



## [English translation by WIPO]

## COMMENTS FROM SPAIN CONCERNING PATENTS AND HEALTH (STANDING COMMITTEE ON THE LAW OF PATENTS – 18th SESSION)

In response to **WIPO** letter **C.8076**, the Delegation of Spain has the pleasure of appending its comments relating to the following documents: **SCP/16/7** (proposal submitted by the Delegation of South Africa, on behalf of the **African Group** and the **Development Agenda Group**) and **SCP/17/11** (proposal submitted by the **United States of America**), both of which relate to "**Patents and Health**".

The Delegation of **Spain** has examined the **proposal** of the **African Group** and the **Development Agenda Group** with great interest, as it focuses on the issue of **access to medicines**, a topic of great interest to our country.

According to information provided at the Committee's previous session (see document SCP17/4), WIPO already cooperates with WHO and WTO on matters relating to access to medicines, and it seems that the relationship between patents and access to medicines should be addressed within the framework of this tripartite cooperation.

In any case, if the Committee should ultimately decide to move forward with an examination of the relationship between **patents** and **health**, it would be necessary to **avoid the duplication of efforts**. With regard to the study on the **use of compulsory licenses**, any duplication of work carried out on **exceptions and limitations** to patent law on the basis of the **proposal from Brazil**. For example, the survey approved at the previous session already includes questions on that topic. It would also be necessary to examine the possible **duplication of efforts** in relation to the work carried out by the **Committee on Development and Intellectual Property (CDIP)**, specifically documents **CDIP/5/4** and **CDIP/7/3**. Furthermore, the future work program presented at the most recent **CDIP** session, focusing on the issue of flexibilities within the intellectual property system, covered the following:

- **technical assistance**, at the request of Member States;
- **organization** of various **seminars** on the topic;
- a **database** on patent-related **flexibilities**, located on the WIPO website, containing national experiences relating to flexibilities.





Moreover, with regard to the third element in the proposal, relating to **technical assistance**, it is important to take into account the **seminars** and **workshops** which are organized periodically on this subject, in cooperation with the **WTO** and **WHO** (see document **SCP 17/4**).

With regard to the **first element**, relating to the **studies**, the Delegation of Spain welcomes the proposal to conduct a study on **Markush claims**, given that they are a technical matter, falling directly within the **Committee's mandate**. Markush claims **pose serious problems** for Patent Offices, as well as **difficulties** with regard to **IPC** classification, because of the large number of symbols assigned to documents, and - of course - when conducting **prior art searches** to assess the novelty and inventive step of the products in question. However, the study proposal features a certain **inherent bias**. As it stands, there is an assumption that the results of the study should confirm the hypothesis that such claims do not meet patentability requirements. The Delegation of Spain proposes that the **Secretariat**, working together with the **Member States**, should **carry out an impartial** and **objective** study on practices in different States with regard to these formulas, a study which could lead to **improvements** in the **handling of Markush-type claims** by Patent Offices.

The proposal of the **African Group** and the **Development Agenda Group** places too great an emphasis on **flexibilities** as means of facilitating access to medicines. The position of the **Spanish authorities** is more in line with the comments made by the **United States of America** in its proposal (**SCP 17/11**), namely that "weakening patent protection for innovative medicines is not a productive approach to improving availability of health care". Although the proposal put forward by the United States of America is very laudable, this does not seem to be an appropriate forum to implement it. The same has also been said of a large part of the African Group's proposal. However, if a decision were to be made to move forward with the African Group's proposal, it would be useful also to move forward with the proposal from the United States of America, at least with regard to the study examining the impact of patent systems on providing lifesaving medicines to developing countries, avoiding the assumption, implied in the proposal, that the impact will be a positive one - even though we may expect that to be the outcome of the study.