



# EVERSHEDS LUPICINIO

IEWS AND COMMENTS ABOUT THE PRELIMINARY FINDINGS OF THE SECTOR  
INQUIRY ON THE PHARMACEUTICAL SECTOR PRESENTED BY THE EUROPEAN  
COMMISSION IN ITS PRELIMINARY REPORT DATED 28<sup>th</sup> NOVEMBER 2008

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## 1. GENERAL INTRODUCTION ABOUT EVERSHEDS LUPICINIO

Eversheds Lupicinio is a long-established Spanish Legal Firm with offices open in Madrid, Barcelona and Valladolid,. Within its areas of expertise, the IP & Pharmaceutical Department with more than 10 year's experience is one of the most well-known departments of the firm, having being ranked in the main Legal Directories such as Legal 500 and Chambers.

The client profile of the firm includes innovative or ethical companies with a vast patent portfolio and a high R+D budget in order to discover new medicines to generic companies with interest in obtaining a good share of the market. Also we advise "mixed" companies with businesses in both sides of the market. Our experience goes to from pharma patent litigation to licence and development agreements.

Having the Commission invited to interested stakeholders to submit their comments about the preliminary findings of the sector inquiry presented in the Preliminary Report by 31 January 2009, our experience allows us to accept that invitation and discuss in a constructive way the preliminary findings reach by the European Commission on its Preliminary Report and exhibit a serial of facts and arguments that may contribute to the improvement of certain aspects or points of the final Report to be reached once the investigation ends.

Our views and comments are not aimed to give a general view of the patent litigation in Europe but it is restricted to the Spanish territory as there are so many differences between Spanish legislation and other European countries' legislation which must be taken into account to have a perfect view of pharma patent litigation in Spain from 2000.

## 2. PRINCIPLE ISSUES THAT JUSTIFY THE LITIGIOUSNESS THAT HAS EXISTED IN SPAIN IN RELATION TO PHARMACEUTICAL PATENT.

In our opinion, the preliminary report issued by the European Commission does not reflect the reasons that have caused that litigiousness has taken place in Spain. Moreover, the report does not analyse the specific situations arisen in Spain regarding pharmaceutical patent conflicts.

We must outline from the very beginning two relevant issues: i) that this litigiousness has not only in one direction but it has been a "return trip", as infringement proceedings filed by patent owners have coexisted, with lawsuits initiated by generic manufacturer companies asking for the nullity or revocation of originators' patents duly granted by the European Patent Office or National Patent Offices when the generics wanted to launch a generic product of an innovator under patent protection, and ii) although we do not have notice of delays in the launch of generic medicines into the market attributable to litigation initiated by patent holders, we do know several cases where generic medicines are commercialised long before the expiration of the basic patent that described, for the first time ever, the active ingredient under protection. .

In any case, there is a series of circumstances or facts that must be considered by the European Commission to understand and evaluate the litigiousness taking place in Spain in the period from the year 2000 to 2007 (hereafter, the analysed period).

- The inexistence of a product patent in Spain until the 7<sup>th</sup> October 1992.

In the preliminary report a certain fact is considered valid to describe the pharma business activity –“ Effective patent protection is vital to sustain this business model, which also ensures there are incentives for further innovation”-. However, that premise valid for many countries where innovative medicines were habitually protected by patents in the analysed period, and that the innovative companies lost their exclusivity when the patents expired is not strictly valid for Spain,

Also the Report adds that some blockbusters lost their patent protection during the analysed period. As we anticipated, this second assertion was not applicable in Spain: in our country, until the 7<sup>th</sup> October 1992 it was not possible to apply for pharmaceutical patent product protection. One of the requirements that the European Community (formerly, European Union) imposed to Spain in order to access to the European market was to join the European Patent system and therefore to join the Munich European Patent Convention (hereafter EPC) dated 5<sup>th</sup> October 1973. However, to protect the primitive national industry, in the Instrument of Adhesion of the 10<sup>th</sup> July 1986 our country formulated a reserve (hereafter Reserve) in whose virtue the European patents of pharmaceutical products were inefficient in Spain. In the same sense, but for national patents, the First Transitory Disposition of the Spanish Patent Act of the 20<sup>th</sup> March 1986 prohibited the patentability of pharmaceutical and chemical products until the date above mentioned.

