Protection of Pharmaceutical and Cosmetic Industry Inventions by means of Spanish Patents: Key Aspects

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Key aspects of Spanish patent regulation are discussed, particularly with regard to the pharmaceutical and cosmetic industries.

1. **Spanish patents versus EU patents:** The protection of inventions in Spain through patents may be achieved in two ways: obtaining a Spanish domestic patent or obtaining an EU patent designating Spain.

   EU patents are governed by the Convention on the Grant of European Patents of 5 October 1973 (the European Patent Convention, as amended by the Act revising the Convention of 29 November 2000), and are granted by the European Patent Office (EPO), based in Munich (Germany). Applications for these patents must state the Member States parties to the Convention – which include Spain – where protection is sought. Once a given EU patent has been granted, several States – such as Spain – require the translation (with the consequent increase in costs) and validation of the EU patent in their domestic patent and trade mark (industrial property) offices for the patent to become effective in their territory. In addition, once the whole process has concluded, the EU patent becomes a 'bundle of patents', wherefore the legal effects of the EU patent in each State are determined by the relevant national legislation. And similarly, not only are claims for infringement determined in accordance with the law of each of the jurisdictions where the harmful acts were committed, but also actions for revocation must be brought in each one of the States where such patent revocation is sought.

   Spanish domestic patents, on the other hand, are granted by the Spanish Patent and Trade Mark Office (abbrev. OEPM) and are governed by the Spanish Patents Act 1986. Although the Official Journal of Spain published on 25 July 2015 the Patents Act 24/2015 of 24 July, this new repealing and replacing law will not come into force until 1 April 2017.

2. **Entitlement to be a patentee:** According to the Patents Act 1986, patents can be obtained by Spanish natural or legal persons and foreign natural or legal persons 'habitually resident' or with a 'real or effective industrial or commercial establishment' in Spain or who enjoy the benefits of the Union constituted under the Convention of Paris for the protection of industrial property, as well as by foreign natural or legal persons that do not meet these requirements, provided that natural or legal persons of Spanish nationality are allowed to obtain equivalent instruments in the State of which said foreign natural or legal persons are nationals.

   However, the new Patents Act of 2015 significantly broadens the discussed entitlement

by providing that "natural or legal persons, including bodies governed by public law, may apply for industrial property instruments". Moreover, the possibility of relying on directly applicable international treaties, where it is more favourable, is set out.

3. **Patentable inventions:** Both the 1986 and 2015 Acts of Parliament set out the traditional patentability requirements for an invention: novelty, inventive step and capability of industrial application. And both statutes, as is common with patent legislation and as is the case of the European Patent Convention, do not define what is meant by an invention, but only offer a negative delimitation according to which the following, in particular, shall not be regarded as inventions: (a) discoveries, scientific theories and mathematical methods; (b) literary and artistic works, or any other aesthetic creation whatsoever, and scientific works; (c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers; (d) presentations of information.

   On this basis, Spanish law introduces some prohibitions to patentability, i.e., cases where, notwithstanding the existence of an invention, its protection by means of a patent is not possible. This is the case of: (a) an invention the commercial exploitation of which would be contrary to public policy or morality; (b) any variety of animal or plant; (c) essentially biological processes for the production of animals or plants; (d) the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene (although an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention); (e) a method of treatment of the human or animal body by surgery or therapy, or a method of diagnosis practised on the human or animal body (with the exception of a substance or composition or the invention of an apparatus or instrument for use in any such method). This prohibition is contained in the Patents Act 2015, but not in the 1986 Act, which instead of prohibiting patentability, creates a fiction, providing that "a method of treatment of the human or animal body by surgery or therapy…shall not be regarded as an invention capable of industrial application". Instead, the 2015 Act is in line with the provisions of the Act revising the Convention of 29 November 2000.

4. **Patentability requirements:** The first requirement to be met by an invention in order to be patentable is that it be new, taking an invention to be new if it does not form part of the state of the art (comprising all matter which has at any time before the date of filing of the patent application been made available to the public, whether in Spain or elsewhere, by written or oral description, by use or in any other way). Worldwide novelty, therefore, is required.

