COMMENTS BY SPAIN IN RESPONSE TO CIRCULAR 8403 OF THE SECRETARIAT OF THE WIPO STANDING COMMITTEE ON THE LAW OF PATENTS (SCP)

Via Circular 8403 of 15 December 2014, the Secretariat of the Standing Committee on the Law of Patents (SCP) requested Member States submit information on inventive step and sufficiency of disclosure requirements:

INVENTIVE STEP

a) **Definition of a person skilled in the art**

b) **Methods used for assessing the inventive step**

c) **In light of the state of the art, the level of inventiveness (obviousness) necessary to fulfil the requirement for inventive step**

Introduction

In Spain the requirement for inventive step is defined by Article 8 of Patent Law No. 11/1986:

Article 8

(1). An invention shall be regarded as involving an inventive step when it does not result from the start of the art in a manner obvious to a person skilled in the art.

(2). Where the state of the art includes documents such as those mentioned in Article 6(3) above, they shall not be taken into consideration when deciding upon the existence of an inventive step.

Article 6 defines the state of the art:

Article 6

(1). An invention shall be considered to be new if it does not form part of the state of the art

(2). The state of the art shall be held to comprise everything made available to the public in Spain or abroad by means of a written or oral description, by use, or by any other way before the date of filing of the patent application.

(3). Additionally, the content of Spanish patent or utility model applications as filed, of which the dates of filing are prior to the date referred to in the preceding paragraph and which were published on or after that date, shall be considered are comprised in the state of the art .

From Articles 8(2) and 6(3), it can be deduced that documents known as “interference” are only used to evaluate novelty in Spain, not inventive step.

(a) PERSON SKILLED IN THE ART

As previously mentioned, the person skilled in the art appears within the definition of inventive step:

Article 8

(1). An invention shall be regarded as involving an inventive step when it does not result from the state of the art in a manner obvious to a person skilled in the art.

For a definition of the person skilled in the art, it is necessary to turn to the Patent Application Examination Guidelines produced by the Spanish Patents and Trademarks Office (*Oficina Española de Patentes y Marcas*, or OEPM). Point 6.5.3.2 defines a person skilled in the art as follows:

"A person skilled in the art is a hypothetical person with typical technical skills and up-to-date general technical knowledge on the date of the application, or priority where applicable. Such a person shall also be considered to have access to everything contained within the "state of the art," in particular, the documents cited in the prior art report, and to be able to avail himself of average skills and means for due experimentation.

Where an invention seeking to solve a problem derived from the closest prior art prompts the skilled person to seek a solution in another technical field, the specialist in that field shall be the person qualified to resolve the problem. As a consequence, the knowledge and skills of such a specialist shall be used to evaluate whether the solution involves inventive step. In certain circumstances, it may be more appropriate to consider the person skilled in the art not as a single person but as a group of persons, for example, a research or production team. This may be the case, for example, in certain cutting-edge technologies, such as computers or telephone networks, and highly specialized processes, such as the commercial production of printed circuits or complex chemical substances."

In a decision dated January 7, 2014, Barcelona Commercial Court No.4 painstakingly defined the concept of a person skilled in the art: "The characteristics of a person skilled in the art are the same in all cases that we must define to be able to evaluate whether this skilled person would have deemed the invention to be obvious:

a) A person skilled in the art is a person (or team of persons) practicing in the field to which the invention pertains, having common knowledge of the relevant technical or scientific field, at the time of filing the application; this is a typical professional possessed of the knowledge common to such professionals.

b) The skilled person is deemed to have knowledge of all of the documents that form the state of the art, which he has read carefully, and naturally those cited in the prior art report.

c) The skilled person has the typical means and abilities to carry out both everyday work and experimentation.

d) The skilled person is proficient in the technical field relevant to the invention (EPO Boards of Appeal, T 641/00, OJ EPO 2003, 352) but does not have inventive capacity (T39/93, OJ EPO 1997, 134). This is exactly the kind of skill that differentiates the inventor from the person skilled in the art.

e) To identify this ideal expert, the starting point must be the technical problem that the invention aims and claims to solve (T 422/93)."

