

The Constitutional Court takes position on mandatory arbitration in generic medicines disputes

CRA – Coelho Ribeiro e Associados, SCARL

João Sequeira Marcelino

Ana Carolina Santos



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Last May, the Portuguese Constitutional Court took a position regarding the Defendant's possibility to claim the nullity or invalidity of patents and SPC's during mandatory arbitrations¹. As per the Constitutional Court, a Defendant may oppose to the Claimant the nullity or invalidity of patents and SPC's with mere inter partes effects. However, this latest decision tends in the opposite direction of another recent judgment of the Supreme Court, in which the arbitral courts are incompetent to appreciate the nullity or invalidity of patents and SPCs².

In the legal file submitted to the Constitutional Court, the arbitration court considered itself incompetent to decide on the invalidity of the Claimant's patent, since it would be a decision merely with inter partes effects. Regarding this decision, the Defendant appealed, which was dismissed by the Court.

¹ Judgement of the Constitutional Court n.º 297/16. It is accessible only in Portuguese at <http://www.tribunalconstitucional.pt/tc/acordaos/20170251.html>

² Please refer to CRA article of 7 March <https://www.lexology.com/library/detail.aspx?g=87326d98-60eb-431d-a5f5-3c31cb6641e0>



As a consequence of this award, the Defendant appealed again, this time to the Constitutional Court, seeking for a judgement of unconstitutionality of the rule resulting, from the combined interpretation of the Articles 2.º of the Law n.º 62/2011, December 12th and 35.º, no. 1 and 101.º, n.º 2 of the Portuguese Industrial Property Code, according to which "in a mandatory arbitration established under that laws, the party is not allowed to defend by exception, invoking the invalidity of an European Patent, for the sole purpose of inter partes effects, even if there is no other basis for it or possibility of defense. The mandatory Arbitration Court shall be materially incompetent to rule on the invalidity of the patent, even though it only has inter partes effects and even where there is no other basis or possibility of defense." For the Appellant, the given interpretation to those articles leads to an unconstitutional rule.

The Appellant claimed that, once the patent invalidation was the only argument of defense in the case, when the Court refuses to judge it, the constitutional right of defense, prescribed in Articles 18.º, n.º 2 and 20.º, n.ºs. 1 and 4 of the Portuguese Constitution, was being denied. Moreover, it argued that pursuant to Article 2.º of the Law n.º 62/2011, December 12th, stating that the dispute of industrial property rights between reference medicines and generic medicines for certain infringement cases of patents are subject to mandatory arbitration, the legislator intention was to concentrate in the Arbitration Courts all the questions that could emerge from those litigations. Therefore, for the Appellant, it would not make sense to force the applicants of a Marketing Authorization to pursue legal actions in the Intellectual Property Court to invalidate the patent with erga omnes effects.

In light of the arguments presented by the Appellant, the Appealed argued that the only Court with competence to judge the nullity or invalidity of patents is the Intellectual Property Court (cfr. Articles 4.º, n.º 2 and 35.º of the CPI, 89.º-A, n.º 1, al. c) of the Law of Organization and Functioning of Judicial Courts³) and such decision holds erga omnes effects. The Appealed considered that, on one hand, if the invalidity of a patent, not declared by the Intellectual Property Court, is assessed in the scope of an arbitration legal action, it would lead to the acceptance of contradictory judgements; on the other hand, it would make the patent only invalid to its offender.

³ Law n.º 62/2013, August 26th.



Furthermore, to the Appellant it was not denied the right of defense since it would be possible to take legal action in the Intellectual Property Court claiming the declaration of invalidity or nullity of the patent – the Appellant has chosen not to do it.

Therefore, the present judgment aimed to decide whether the rule that resulted from the interpretation of the Articles 2.º of the Law n.º 62/2011, December 12th and 35.º, no. 1 and 101.º, nº 2 of the Portuguese Industrial Property Code, in the sense that the party is not allowed in mandatory arbitrations to invoking the invalidity of a Patent or a SPC, even with merely inter partes effects. At stake is the principle of prohibition of defenseless, together with the adversarial principle which englobes rule of admissibility of the defense by exception.

