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## 世界知识产权组织标准委员会(CWS)

第三届会议 2013年4月15日至19日,日内瓦

修订 WIPO 标准 ST. 9

秘书处编拟的文件

- 1. 2012年10月28日,德国专利商标局(DE局)给国际局发来一份文件,要求修订WIPO标准ST.9下的"国际承认的(著录项目)数据识别代码"(INID)代码表。所建议的修订是对某些著录项目数据的说明进行更新,并增加一个关于药品(含儿科用药品)补充保护证书的新代码。与这项要求一同,DE局还要求将与该修订有关的相关信息在WIPO《工业产权信息与文献手册》第8.1部分"工业产权信息与文献词汇表"(《词汇表》)中予以反映。
- 2. 现将 DE 局的上述要求转录于本文件附件一,其中载有背景信息,包括修订的预期好处,以及有关增加新 INID 代码(98)和修订代码(92)、(93)和(95)的具体提案。在附件一的附录中,DE 局还陈述了建议对《词汇表》进行的后续修改。
- 3. 在第 33 号任务("WIPO 标准的不断修订")的框架内,并根据 DE 局的要求,国际局编拟了一份 WIPO 标准 ST. 9 附录 1("著录项目数据识别用 INID 代码和最低要求")的修订稿草案,现转录于本文件附件二,供 WIPO 标准委员会(CWS)审议和批准; DE 局所建议的修改作了加亮显示。
- 4. 考虑到标准第 6 段,国际局随后将对标准附录 2("附录 1 所列代码表的删除与修正")进行更新,该附录中"载有曾在一段时期使用,但要么不再提供使用,要么已经过修正的 INID 代码,并附有这些代码的定义和/或注释"。

## 5. 请标准委员会:

- (a) 注意本文件附件一中所载的 DE 局 关于修订 WIPO 标准 ST. 9 和《词汇表》的 要求;
- (b) 审议并通过上文第 3 段中所述、 转录于本文件附件二的关于修订 WIPO 标准 ST. 9 附录 1 的提案;
- (c) 注意上文第 4 段中所述对 WIPO 标准 ST. 9 附录 2 的文字修改;并
- (d) 审议并批准按上文第 2 段中所述 在《词汇表》中采用转录于本文件附件一 附录中的提案。

[后接附件]

## 关于修订WIPO标准ST. 9 的要求

#### 德国专利商标局编拟的文件

## 对问题或具体需求的说明

- 1. WIPO 标准 ST. 9 "关于及有关专利和补充保护证书的著录项目数据的建议"最后一次修订是在 2008 年 2 月。尽管标准中所含的多数建议仍然有效,但其中一些需要进行修正,使之更明确。
- 2. 欧洲议会和理事会关于儿科用药品的第(EC)1901/2006 号条例及欧洲议会和理事会关于药品补充保护证书的第(EC)469/2009 号条例要求欧洲联盟成员国公布有关补充保护证书的某些数据。这些数据中,并非所有都能明确地分配现有的 INID 代码。
- 3. INID 代码的现有形式未反映儿科用药品延期的可能性。例如,关于延期申请、关于撤销延期以及关于更正期限的数据应当用哪些 INID 代码公布,并不明确。
- 4. 此外,现行 INID 代码仅提及药品补充保护证书,而补充保护证书也可用于植物保护产品。

#### 需求是怎样确定的

5. 德国专利商标局在公布活动中遇到了问题。

## 备选解决方案

- 6. 鉴于上述,可以考虑修改 WIPO 标准 ST. 9 中 INID 代码(92)、(93)和(95)说明部分目前的措辞, 并增加一个新的 INID 代码(98)。
  - INID 代码(92): INID 代码(92)的新说明将为:
    - "用于补充保护证书,第一次国家许可产品作为药品或植物保护产品上市的号码和日期。"
  - INID 代码(93): INID 代码(93)的新说明将为:
    - "用于补充保护证书,在一个地区性经济共同体中第一次许可产品作为药品或植物保护产品上市的号码、日期以及,适用时,原属国。"
  - INID 代码(95): INID 代码(95)的新说明将为:
    - "受基础专利保护并且已申请或被授予补充保护证书或补充保护证书延期的产品的名称。"
  - 新 INID 代码(98): 新 INID 代码(98)的说明将为:
    - "用于补充保护证书,关于延期申请、撤销延期以及更正期限的数据。"
  - <u>修订《词汇表》</u>:由于拟议的修订,《词汇表》也将需要修改。修正《词汇表》的措辞时,可以增加关于植物保护产品和儿科延期可能性的表述。(见附录。)