This meant that in our country the innovative pharmaceutical companies were not able to obtain effective product patent protection for those pharmaceutical products that have caused litigiousness during the analysed period. Moreover, the protection of those products could only be realised by the indirect and much more vulnerable route of patenting some manufacturing procedures that have been proven to be more easily infringed or circumvented.

- Weakness of process patents to protect very costly and valuable therapeutic inventions of the pharmaceutical industry.

Meanwhile product patents legally guarantee the pharmaceutical laboratories the exclusive right to prevent third parties exploiting the demanded medications and give them expeditious judicial actions to defend themselves in the different Courts of Justice before any act of infringements made against their legally granted rights, pharma process patents are the weakest intellectual property right of all those rights that the Spanish Patent Act recognises. We say this because the claimed invention in these patents is not the pharmaceutical ingredient as such, but merely a chemical manufacturing process to obtain such active ingredient. In this way, despite the innovative laboratories having invented innovative medicines, thanks to huge financial investments in R&D+i, that are capable of curing or alleviating serious pathological diseases, the Spanish protectionist legislation stopped them from patently protecting these valuable products and made them claim their manufacturing methods with the unkind and disheartening consequences that we mention below..

- The inexistence of a sophisticated doctrine about the equivalent doctrines.

The work experience accumulated by this firm through these years in which that we have assisted pharmaceutical companies before the Spanish Courts of Justice tribunal in lawsuits relating to infringement process patents has confirmed, to us, the vulnerability of these patents in front of the copyist company. In principle, according to Spanish case law, legally and for the examination of the Courts, a chemical process is described by three essential elements: one or various starting materials,, ways of actuations (chemical operations) and the final product. Logically, the improvement of the Organic Chemistry theories and investigations allows to obtain the final product – which is the invented

element and the essential component of the manufacturing process in offering the palliative and curative effects of any medication – with the introduction of mere variations or alterations to the starting materials or the chemical operations carried out described in the patent granted. In this context, the effective defence of a patent right limited by the ministry of the law demanded an expansive application of the so called “doctrine of equivalents”, in such a way that the protection of the patents would extend not only to the elements described literally in the patent title, but to those other equivalents, avoiding the deceitful, fraudulent and unpunished violation of the weak process patents.

However, in this country, until the 12<sup>th</sup> December 2008 when the EPC and the Interpretative Protocol of Section 69 of that EPC as agreed in 200 Munich Convention were vigorously introduced it, the doctrine of equivalents was not legally recognised. However, the Courts of Justice did previously recognised such doctrine<sup>1</sup> but its temporal development has been ambiguous and constantly changing up to the point that four different theories were successively considered – essence of innovation theory, triple identity theory, double identity theory and creativeness and obviousness theory – with no agreement to use one or other depending the technical field, generating an enormous interpretive disparity and as a consequence, legal and business insecurity.

The uncertainty of the litigation outcome provoked numerous litigations in which the Courts gave very different answers to similar questions. If the legislator had codified before this doctrine of equivalents the justice tribunals would have created a unique case law and this would have avoided numerous litigations in which different interpretations of this doctrine, based on the law compared with the countries of our environment, were defended.

- Limited application of the reversal of the burden of the proof.

One of the major weaknesses of the process patents came from the impossibility of the patent holder to certainly verify the chemical manufacturing procedure. In contrast to that which occurs with other intellectual property rights (like industrial designs, trademarks or copyrights and other similar rights), in those which the examination of the objects created or produced by the competitor (for example merchandise, sculpture or songs) allow the holder to value the existence of the infringement outside of the litigation process, in patent litigation relating to pharmaceutical processes this previous examination was out of the pharmaceutical laboratories’ reach because the analysis of the competitive medicines themselves did not allow to know the actual manufacturing procedure used on their manufacture.

To ease this limitation, Section 61.2 of our Patent Act introduced a legal mechanism to reverse the burden of the proof<sup>2</sup>, in whose virtue the medicines of the same characteristics to the one described in a process patent were presumed to have been fabricated by the patented procedure, as long as the product described on the process patent was new. This requirement of novelty of the final product in the process patent was interpreted very restrictively by our tribunals in detriment of the innovative laboratories. As it is known, when a laboratory selects a novel compound that finally could have therapeutic effectiveness, applies for patent protection in order to have a future protection to its economic investment in due course. This patent protection is always provisional, thus as a result of the advances in the investigation, more

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<sup>1</sup> Actually, there is no a unique doctrine but some depending on the technological field which the patent is granted for.