   In connection with pharmaceutical industry inventions, it should be borne in mind that both the European Patent Convention and the Patents Act 2015 contain explicit provisions which take to be new inventions that, comprising first and further medical uses of a known substance, rely on claims of the type: "composition X for the treatment of disease Y" or "composition X for use in the treatment of disease Y"; note, however, that the Patents Act 1986 does not contain equivalent provisions, leading the OEPM to reject the aforementioned claims and to allow only claims of the format "use of X in the preparation of a medicament" or "use of X in the preparation of a medicament for the treatment of disease Y"(so-called Swiss-type claims).

   Similarly, for the purposes of novelty, Spanish legislation provides that the disclosure of matter constituting an invention shall be disregarded, when determining the state of the art, if such disclosure occurred no earlier than six months preceding the filing of the patent application and if it was due to, or in consequence of: (a) an evident abuse in relation to the applicant or his predecessor in title; or (b) the fact that the applicant or his predecessor in title has displayed the invention at an official, or officially recognised, international exhibition falling within the terms of the Convention on international exhibitions signed at Paris on 22 November 1928 and last revised on 30 November 1972. Though missing in the 2015 Act, under the 1986 Act there is another case of

non-prejudicial disclosure: that of trials conducted by the applicant or his predecessors in title that do not involve the invention being commercially worked or offered to sell.

As regards the inventive step, an invention shall be taken to involve an inventive step if it is not obvious to a person skilled in the art. That is, it is necessary that the invention is not a simple corollary of what was already known, to the extent that anyone with ordinary skill in the art could have derived it. It requires, in short, a non-obvious invention. And, in turn, the capability of industrial application requirement is met, according to Spanish law, when the invention can be made or used in any kind of industry, including agriculture.

5. **The right to apply for a patent:** The right to apply for a patent belongs to the inventor or his successors in title and is transferable by all means recognized by law. If the invention has been made by several persons jointly, the right to obtain a patent shall belong to them jointly. In contrast, when the same invention has been made by several people independently, the right to the patent shall belong to whoever's application has an earlier filing date in Spain.

   Spanish legislation gives special attention to inventions made by an employee under a contract of employment or a worker under a work for hire agreement. Such inventions raise the question of whether the entitlement to the patent lies with the employee/worker or with the employer/hirer. In this regard, the 2015 Act (in parallel to the 1986 Act) distinguishes three cases: "inventions belonging to the employer/hirer" (those made by the employee/worker during the course of employment/hire and which are the result of research explicitly or implicitly included in the subject matter of the employment contract or work for hire agreement); "inventions takeable by the employer/hirer" (those made by the employee/worker in connection with his duties and based predominantly on knowledge acquired at or the use of resources provided by the employer/hirer); and "inventions belonging to the employee/worker" (those that do not fall within the above case).

6. **The grant procedure:** Under the Patents Act 1986, Spanish patents can be granted by the OEPM with or without a preliminary examination of the patentability requirements. After accepting the application of the grant procedure with preliminary examination to patent applications in the food sector (Royal Decree 812/2000 of 19 May), the Government allowed the same in general and not just for the food sector (Royal Decree 996/2001 of 10 September).

   Although, as of yet, it is up to the applicant to request, of his own volition, the aforementioned preliminary examination, the Patents Act 2015 aligns itself with what happens at the EPO and prescribes a preliminary examination in respect of all patent applications. Note, however, that the new statute, just as the Patents Act 1986, also provides that "patents are granted without prejudice to third parties and without any guarantee from the State as to the validity of the same and the utility of the invention on which it rests".

   Moreover, the 1986 Act provides that third parties may give notice of opposition, in the grant procedure, to the grant of a patent. The 2015 Act, however, instead of pre-grant oppositions, provides the mechanism of post-grant opposition, whereby within six months of the publication of the mention of the grant of a patent in the Spanish patents journal (*Boletín Oficial de la Propiedad Industrial*), any person may give notice of opposition to that patent on the grounds that the claimed invention does not meet any of the patentability requirements, the specification of the patent does not disclose the invention clearly enough and completely enough for it to be performed by a person skilled in the art, or the matter disclosed in the specification of the patent extends beyond that disclosed in the application for the patent, as filed.