## 预期好处

- 7. 所建议的修订有以下预期好处:
  - 向公众提供更好的信息,
  - 主管局的公报和注册簿将在结构和清晰度上得到优化,
  - 使 WIPO 标准 ST. 9 根据目前的法律形势得到更新和调整。

[后接附录]

#### APPENDIX:

ADDITIONS TO THE GLOSSARY OF TERMS CONCERNING INDUSTRIAL PROPERTY INFORMATION AND DOCUMENTATION

## Supplementary Protection Certificate

A Supplementary Protection Certificate is an industrial property right which is granted for a product which has obtained authorization to be placed on the market as a medicinal product or plant protection product. The certificate takes effect at the end of the term of a patent which protects the product as such, a process to obtain the product or an application of the product. The certificate extends the protection conferred by the said patent, but only in respect of the product covered by the said authorization and any use of that product as a medicinal product or phytopharmaceutical plant protection product that has been authorized before expiry of the certificate. The certificate does not extend the term of the said patent.

The duration of a supplementary protection certificate can be extended for medicinal products for paediatric use when all the measures in the agreed paediatric investigation plan have been complied with. That fact should be recorded in the marketing authorization.

## In this context:

- "medicinal product" means any substance or combination of substances presented for treating or preventing diseases in human beings or animals or any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals;
- "phytopharmaceutical plant protection product" means any active substance or preparation containing one or more active substances, put up in the form in which it is supplied to the user, intended to:
  - (i) protect plants or plant products against all harmful organisms or prevent the action of such organisms, in so far as such a substance or preparation is not otherwise defined below;
  - (ii) influence the life processes of plants, other than as a nutrient (e.g., plant growth regulators);
  - (iii) preserve plant products, in so far as such a substance or product is not subject to special Council or Commission provisions on preservatives;
  - (iv) destroy undesirable plants; or
  - (v) destroy parts of plants, check or prevent undesirable growth of plants;
- "product" means the active ingredient or combination of active ingredients of a medicinal product or phytopharmaceutical plant protection product.

A notification of the application for a supplementary protection certificate and of the fact that the certificate has been granted or the application for the certificate has been rejected is published by the industrial property office with which the application was lodged.

The following notifications regarding a supplementary protection certificate are published by the concerned industrial property office:

- the application for the certificate
- the grant of the certificate
- the rejection of an application for the certificate
- the application for an extension of the duration of the certificate
- the grant of an extension of the duration of the certificate
- the rejection of an application for an extension of the duration of the certificate
- the application for a revocation of an extension of the duration of the certificate
- the revocation of an extension of the duration of the certificate
- the rejection of an application for a revocation of an extension of the duration of the certificate
- the application for a correction of the duration of the certificate
- the correction of the duration of the certificate
- the rejection of an application for a correction of the certificate
- the lapse or invalidity of the certificate

[后接附件二]

## ST.9 - APPENDIX 1

# INID CODES AND MINIMUM REQUIREMENTS FOR THE IDENTIFICATION OF BIBLIOGRAPHIC DATA ELEMENTS

- (10) Identification of the patent, SPC or patent document
  - \* (11) Number of the patent, SPC or patent document
  - \* (12) Plain language designation of the kind of document
  - \* (13) Kind-of-document code according to WIPO Standard ST.16
  - (15) Patent correction information
  - \* (19) WIPO Standard ST.3 code, or other identification, of the office or organization publishing the document
  - Notes: (i) For an SPC, data regarding the basic patent should be coded by using code (68).
    - (ii) \* Minimum data element for patent documents only.
    - (iii) With the proviso that when data coded (11) and (13), or (19), (11) and (13), are used together and on a single line, category (10) can be used, if so desired.
    - (iv) Data to be given under code (15) should be presented in accordance with the provisions set out in WIPO Standard ST.50.
- (20) Data concerning the application for a patent or SPC
  - \* (21) Number(s) assigned to the application(s), e.g., "Numéro d'enregistrement national", "Aktenzeichen"
  - \* (22) Date(s) of filing the application(s)
  - \* (23) Other date(s), including date of filing complete specification following provisional specification and date of exhibition
  - (24) Date from which industrial property rights may have effect
  - (25) Language in which the published application was originally filed
  - (26) Language in which the application is published
  - (27) Reference to a previously filed application for the purpose of obtaining a filing date under the Patent Law Treaty (PLT), Article 5(7)
  - Notes: (i) The document "Terms of Protection", which provided information related to code (24), has been moved to the Archives.
    - (ii) The languages under codes (25) and (26) should be indicated by using the two-letter language symbols according to International Standard ISO 639:1988.
    - (iii) With regard to code (27), the reference shall be made by indicating the WIPO Standard ST.3 code of the office with which the previous application was filed, the application number of the application, and, if required, the filing date.
- (30) Data relating to priority under the Paris Convention or the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)
  - \* (31) Number(s) assigned to priority application(s)
  - \* (32) Date(s) of filing of priority application(s)
  - \* (33) WIPO Standard ST.3 code identifying the national industrial property office allotting the priority application number or the organization allotting the regional priority application number; for international applications filed under the PCT, the code "WO" is to be used