Decision No. 367/2013 of the Barcelona Provincial Court (Division 15), of October 22, 2013, defines the person skilled in the art as follows: "As previous decisions have stated (*inter alia*, decisions of May 9, 2008 and February 8, 2007), the criterion for evaluating inventive step is whether a person skilled in the art, using the aforementioned information and on the basis of his own knowledge, is able to achieve the same result in an obvious way, without applying his ingenuity. As the Boards of Appeal of the European Patent Office have asserted, in evaluating inventive step, the correct criterion is not whether the claimed invention would have been obvious to an inventive person, aside from the actual inventor, but whether it would have been obvious to a skilled yet unimaginative person who meets the criteria for a person skilled in the art (T 39/93, OJ 1997, 134). […] As the decision of the Court of May 9, 2008 states, for an expert to be able to assume the point of view of a person skilled in the art – necessary in this case to evaluate inventive step – it is not essential that the expert be a person skilled in the art; rather, on the basis of his training and experience, such a person should be able to put himself in the position of "a person skilled in the art". In response to the questions from counsel for AstraZeneca in the proceedings, as to the importance of general common knowledge of clinical practice in treating psychiatric illnesses, the expert Mr. Fructuoso Marcial – who, as previously mentioned, underlined that the purpose of the patent was the pharmaceutical formulation – acknowledged that the skilled person who could treat patients and knew about the issues relating to treatment adherence would be a psychiatrist, but he added that there were indications in the literature of the importance of adherence to treatment for patients with schizophrenia."

(b) METHODS USED TO EVALUATE INVENTIVE STEP

All of the information regarding the evaluation of inventive step at the OEPM can be found in Chapter 6.5 of the OEPM Patent Application Examination Guidelines ("OEPM Patent Guidelines"). With regard to the method used to evaluate inventive step, **it is recommended that examiners use the problem-solution method, although this is not compulsory**. This method is described in point 6.6.1 of the OEPM Patent Guidelines. As is well known, this method consists of answering the following five questions:

1. What is the closest prior art?
2. In terms of the claimed technical features, what is the difference between the claimed invention and the closest prior art?
3. What is the technical effect derived from this difference?
4. Consequently, what is the objective technical problem underlying the claimed invention?
5. Could a person skilled in the art, on the basis of the entire knowledge contained in the state of the art and without using any inventive skill whatsoever:

a. Recognize the problem? and

b. Resolve it in the indicated manner?

This method is generally adopted by the Specialized Courts in Spain. Here are some examples: judgment of Barcelona Commercial Court No. 4 of January 7, 2014, in Ordinary Case No. 603/12-X, following submissions on the invalidity of the European patent validated in Spain under the Spanish publication number ES2203495; decision no. 18/2008 of the Barcelona Provincial Court (Division 15), of January 24, 2008, impugning the European patent with the Spanish validation number ES2082011; decision 15/2014 of the Pamplona Provincial Court (Division 3), of February 11, 2014, impugning the European patent with the Spanish publication number ES2120451; and decision 71/2013 of the Madrid Provincial Court (Division 28), of March 4, 2013, impugning the European patent validated under the Spanish publication number ES2105774.

Decision **283/2011** of the Madrid Provincial Court (Division 28), of October 3, 2011, states with regard to the validity of the European patent validated in Spain under publication number ES2204679T, referring to a "high-frequency phase shift module" for antennas, it was considered that an expert report could not be taken as a decisive indication, as the evaluation of the requirement for inventive step had not been conducted in line with the "problem-solution approach". A very similar situation can be found in decision **252/2013** of the Madrid Provincial Court, of September 18, 2013, on the infringement and invalidity by counterclaim of the utility model with the application number **U200102995**.

(c) **IN LIGHT OF THE STATE OF THE ART, THE LEVEL OF INVENTIVENESS (OBVIOUSNESS) NECESSARY TO FULFIL THE INVENTIVE STEP REQUIREMENT**

As mentioned in the introduction, Article 8(1) of Patent Law No. 11/1986 sets out the Spanish definition for the inventive step requirement:

"An invention shall be regarded as involving an inventive step when it does not result from the state of the art in a manner obvious to a person skilled in the art."