<sup>2</sup> Under Spanish Procedural Law, the parties must effectively prove their allegations in the litigation and in case of failure to do so, their petitions are rejected by lack of evidence.

sophisticated and more efficient procedures have arisen that due to their novelty and inventive activity deserve patent protection.

As it was not possible to obtain patent protection, the innovative laboratories thought fairly that this legal institution should have been extended to all of the patented procedures, because to the contrary the scientific research led by innovative laboratories would be judicially penalised. Unfortunately, this interpretation did not prosper and our tribunals reported that only the first patent turned out to be beneficial for the investment of the test charge, which expanded the circular route of patents enormously.

A fair application of the reversal of the burden of the proof would have meant that the defendant should have proved beyond any doubt that the manufacturing process used was different to the one patented to succeed on the litigation. However, the test applied for the Spanish Court was not enough demanding and the defendants beat the reversal without really proving that the process used was different to the one patented. For the Spanish Court, a simple declaration of a technician alleging to have seen some papers was enough to exceed the reversal.

- No Commercial Courts specialised commercial tribunals in patent litigation until 2007.

In our country, there are no specialised Courts of Justice in intellectual property matters and in particular in patent issues or more specifically, there is no a single Court specialised in chemical-pharmaceutical patents.

Only in September 2003, and because of an amendment of the Spanish Bankruptcy Act, some First Instance Courts and Court of Appeal were created in Spain with jurisdiction and competence regarding IP matter including copyrights, patents, trademarks and designs but also with competence in the following matters: insolvency proceedings, national and international Transport Law, Company Law, Maritime Law, general Terms and Conditions issues, Resolutions of the Spanish General Directory of the Registers and Notary Public Committee, Competition Law and finally Unfair Competition Law.

Without prejudice of the diversity of matters covered by such Courts impedes an adequate specialisation, the judges and magistrates that occupied those tribunals gained their seats in the majority of the cases by a system based primarily on theoretical examinations. For that, it can be argued that those Courts did not acquire the necessary experience to indict the controversies of the pharmaceutical patents until a minimum period of 4 years has spent i.e. September 2007,

In summary, this implies that the patent litigations were indicted and ruled in Spain during the analysed period by judges without actual experience in pharmaceutical matters.

The above alongside with certain pathologies that we will mention in the following paragraphs,, justifies a very limited reliability of the legal decisions given out by the Spanish legal tribunals in the conflict relating to pharmaceutical patents.

- Limited scope of the Anton Piller actions regulated in the Patent Law.

One of the causes that justified patent litigation in our country was the limited objective scope of the so called Anton Piller actions which are essential in order to obtain documentary evidence regarding the manufacturing procedures used by the potential infringing companies before entering into litigation.



Theoretically speaking, Anton Piller actions are used to obtain evidences that allow patent holders to either consider the start of the litigation or to completely disregard it.

However, in order to get the judicial protection, firstly Section 129 of the Patent Law requires that the patent holder files its Anton Piller application with a sign of evidence about the allegedly infringement of the patent, which is certainly difficult when dealing with process patents. Secondly, it demands that the applicant shows firmly that those actions were the only way to prove the reality of the patent infringement. The Spanish tribunals were very demanding in their evaluation of these requirements and rejected a lot of petitions. Finally, regarding the scope of the investigation, the Patent Act refers to the inspection of the machines, mechanisms and installations, and the determination as to whether or not those elements can serve in order to commit this violation, which in reference of chemical procedures turned out to be manifestly insufficient to prove the manufacturing process used.

As a result of the uselessness of the diligences of Antón Piller that has been exposed above the patent holders were heading towards the filing of ordinary lawsuits to know exactly the chemical procedures that its competitor in many cases had only manifested to be using before being into litigation.

- Inexistence of preliminary diligences until the 5<sup>th</sup> June 2006.

In our country, until the legal implementation of Directive 2004/48 on the 6<sup>th</sup> June 2006, on the enforcement of intellectual property rights, preliminary diligences at the disposal of the patents holders in order to obtain dates about the origin and networks of distribution of the medicines that offended the patens did not exist, including dates relating to products, fabricants, distributors, suppliers, quantities made and served, satisfied prices, characteristics of these medicines, etc.