- (34) For priority filings under regional or international arrangements, the WIPO Standard ST.3 code identifying at least one country party to the Paris Convention or member of the World Trade Organization for which the regional or international application was made
- Notes: (i) With the proviso that when data coded (31), (32) and (33) are presented together, category (30) can be used, if so desired. If an ST.3 code identifying a country for which a regional or international application was made is published, it should be identified as such using code (34) and should be presented separately from elements coded (31), (32) and (33) or (30).
  - (ii) The presentation of priority application numbers should be as recommended in WIPO Standards ST.10/C and in ST.34.
- (40) Date(s) of making available to the public
  - \* (41) Date of making available to the public by viewing, or copying on request, an unexamined patent document, on which no grant has taken place on or before the said date
  - \* (42) Date of making available to the public by viewing, or copying on request, an examined patent document, on which no grant has taken place on or before the said date
  - \* (43) Date of making available to the public by printing or similar process of an unexamined patent document, on which no grant has taken place on or before the said date
  - \* (44) Date of making available to the public by printing or similar process of an examined patent document, on which no grant or only a provisional grant has taken place on or before the said date
  - \* (45) Date of making available to the public by printing or similar process of a patent document on which grant has taken place on or before the said date
  - (46) Date of making available to the public the claim(s) only of a patent document
  - \* (47) Date of making available to the public by viewing, or copying on request, a patent document on which grant has taken place on or before the said date
  - \* (48) Date of issuance of a corrected patent document

Note: \* Minimum data element for patent documents only, the minimum data requirement being met by indicating the date of making available to the public the patent document concerned.

## (50) Technical information

- \* (51) International Patent Classification or, in the case of a design patent, as referred to in subparagraph 4(c) of this Recommendation, International Classification for Industrial Designs
- (52) Domestic or national classification
- \* (54) Title of the invention
- (56) List of prior art documents, if separate from descriptive text
- (57) Abstract or claim
- (58) Field of search
- Notes: (i) The presentation of the classification symbols of the International Classification for Industrial Designs should be made in accordance with paragraph 4 of WIPO Standard ST.10/C.
  - (ii) With regard to code (56) attention is drawn to WIPO Standard ST.14 in connection with the citation of references on the first page of patent documents and in search reports attached to patent documents.
- (60) References to other legally or procedurally related domestic or previously domestic patent documents including unpublished applications therefor
  - \* (61) Number and, if possible, filing date of the earlier application, or number of the earlier publication, or number of earlier granted patent, inventor's certificate, utility model or the like to which the present patent document is an addition
  - \* (62) Number and, if possible, filing date of the earlier application from which the present patent document has been divided up
  - \* (63) Number and filing date of the earlier application of which the present patent document is a continuation