   With this regulation, the 2015 Act's opposition is similar to that provided in the EPC, a centralized procedure, where in the nine months time limit as of publication of the grant of the European patent in the European Patent Bulletin assimilates European patent, any person may

give notice to the EPO of opposition to that patent. (This opposition is a way of obtaining the revocation of the patent by the EPO, of a centralized nature, and of avoiding having to resort to national court proceedings to contest the validity of a European patent).

7. **Patent applications and patents as subject matter of property rights:** Spanish legislation not only allows and regulates co-ownership of patents and the expropriation of the same - as well as transfers, licenses and liens - but also provides that licensing by the proprietor may be compulsory when any of the following circumstances applies: (a) the patented invention is not being commercially worked or is being commercially worked insufficiently; (b) the exploitation of a dependent patent or plant variety right is prevented or hindered; and (c) there are reasons of public interest. Note, however, that pursuant to the new 2015 Act, to the foregoing circumstances we must also add to remedy anti-competitive practices or for the manufacture of pharmaceutical products for export to countries with public health problems.

8. **Content and defence of the right:** Patents have a non-extendable term of 20 years, beginning with the date of filing the application, which takes effect as of the date on which notice of its grant is published in the journal.

   The industrial property right granted in a patent makes it possible to prohibit and react to direct or indirect acts of infringement. Direct infringements occur when a third party, without the consent of the proprietor, replicates the elements of the patented invention. In these cases, the infringement can be literal (when the infringing product or process incorporates all the elements of the invention), or under the doctrine of equivalents (when one element is substituted by another that plays an equivalent role). Spanish case law having embraced the aforementioned doctrine, the 2015 Act now expressly mentions it.

   Similarly, a patentee may also see his exclusive rights infringed by way of an indirect infringement. It is thus provided in the 1986 and 2015 statutes that a patent also gives its proprietor the right to prevent any third party from, without the consent of the proprietor, supplying or offering to supply a person other than a licensee or other person entitled to work the invention with any of the means, relating to an essential element of the invention, for putting the invention into effect when he knows, or it is obvious to a reasonable person in the circumstances, that those means are suitable for putting, and are intended to put, the invention into effect.

   Actions, of any kind or nature, may be brought to court by the proprietor of a patent against whosoever harms his rights, claiming the relief necessary to safeguard the same. In civil proceedings, a claim may be made: (a) for an injunction or interdict restraining the defendant from any apprehended act of infringement; (b) for damages in respect of the infringement; (c) for the seizure of the infringing product produced or imported and of the means exclusively used for such production or for carrying out the patented process; (d) the assignment in property of products or means seized where possible, in which case the value of the affected property will be regarded as compensation; (e) the adoption of the necessary measures to prevent further infringement of the patent; and (f) publication of the judgment for the claimant.

9. **Utility models:** Aside from patents, Spanish patent legislation (both the 1986 and the 2015 statutes) also envisages 'utility models', by means of which a person can protect industrially applicable inventions which, being new and involving an inventive step, consist in giving a matter or product a configuration, structure or composition that results in a functional improvement in its use or manufacture. Utility models grant protection for a non-extendable term of 10 years as of application for the same.

   The new Patents Act introduces the possibility of protecting, as utility models, inventions consistent in a new composition of a product, a possibility that is not provided for in the 1986 Act. However, having provided this new possibility of protecting the composition of chemicals, a restriction is laid down by prohibiting the protection as utility models of inventions that rest on pharmaceutical substances and compositions.

   Moreover, and with regard to protection requirements, whilst in the 1986 Act novelty

need only be national, the 2015 Act requires worldwide novelty, as with patents. However, in terms of inventive step, a degree lower than that for patents is still required, providing both the 2015 and 1986 statutes that "for its protection as a utility model, an invention is regarded as involving an inventive step if it is not very obvious to a person skilled in the art".

10. **Supplementary protection certificates:** After expiry of a domestic patent on a medicinal product, a supplementary protection certificate may be requested. Although such a certificate is governed by Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6th May 2009, it is actually a domestic industrial property instrument, fully subject to the principle of territoriality, and granted by domestic offices. Hence, the new Patents Act contains different provisions on supplementary protection certificate applications, processing and renewals.