Point 6.5.2 of the OEPM Patent Guidelines discusses the term "obvious":

"The meaning of the term 'obvious' is that something does not transcend normal technological progress, it is deduced simply or logically from the state of the art, i.e., it does not involve the use of any skill or ability beyond that expected of a person skilled in the art.

The invention as a whole is obvious if, on the filing date, or priority date where applicable, a person skilled in the art would have been led or prompted by an element of the state of the art or by his general knowledge to replace, combine or change the contents of one or more elements of the state of the art with a reasonable hope of success in achieving the claimed invention."

In decision **71/2013**, the Madrid Provincial Court (Division 28) found invalid the European patent validated in Spain under number E52105774T, which claimed a (particularly low) specific dosage of a pharmaceutical compound (finasteride, for the oral treatment of androgenetic alopecia). In the reasoning, the problem-solution method is applied, resulting in the finding that the differential technical feature with regard to the closest prior art is the use of a low dose of medication (the smallest possible dose maintaining the compound's efficacy), and it was held that the invention did not therefore involve inventive step as obtaining the lowest effective dose is an inherent element of all pharmaceutical research.

In decision 268/2013, of 27 September 2013, the Madrid Provincial Court (Division 28) sets forth what it considers to be inventive step or level of inventiveness in the following terms: "the absence of inventive level is observed […] if on the filing date, or priority date where applicable, the person skilled in the art would have been prompted by an element of the state of the art or by his general knowledge to replace, combine or change the contents of one or more elements of the state of the art with a reasonable hope of success in achieving the claimed invention […]" (In this connection, see OEPM Patent Guidelines, Version 1, 2006, p.152).

The analysis of the prior art by a person skilled in the art need not be limited to an isolated approach (as would be the case in the examination of the novelty requirement), instead, even on the assumption that the invention has not been described in the state of the art, it is necessary to evaluate whether the person skilled in the art, with the sum of the information extant prior to the request (which provides for it being compiled from different sources) as well as his own knowledge, would have arrived at the same conclusion as the inventor because the proposed solution would have been obvious to him. As the OEPM Patent Guidelines indicate, to discount the presence of the inventive step, it is not enough that, having understood the entire state of the art, the skilled person be capable of arriving at the proposed solution for the relevant patent; he must also be able to do so via mere deduction, without resorting to ingenuity (the invention is derived simply or logically from the prior art, in a manner that does not involve the use of any skill or ability beyond that expected of a person skilled in the art). Furthermore, despite the greater or lesser degree of simplicity that may be apparent in the invention, in an "*ex post facto*" analysis, the knowledge available retrospectively through the very claim whose validity is in dispute must not be allowed to influence the result of the examination of obviousness."

It must be noted that the level of inventive activity required to obtain protection is lower for utility models, given that Article 146 of Patent Law No. 11/1986 provides:

Article 146

1. *For protection as a utility model, an invention shall be deemed to involve an inventive step if it does not **very obviously** result from the state of the art in for a person skilled in the art.*

In relation to "obvious" and "very obvious," Supreme Court Judgment No. 717/2011 states: "Whereas

obvious is that which is so clear that it is indubitable and undeniable, the **very obvious** is that which jumps off the page, leaving no doubt whatsoever.

In the OEPM Utility Model Examination Guidelines, there is information on evaluating the inventive step of utility models.

SUFFICIENCY OF DISCLOSURE

a) Enabling disclosure requirement

b) Support requirement

c) Written description requirement

a) ENABLING DISCLOSURE REQUIREMENT

This requirement is defined in Article 25(1) of Patent Law No 11/1986:

Article 25

1. *The invention shall be described in the patent application in a sufficiently clear and comprehensive manner to enable a person skilled in the art to execute it.*

With regard to inventions involving biological material, Sub**-Articles 25(2), 25(3) and 25(4)** apply:

