



SCT/16/3

**ORIGINAL:** English

**DATE:** September 1, 2006

## WORLD INTELLECTUAL PROPERTY ORGANIZATION

**GENEVA** 

# STANDING COMMITTEE ON THE LAW OF TRADEMARKS, INDUSTRIAL DESIGNS AND GEOGRAPHICAL INDICATIONS

### Sixteenth Session Geneva, November 13 to 17, 2006

MARKS AND INTERNATIONAL NONPROPRIETARY NAMES FOR PHARMACEUTICAL SUBSTANCES (INNs)

Document prepared by the Secretariat

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#### I. INTRODUCTION

- 1. At the fifteenth session of the Standing Committee on the Law of Trademarks, Industrial Designs and Geographical Indications (SCT), held in Geneva from November 28 to December 2, 2005, the SCT asked the Secretariat of the World Intellectual Property Organization (WIPO) to hold consultations with the World Health Organization (WHO) on appropriate ways to make information on international nonproprietary names for pharmaceutical substances (hereinafter called INNs) available to Member States and to report back to the SCT (see document SCT/15/4, paragraph 14). Those consultations were held during the first half of 2006, as part of which the Secretariat attended the Forty-Second Consultation on International Nonproprietary Names for Pharmaceutical Substances, i.e., the regular meeting of the WHO Expert Panel on the International Pharmacopoeia (the INN Expert Group).
- 2. By way of background, it is recalled that the SCT had already dealt to some extent with the question of INNs and, in particular, with trademark offices practices as regards examination of trademarks as to conflicts with INNs (see documents SCT/1/6, paragraph 34, SCT/3/7 and SCT/3/9, paragraph 11). The SCT agreed in its first session, from July 13 to 17, 1998, to conduct a survey concerning the examination practices of trademark offices regarding INNs. The results of that survey were discussed in its third session, from November 8 to 12, 1999, and it was concluded that the majority of the offices that replied to the survey examined trademarks against conflicting INNs. The availability of the lists of INNs, however, could be improved. Following a suggestion by the SCT, the WIPO Secretariat maintained consultations with WHO in order to find ways of facilitating the dissemination of information on INNs and, in particular, making available such information in an electronic format to interested offices of WIPO Member States.
- 3. The present document provides information on INNs and their relation with marks and describes how lists of INNs are published at present, and reports on the latest consultations between the Secretariat and the members of the INN Expert Group.

#### II. BACKGROUND

4. INNs identify pharmaceutical substances or active pharmaceutical ingredients. Each INN is a unique name that is a globally recognized generic name for an active substance used in pharmaceutical preparations. The system of INNs as it exists today was initiated in 1950 under the auspices of WHO by World Health Assembly Resolution WHA3.11 and began operating in 1953, when the first list of INNs was published. The cumulative list of INNs stands now at some 8,000 published INNs. The aim of the INN system is to provide health professionals with a unique and universally available designated name to identify each pharmaceutical substance<sup>1</sup>.

5. With the growing number of INNs and trademarks, the possibility of conflicts between them has gradually increased. The main source of conflict is usually an attempt by a manufacturer to propose a new trademark containing "stems", which are word elements established in the INN system to demonstrate the relationship between pharmacologically related substances. By the use of common "stems" the medical practitioner can recognize that the substance belongs to a group of substances having similar pharmacological activity. To prevent conflicts between INNs and trademarks, the World Health Assembly Resolution WHA46.19 was issued in 1993, requesting the Member States of WHO to develop policy guidelines on the use and protection of INNs, and to discourage the use as trademarks of commercial names derived from INNs and, particularly, names including established INN "stems".

