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BRIEFING

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THE IMPLEMENTATION OF MANDATORY ARBITRATION FOR PATENT RELATED DISPUTES INVOLVING REFERENCE AND GENERIC MEDICINES

INTELLECTUAL PROPERTY

On December 12th, 2011, Law no. 62/2011 ("Law 62/2011") was published in the Official Bulletin of the Portuguese Republic, thus introducing into Portuguese law a new dispute resolution mechanism specifically targeted at industrial property litigation between reference (i.e. patent protected) and generic medicines. In addition, Law 62/2011 also introduces important changes to the Legal Regime of Human Use Medicines (Law-Decree no. 176/2006 of August 30th)[1] and the General Regime of State Co-Payments related to Medicine Prices (Law-Decree no. 48-A/2010 of May 13th).[2]

Over the last decade, Portugal has been somewhat of a case-study with regard to the collision between reference and generic medicines. Pinpointing the origin of the clash is complex but most observers would agree that it coincides with the aggressive and full-fledged entry of generic medicine companies into the Portuguese market, many-a-times encouraged by governmental policies.

The situation up to the passing of Law 62/2011 can be summarized as follows:

– Similarly to what occurs in other EU countries, to place a medicine in the Portuguese market, it is necessary to undergo an administrative process in order to obtain a Marketing Authorization ("MA") from the Portuguese Medicine Regulatory Authority ("INFARMED") and also a public sale price from the General Directory of Economic Activities ("*Direcção-Geral das Actividades Económicas*" or "*DGAE*"). With the mass entry of generic medicine companies into the Portuguese market, reference medicine owners began to detect that amongst the various authorization applications filed with INFARMED and DGAE (and then approved by these public entities), several covered active ingredients that were still (arguably) covered by patent protection.[3]

[1] Amended by Law-Decrees nos. 182/2009 of August 7th, 64/2010 of June 9th, 106-A/2010 of October 1st and Law no. 25/2011 of June 16th.
[2] Amended by Law-Decree 106-A/2010 of October 1st.
[3] Or by Supplementary Protection Certificates (SPCs).

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– Faced with this threat, reference medicine owners initiated litigation in the administrative courts against INFARMED and DGAE, seeking to obtain the suspension of the generic medicine's MA and/or the fixing of its public sale price. The main argument upon which the reference medicine owners rested their cases addressed the fact that industrial property rights are fundamental rights (in light of their private and exclusive nature) and therefore the State has the duty to guarantee their respect and enforcement. In harmony with this obligation, the State, by way of its administrative bodies, should not approve the entry of generic medicines into the market while industrial property rights over the reference medicine's active ingredients were still in force in Portuguese territory.

– This approach, known as "patent linkage" in the English language, has produced a large amount of contradictory case-law in Portugal, the majority of which has been favourable to the reference medicine owners.

Law 62/2011 therefore arises precisely from the need to resolve these legal conundrums and provides the pharmaceutical sector in Portugal with a new legal framework specifically targeted at resolving the disputes between reference and generic medicines involving industrial property rights. The way in which the Portuguese lawmaker proposes to do this is by removing this type of litigation from the judicial courts and forcing the litigating parties to resort to arbitration resolution mechanisms.

BASIC STAGES OF THE NEW DISPUTE RESOLUTION MECHANISM

(i) INFARMED is from now on obliged to publish on its website all MA applications or registrations for generic medicines. Said publication must occur 5 days after the 10 day period that INFARMED has to review the application and request corrections and clarifications. The publication must include the following information: (a) the name of the MA applicant; (b) the application date; (c) the substance, dosage and pharmaceutical form of the medicine; and (d) the reference medicine.

(ii) The publication of the MA application then opens a 30 day period for any interested party to invoke an incompatible industrial property right. In other words, there is now a 30 day period within which an interested party may oppose the generic medicine.[4]

[4] In accordance to the transition regime established by article 9 of Law 62/2011, INFARMED must, within 30 days of the entry into force of said law, publish the basic information of the MA applications that are still pending in the various stages of the process. The interested parties then have a 30 day period during which they can oppose and litigate by means of the mandatory arbitration mechanism.

It is now expressly stated in the law that the aforementioned decisions do not have to take into consideration existing industrial property rights, nor do they infringe said rights.

(iii) The opposition must be filed with an institutionalized arbitration court or a request must be made to submit the litigation to an ad-hoc arbitration court. It is necessary to combine these new legal provisions with the new voluntary arbitration law (Law no. 63/2011), published on December 14th, 2011. All evidence must be presented simultaneously with the filing of the opposition.

(iv) Once the MA applicant has been notified of the opposition, it will have a 30 day period to counter-argue and present the supporting evidence. Failure to do so during the aforementioned deadline will result in the MA applicant being prohibited from marketing and exploiting the generic medicine while the industrial property right(s) of the opponent is(are) still in force in Portuguese territory.

(v) If the MA applicant decides to contest the opposition, shortly after[5] the filing of the counter-arguments and supporting evidence, a date and time is set for the presentation and discussion of the oral evidence (i.e. testimonies, expert witnesses, etc.).

(vi) Without prejudice to the general regime on voluntary arbitration, the final decision of the arbitration court (irrespective of whether it decides on the merits of the case or in favour of the opponent due to the lack of counter-argument by the MA applicant) is communicated by electronic means to the parties involved, as well as INFARMED and the Industrial Property Institute ("INPI"), the latter being responsible for the publication of the decision in the Industrial Property Bulletin.

(vii) The decisions of the arbitration court are appealable to the competent second instance court (*Tribunal da Relação*). It should be noted, however, that appeals do not suspend the execution of the decision while they are pending. In other words, an appeal serves as a mere re-assessment of the merits of the arbitration court's decision. This measure is clearly aimed at providing the first instance winning party with an executable judgment in a much shorter period of time.

New defence strategy of IP pharmaceutical rights

In addition, seeking to resolve the legal issue of whether the decisions rendered by the public entities involved in the administrative process of approving the entry of a generic medicine into the Portuguese market may be challenged by reference medicine owners in the administrative courts, Law 62/2011 has introduced significant changes to the Legal Regime of Human Use Medicines and the General Regime of State Co-Payments towards Medicine Prices. It is now expressly stated

[5] 60 days maximum.

This new law deserves the close attention of all reference medicine companies with interests in Portugal, namely in terms of a reinforced monitorisation of INFARMED's website and the rethinking of their defence strategy so as to protect their exclusive rights at all levels.

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Lastly, it is worth highlighting that many of the legal solutions introduced into Law 62/2011 were highly criticized by most of the entities[6] that were invited to comment on the proposed legal text before becoming law. Indeed, the law's possible unconstitutionality was raised during the discussion of the bill in the Portuguese parliament and it seems fairly clear that further challenges will be made to some aspects of Law 62/2011 in the near future.

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Morais Leitão, Galvão Teles, Soares da Silva & Associados is closely monitoring all developments related to the implementation and applicability of Law 62/2011. If you are interested in obtaining more information regarding this issue, please let us know at apleite@mlgts.pt or tvpinto@mlgts.pt.

[6] For example, the Portuguese Bar Association, the Portuguese Arbitration Association, INFARMED and APIFARMA (the Portuguese Association of the Pharmaceutical Industry).

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