- \* (64) Number of the earlier publication which is "reissued"
- (65) Number of a previously published patent document concerning the same application
- (66) Number and filing date of the earlier application of which the present patent document is a substitute, i.e., a later application filed after the abandonment of an earlier application for the same invention
- (67) Number and filing date of a patent application, or number of a granted patent, on which the present utility model application or registration (or a similar industrial property right, such as a utility certificate or utility innovation) is based
- (68) For an SPC, number of the basic patent and/or, where appropriate, the publication number of the patent document
- Notes: (i) Priority data should be coded in category (30).
  - (ii) Code (65) is intended primarily for use by countries in which the national laws require that re-publication occur at various procedural stages under different publication numbers and these numbers differ from the basic application numbers.
  - (iii) Category code (60) should be used by countries which were previously part of another entity for identifying bibliographic data elements relating to applications or grants of patents which data had initially been announced by the industrial property office of that entity.
- (70) Identification of parties concerned with the patent or SPC
  - \* (71) Name(s) of applicant(s)
    - (72) Name(s) of inventor(s) if known to be such
  - \* (73) Name(s) of grantee(s), holder(s), assignee(s) or owner(s)
  - (74) Name(s) of attorney(s) or agent(s)
  - \* (75) Name(s) of inventor(s) who is (are) also applicant(s)
  - \* (76) Name(s) of inventor(s) who is (are) also applicant(s) and grantee(s)
  - Notes: (i) \* For patent documents for which grant has taken place on or before the date of making available to the public, and gazette entries relating thereto, the minimum data requirement is met by indicating the grantee, and for other documents by indication of the applicant.
    - (ii) Codes (75) and (76) are intended primarily for use by countries in which the national laws require that the inventor and applicant be normally the same. In other cases codes (71) or (72) or (71), (72) and (73) should generally be used.
- (80) (90) Identification of data related to International Conventions other than the Paris Convention, and to legislation with respect to SPCs
  - (81) Designated State(s) according to the PCT
  - (83) Information concerning the deposit of microorganisms, e.g., under the Budapest Treaty
  - (84) Designated Contracting States under regional patent conventions
  - (85) Date of commencement of the national phase pursuant to PCT Article 23(1) or 40(1)
  - (86) Filing data of the PCT international application, i.e., international filing date, international application number, and, optionally, the language in which the published international application was originally filed; or, in the case of design patents, registration data of the Hague Agreement international application, i.e., international registration date and international registration number
  - (87) Publication data of the PCT international application, i.e., international publication date, international publication number, and, optionally, the language in which the international application is published
  - (88) Date of deferred publication of the search report
  - (91) Date on which an international application filed under the PCT no longer has an effect in one or several designated or elected States due to failure to enter the national or regional phase or the date on which it has been determined that it had failed to enter the national or regional phase

- (92) For an SPC, number and date of the first national authorization to place the product on the market as a medicinal product or plant protection product
- (93) For an SPC, number, date and, where applicable, country of origin, of the first authorization to place the product on the market as a medicinal product or plant protection product within a regional economic community
- (94) Calculated date of expiry of the SPC or the duration of the SPC
- (95) Name of the product protected by the basic patent and in respect of which the SPC or the extension of the SPC has been applied for or granted
- (96) Filing data of the regional application, i.e., application filing date, application number, and, optionally, the language in which the published application was originally filed
- (97) Publication data of the regional application (or of the regional patent, if already granted), i.e., publication date, publication number, and, optionally, the language in which the application (or, where applicable, the patent) is published
- (98) For an SPC, data concerning the application for an extension of the duration, the revocation of an extension of the duration and the correction of the duration
- Notes: (i) With regard to patents for invention, the codes (86), (87), (96) and (97) are intended to be used:
  - on national documents when identifying one or more of the relevant filing data or publication data
    of the PCT international application or of the regional application (or of the regional patent, if
    already granted), or
  - on regional documents when identifying one or more of the relevant filing data or publication data
    of the PCT international application or of another regional application (or the regional patent, if
    already granted).
  - (ii) All data in codes (86), (87), (96) or (97) should be presented together and preferably on a single line. The application number or publication number should comprise the three basic elements as shown in the examples in paragraph 17 of WIPO Standard ST.10/B.
  - (iii) When data to be referenced by codes (86), (87), (96) or (97) refer to two or more PCT international applications and/or regional applications (or regional patents, if already granted), each set of relevant filing or publication data of each such application (or granted patent) should be displayed so as to be clearly distinguishable from other sets of relevant data, e.g., by presenting each set on a single line or by presenting the data of each set grouped together on adjacent lines in a column with a blank line between each set.
  - (iv) The languages under codes (86), (87), (96) and (97) should be indicated by using the two-letter language symbols according to International Standard ISO 639:1988.
  - (v) The country of origin in code (93), if mentioned, should be indicated by using the two-letter code according to WIPO Standard ST.3.
  - (vi) The document "Terms of Protection", which provided information related to code (24), has been moved to the Archives.

[附件二和文件完]

<sup>\*</sup> For the meaning of the asterisk, see paragraph 7 or 8 of this Recommendation. [WIPO Standard ST.9]