoped that the recommended guidelines in this document will make a useful contribution to enhancing the functioning and transparency of the patent system in the public interest.



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The Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS Agreement) establishes minimum standards for the protection of intellectual property rights by members of the World Trade Organization (WTO). Beyond these minimum standards, however, it leaves many 'flexibilities' that allow WTO members to define their own policies and standards on various matters.

One important flexibility allowed to WTO members is determining what is meant by 'invention'– a concept that is not defined in the TRIPS Agreement. In fact, there is significant diversity in national laws and practices around the notion of invention, and to date, no complaint has been raised to the WTO regarding a definition of this concept. In particular, national laws may require a determination of whether an invention exists before entering into the analysis of compliance with the patentability requirements.

Similarly, the TRIPS Agreement obligates WTO members to grant a patent when patentability requirements are met, but it does not define those requirements. Thus WTO members may adopt different concepts of novelty (universal, local or a mix); inventive step or non-obviousness; and industrial applicability or utility.

Nothing prevents WTO members from applying rigorous patentability criteria to avoid low-quality patents. Similarly, WTO members retain flexibility to determine the rules applicable to the disclosure of the invention in order to ensure its reproducibility and to avoid broad, generic claims.

There has been growing attention, particularly in the area of public health and pharmaceuticals, to the need to ensure an appropriate balance between the interests of patent holders and technology users (as per the requirements of articles 7 and 8 of the TRIPS Agreement). In this respect, several countries (e.g. Argentina, Ecuador, India and the Philippines) have adopted legislation or policies for examining patent applications relating to pharmaceutical products and processes in a manner that accounts for public health considerations. Analysis of pharmaceutical patent claims has shown that the proper application of patentability standards can prevent the grant of 'poor quality' or trivial patents, which, by preventing the timely entry of generic competition, may harm public health.

This document, *Guidelines for the Examination of Patent Applications relating to Pharmaceuticals,* is intended as a contribution towards efforts to enhance the functioning and transparency of the patent system in the public interest. It proposes recommendations that can be adopted to incorporate public health perspectives in procedures for granting pharmaceutical patents.

It is important to note that the recommended guidelines do not intend to modify the standards of patentability