For the Constitutional Court, once the rule does not admit defense by exception it could configure a restriction of the fundamental right of defense, disposed in the article 20.º of the Portuguese Constitution⁴. Nevertheless, by the Court it was also stated that a restriction does not imply a violation of the referred disposal and, for that matter, it is vital to analyze if such restriction is constitutionally admissible, namely, if the purposes of it are sustained with constitutional grounds, respecting the proportionality principle.

Firstly, the Constitutional Court acknowledged that the exclusive competence of the Intellectual Property Court to judge about the nullity or invalidity of patents protects interests which derives from fundamental rights, the public order and the uniformization of the administration of justice: The nullity or invalidity of patents, as a public act that grants an absolute right, is a matter of public economic interest (competition) and the proper mean to decide should be a legal action to declare de nullity with erga omnes effects;

⁴ Article 20.º - Access to law and effective judicial protection:

1. The access to the law and to the courts in defense of legally protected rights and interests is guaranteed to everyone and justice cannot be denied due to insufficient financial means.
2. Everyone is entitled, under the terms of the law, to legal information and consultation, to judicial patronage and to be accompanied by counsel before any authority.
3. The law defines and ensures the adequate protection of the secrecy of justice.
4. Everyone has the right to have a case heard by a court within a reasonable time and by a fair hearing.
5. To protect personal rights, freedom and guarantees, the law ensures citizens with judicial procedures characterized by speed and priority, to obtain effective and timely protection against threats or violations of these rights.



Moreover, it serves the fundamental purpose to concentrate in the Intellectual Property Court the litigation regarding to Industrial Property. Besides, it was also necessary to evaluate if the concerned rule serves the whole purpose of its goal. The appealed sentenced stating that the exclusive competence of the Intellectual Property Court in this matter, establishes that such defect must be declared in the referred court with erga omnes effects, thus the Arbitration Courts represents a limited solution.

However, for the Constitutional Court, an imperative question remained: does the encumbrance imposed to the applicant of a Marketing Authorization – the obligation to pursue an individual legal action in the Intellectual Property Court – respect the proportionality principle and a reasonable and acceptable restriction of the Article 20.º of the Portuguese Constitution?

The Constitutional Court gave a negative answer to this question based on the following arguments: (i) considering the time it would take to have a final judgement regarding the validity of the patent, the most likely is that this judgment occurs only after the Arbitration Court decision. Therefore, it would not affect the arbitration decision; (ii). even though the declaration of nullity of the patent has ex tunc effects, Article 36.º of the Portuguese Industrial Property Code establishes an exception for the legal effects produced in the scope of the first decision – in this case, the arbitration decision. This means that even if the nullity of the patent is declared, the company of generic medicines will always be subject to compensations and pecuniary sanctions due to the infraction of a patent that was, after all, invalid. In light of the above, the Constitutional Court stated that the possibility of pursuing a legal action to invalidate the patent is not enough to guarantee the right of defense of the applicant of a Marketing Authorization.

For the Constitutional Court, the possibility of requiring the suspension of the mandatory arbitration until the Intellectual Property Court's decision (something that the Supreme Court sees as a valid and feasible alternative) is uncertain, given the disposed on the Article 292.º, n.º 2 of the Civil Procedure Code: if there are reasons to believe that such action is being pursued with the purpose to benefit from the suspension or if the prejudicial cause is so advanced that the damages from the suspension are bigger than the benefits, the suspension should not be granted. Moreover, the Constitutional Court states that such suspension goes against the arbitration principles – it is supposed to be a faster procedure.



In view of the above considerations, the Constitutional Court concluded that in these circumstances the constitutional rights of defense and of a fair trial are offended (Articles 20.º and 18.º, n.º 2 of the Portuguese Constitution).

With reference to this it was judged as unconstitutional the rule that results from the interpretation of the Articles 2.º of the Law n.º 62/2011, December 12th and 35.º, no. 1 and 101.º, n.º 2 of the Portuguese Industrial Property Code, by which a Defendant in a mandatory arbitration may not oppose to the Claimant the nullity or invalidity of patents and SPC's with mere inter partes effects.

Practitioners are now attentive to what will be the reaction of the arbitration courts and ordinary courts of appeal to this constitutional decision.