2. *Where the invention refers to biological material not available to the public, or for its use, and where the biological material cannot be described in the patent application such that an expert is able to reproduce the invention, the description shall only be considered to fulfil the provisions of Article 25(1) if the following requirements are met:*

    a. *The biological material was deposited no later than the filing date of the patent application with an authority legally recognized for that purpose. In any event, recognition shall be given to the International Depositary Authorities so empowered pursuant to Article 7 of the Budapest Treaty of 28 April 1977, on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, hereinafter the Budapest Treaty.*

    b. *The application, as filed, contains the relevant information available to the applicant on the features of the deposited biological material.*

    c. *The patent application indicates the name of the depositary institution and the deposit number.*

3. *Where the biological material deposited in compliance with Article 25(2) is no longer available at a recognized depositary authority, a new deposit of the material shall be authorized under conditions equivalent to those stipulated in the Budapest Treaty.*

4. *All new deposits shall be accompanied by a statement signed by the applicant certifying that the new deposit of biological material is the same as the material initially deposited.*

Where the applicant requests a preliminary examination, compliance with the sufficiency of disclosure requirement shall be examined. **Article 39:**

Article 39(2)

2. *Within three months of the publication of the prior art report, the applicant may request an examination of **sufficiency of disclosure**, novelty and inventive step for the patent application.*

The guidelines for the examination of sufficiency of disclosure in Spain can be found under point 5.5 of the OEPM Patent Examination Guidelines.

With regard to the sufficiency of disclosure requirement, of note is the **Madrid Provincial Court (Division 28) decision 194/09** of December 16, 2009, (Janssen Pharmaceutica NV-Janssen-Cilag, S.A. *vs.* Teva Genéricos Española, S.L.), relating to the Spanish patent ES200428T, the validation of European patent EP236684 for the active substance galantamine used in treating Alzheimer's disease. This decision states that, in European law, "it is not always necessary for the results of clinical trials to be given on the date; what is required, however, is that the patent/application supply certain information relating to a direct effect of the claimed compound on a metabolic process specifically implicated in the disease. Provided this information is available in the patent/application, evidence published at a later date may be taken into account to support the description in the patent application."

Another relevant instrument is decision **00122/2008** of May 16, 2008, **issued by the Madrid Provincial Court (Division 28)** (Diffusion Bacteriologie du Var, SA *vs.* International Microbio SA - Biomerieux España, S.A.), which considers the possible invalidity of Spanish patent ES2024687T, validating the European patent EP311541. The finding was that the patent did not fulfil the requirement for sufficiency of disclosure (for requiring excessive experimentation), given that it did not provide the necessary data to execute the only example included in the description. It was proven that more than 900 experiments were necessary to execute the patent.

The decision of January 3, 2000 on **Appeal No. 1525/1996, issued by the Madrid Provincial Court (Division 15)** (Bayer AG *vs*. Rasfer S.A.) on the validity of patent ES505138, the object of which was a process for manufacturing ciprofloxacin and enrofloxacin, states that "the patent did not contain all the necessary information for a skilled person, on the priority date, to be able to obtain the initial substance (fluoroquinolonic acid), which was not available at that time." "The patent describes a process for obtaining ciprofloxacin and enrofloxacin, but the Markush structure used is incomplete and does not allow a skilled person to obtain ciprofloxacin and enrofloxacin", "in the experimental section there is no example of the synthesis of the quinolinic compounds", "thus being insufficient for the simple possibility of

'fluoroquinolonic acid' being formulated from patent 478.047."

In a decision dated **July 18, 2014, the Madrid Provincial Court (Division 28)** determined Appeal No. 804/2012 (BOSCHUNG MECATRONIC, A.G. and FRIBAIR S.A. *vs.* VYR VALVULERÍA Y RIEGOS POR ASPERSIÓN S.A. and EUROPISTAS CONCESIONARIA ESPAÑOLA S.A.) on the invalidity of European patent EP98105077. The applicants argued that Patent Claim No. 10 lacked sufficiency of disclosure. Nevertheless, the Court concluded that "the allegation of insufficient disclosure […] fails, given that the interpretation of the patent text must be based on the text itself (it must treat the claims, which must be interpreted with the help of the description and drawings) and not on external elements that could be used as grounds for tendentious disputes. According to what we were able to prove from the written description of the patent, the provision […] is for one spray point for every 15 to 40 m² of circulation surface area, without, as the expert Mr. Alvaro explained, it being reasonable to contemplate, when interpreting Claim No. 10, of a distribution of 15 to 40 spray points per square meter (which dispels any doubts that could have been raised at the time not by the patent itself but by a statement included in the report of another expert, Mr. Damaso). Accordingly, the invention is perfectly reproducible for a person skilled in the art, without causing him to doubt his reasonable understanding of the nature of the patent."