This circumstance, as that shown in the previous paragraph, obliged the patent holders up until this date to provide the indicated ordinary lawsuits on the merit.

- Negative predisposition of the civil and commercial Courts to concede precautionary measures.

In the preliminary report it is highlighted, amongst other things, the number of applications for precautionary measures rejected to the patent holders, and from this fact it is deduced that the laboratories affected abused of those proceedings. Our experience on litigation tells us that this deduction is entirely incorrect. In Spain, the justice administration works very deficiently, which translates, amongst other things, to mean that the legal proceedings of patents last until its definitive resolution by the Supreme Tribunal no fewer than 11 years later. One of the consequences of this deficient functioning is the clear negative predisposition of our tribunals to concede precautionary measures in any procedure, and especially when the litigant companies are pharmaceutical laboratories and the right invoked is a process patent. We do not know any reference to the existence of statistics in relation to the percentage of precautionary measures grantes, but the Commission will be able to obtain this information asking to Spanish Ministry of Justice.

This negative predisposition, known by the plaintiff companies, delegitimizes in some manner the Report's affirmation that certain companies would have used litigation to dissuade the entrance of generic medicines into the market. Who knows and is familiar with its scant possibilities of procedural success cannot dissuade to anybody when it precautionary actions mostly rejected are applied for.

- Confusion derived from the late introduction of the Bolar clause.

It is said in the preliminary report that originator companies argued that marketing authorisations and/or obtaining pricing or reimbursement status could violate their patent rights, even though marketing bodies may not take this argument into account.

This has been caused by the late and inexact introduction of the Bolar clause into the Spanish legislation.

Section 10. 6 of the Directive 2001/83/EU as amended by the Directive 2004/27/CE introduced on the European legislation the Bolar Clause<sup>3</sup>. This clause is an exemption to the patent exclusive right permitting generic companies to conduct certain activities in order to obtain the marketing authorization for their products. However, the introduction of such clause within the Spanish legislation has been made through the 29/2006 Act with an unclear wording which create interpretative problems.

Moreover, the late introduction of this clause has created more litigiousness between generics and innovators as before its introduction the limits of what was considered a patent infringement in relation to the activities carried by generics asking for a marketing authorization were undefined and companies sought Court interpretation to know exactly the scope of patent protection.

### 3. Irrelevance in Spain of the performances of the innovative companies before the Spanish Medicines Agency.

It is suggested in the Preliminary Report that i) interventions by originator companies before national authorities other than Patent Offices occurred in a significant number of cases; ii) that originators claimed in their interventions that generic products were less safe, effective and/or of inferior quality, and iii) interference by originator companies in administrative proceedings for generic medicines might have led to delays in generic market entry.

This is clearly incorrect in Spain. In our country, during the enforceability validity until 28<sup>th</sup> of July 2006 of the former Medicament Act 25/1990, and the Regulations that developed such Act in relation to applications of marketing authorisations (Royal Decree 767/1993), the applications of generic medicines were not officially published nor communicated to the holders of the reference medicines, so it is really difficult to understand how the innovator companies could intervene and interfere in the authorisation process of generics.

The Spanish Medicament Agency, following the interpretation made by the contentious-administrative Courts of Justice, understood that the administrative authorisation procedures of generic medicines had as an exclusive aim to verify the security and efficiency of those medicines, without any consideration to patent rights from third companies that could be affected by the authorisation and commercialisation of such medicines. These innovative companies invoked the condition of the interested third parties but the Spanish Medicament Agency and the Courts rejected this condition and denied them any legitimacy to intervene in those administrative proceedings.

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<sup>3</sup> “*Conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3 and 4 and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products*”.

Taking into account this, this firm has not known any case in which the approval and launch of a generic medicine has been affected by the administrative interference of an innovative laboratory.

4. Aim of these views and comments.

The aim of these views and comments is not criticised the Preliminary findings included in the Report issued by the European Commission on the 28<sup>th</sup> November 2008 but to give the Commission an independent view to understand the particularities of Spanish legal system in relation to pharma industry.

With such aim, we are at the disposition of the European Commission to clarify or extend our views and comments.

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