# III. PUBLICATION OF LISTS OF PROPOSED AND RECOMMENDED INTERNATIONAL NONPROPRIETARY NAMES

- 6. WHO collaborates closely with INN experts and national nomenclature committees to select a single name of worldwide acceptability for each active substance that is to be marketed as a pharmaceutical. The INN Expert Group convened by WHO rejects any proposal that could result in a conflict with known trademarks. Selected names are published in a WHO periodical ("WHO Drug Information")<sup>3</sup> as proposed INNs and interested parties are given a period of four months to raise an objection to a proposed INN. An objection may be based, for example, on similarity between the proposed INN and a trademark in which the interested party has proprietary rights. When an objection has been raised, WHO will actively pursue an arrangement to obtain the withdrawal of such an objection or will reconsider the proposed INN. As long as the objection exists, WHO will not publish it as a recommended INN<sup>4</sup>.
- 7. Two lists of proposed INNs and two lists of recommended INNs are published every year. The lists are trilingual, in English, French and Spanish, and include Latin INNs. Furthermore, all recommended INNs are published in a cumulative list, which is updated periodically and includes INNs also in Arabic, Chinese and Russian, as well as reference to other generic names, such as national nonproprietary names and names used by the International Organization of Standardization, pharmacopoeial monographs, the List of Narcotic Drugs under International Control, and other sources.
- 8. In order to improve access to the relevant information, a free-of-charge on-line database on proposed and recommended INNs has been made available on the WHO website at http://www.who.int/druginformation/general/innlists.shtml. In addition to the on-line database, a CD, containing updated lists of proposed and recommended INNs, is sent every two years to the Health Ministries of the Member States of the WHO, and to the industrial property offices of those States.

# IV. CONSULTATION ON INTERNATIONAL NONPROPRIETARY NAMES FOR PHARMACEUTICAL SUBSTANCES

- 9. As part of the consultations between the WIPO Secretariat and WHO, WIPO participated in the Consultation on INNs for Pharmaceutical Substances of the INN Expert Group, which took place at the WHO headquarters, from April 4 to 6, 2006. In that meeting the following potential course of action to improve the accessibility of the lists of proposed and recommended INNs was considered:
- (i) The website address of the WHO on-line INN database could be made available to all national and regional industrial property offices of WIPO Member States. The International Bureau of WIPO could, for example, send a circular letter to those industrial property offices, transmitting information on the WHO on-line INN database. Moreover, industrial property offices could be invited to publish on their websites a link to the WHO on-line INN database.
- (ii) As regards those offices which have difficulties to access the WHO on-line INN database through Internet, a CD containing updated lists of proposed and recommended INNs could be made available. One possibility would be that the International Bureau of WIPO distribute those CDs directly to the national and regional industrial property offices of WIPO Member States.
- 10. Subsequently to the meeting of the WHO INN Expert Group, WHO has informed WIPO that an updated "CD-ROM/Cumulative list 12" would be published at the end of the year 2006, and that WHO will transmit to WIPO the required number of copies of that CD-ROM, for distribution. In the future, an updated "CD-ROM/Cumulative list" will be published and distributed every two years.
- 11. In addition, WHO has proposed to inform WIPO of every new list of proposed and recommended INNs published on its website. Consequently, the International Bureau could inform, by means of a circular letter, the national and regional industrial property offices of WIPO Member States, of the publication of each new list of proposed and recommended INNs and provide the hyperlink to the electronic version of such list, available on WHO's website.
  - 12. The SCT is invited to consider the contents of the document and to indicate whether it wishes
  - (i) to approve the proposals for an improved circulation of information on INNs as outlined in paragraphs 9 to 11, and
  - (ii) to make any further recommendation on trademarks and INNs.

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[Endnote continued from previous page]

- <sup>2</sup> "Guidelines on the Use of International Nonproprietary Names (INNs) for Pharmaceutical Substances" at http://whqlibdoc.who.int/hq/1997/WHO\_PHARM\_S\_NOM\_1570.pdf.
- http://www.who.int/druginformation/general/innlists.shtml.
- "Guidelines on the Use of International Nonproprietary Names (INNs) for Pharmaceutical Substances" at http://whqlibdoc.who.int/hq/1997/WHO\_PHARM\_S\_NOM\_1570.pdf.

<sup>&</sup>quot;Guidance on INN" at http://www.who.int/medicines/services/inn/innguidance/en/index.html.