With regard to utility models, the examination of sufficiency of disclosure shall only be subject to examination where challenges are formed, pursuant to Article 45 of the Implementing Regulation for the Patent Law:

Article 45

(1). "Within two months of publication of the application, any legitimately interested party may challenge the protection requested for the utility mode, by alleging the failure to fulfil any of the requirements for the granting of protection, including the lack of novelty, inventive step or sufficiency of disclosure." (Article 149(1) of the Law).

b) Support requirement

This requirement is provided for in Article 26 of Patent Law No 11/1986:

Article 26

*Claims shall define the object for which protection is sought. They must be clear and concise and **shall be based on the description**.*

The OEPM Patent Guidelines discuss this requirement in point 2.3.4, under the heading "**Supporting claims in the description**" and in point 3.2.4, "**Claims that define the invention depending on the desired result**".

Decision **32/2010 of Barcelona Provincial Court (Division 15)**, relating to the invalidity of patent

ES2237331B1 on a kit for applying hair extensions and a process for applying the extensions, states that "insufficiency of disclosure must be relevant for it to justify the invalidation of the patent, which only occurs if it raises serious doubts, supported by verifiable data," and that "the lack of precision of a claim, in other words, the fact that it is too broad, is not reason enough to find the disclosure insufficient. What is really important is that the understanding of the patent allows a person skilled in the art, not a beginner, to execute the invention."

Barcelona Commercial Court No. 6, in the **decision of July 8, 2013**, determined **Appeal No. 758/2009,** on the invalidity of the European patent EP03748142 and the failure to disclose the invention in a manner sufficiently clear and complete for a person skilled in the art to execute it, as the claims did not specify the cone angle, preventing the skilled person from executing the patent. The decision concludes that "in the light of the foregoing, it is deemed that any expert, having seen the first claim, the description and the drawings of the patent, and using rudimentary empirical tests, i.e., trial and error, could easily determine the appropriate angles."

c) Written description requirement

Article 5 of the Implementing Regulation of the Law of Patents sets out the formal requirements that must be fulfilled in the description:

Article 5

1. *The description shall be drafted as clearly and as concisely as possible, without redundancy, and be consistent with the claims.*
2. *The description shall also contain the following information:*
    a. *The title of the invention in its original wording;*
    b. *An indication of the technical field to which the invention belongs;*
    c. *An indication of the prior art known to the applicant on the date of the priority and possibly useful in the understanding of the invention and the creating of the prior art report, citing, where possible, any documents that would help reflect the prior art;*
    d. *A description of the invention, exactly as it is characterized in the claims, that allows understanding of the technical problem raised, as well as the solution thereto, indicating, where applicable, the advantages of the invention in relation to the prior art;*
    e. *A brief description of the drawings, if any;*
    f. *A detailed presentation of at least one embodiment of the invention, which may be supported with examples and, where applicable, references to drawings, where they are included;*

g. *An indication of how the invention is susceptible of industrial application, where it is not obvious from the description or the nature of the invention.*

3. *The description shall be presented in the manner and the order stipulated in Article 5(2), unless the nature of the invention dictates a different manner or order to allow a better understanding and a more concise presentation.*

4. *Where the invention refers to a microbiological procedure, the description shall meet the requirements set out in Article 25(1), 25(2)(a) and (b) of the Law. The applicant shall likewise indicate in the description the name of the recognized authority with which a culture sample of the microorganism has been deposited and state the number or code identifying it to the recognized authority.*

The guidelines for the examination of these aspects can be found under Guideline **2.3.5** of the OEPM Patent Guidelines.

Madrid, February 19, 2015