

Supreme Court takes position on mandatory arbitration in generic medicines disputes

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The **Supreme Court** answers (albeit not definitely) the *vexata quaestio* about whether a Defendant may challenge in the arbitration procedure the validity of patents or SPCs invoked by the Claimant by deciding that **arbitral courts are incompetent to appreciate the nullity or invalidity of patents and SPCs.**

In Portugal, disputes between reference medicines and generic medicines for certain infringement cases of patents and Supplementary Protection Certificates (“SPCs”) are subject to *ad hoc* or institutionalized mandatory arbitration, such arbitration to be launch by the patent holder, licensee or the Marketing Authorization (“MA”) holder for the reference medicine within 30 days counting from publication of application for the generic medicinal product. Arbitral awards are subject to appeal to the State Courts.

One hot topic that has dividing academy and arbitral as well as court of appeal case law is to whether a Defendant may challenge in the arbitration procedure the validity of patents or SPCs invoked by the Claimant. By **judgment of 14 December 2016, the Supreme Court has taken for the first time a position on this matter¹.**

The **arguments for and against** can be summarised as follows:

Against the competence of an arbitral court to declare the nullity of a Patent or the invalidity of a SPC is generally argued that:

¹ Judgement of the Supreme Court n° 1248/14.6YRLSB.S1. It's accessible only in Portuguese at <http://www.dgsi.pt/jstj.nsf/954f0ce6ad9dd8b980256b5f003fa814/ceeda3a230b3c6648025808900637340?OpenDocument>.

- (i) the decision to declaration of nullity should be *erga omnes*, while arbitral decisions are only binding *inter partes*;
- (ii) Portuguese Industrial Property Code establishes an exclusive competence of the state intellectual property courts to declare the nullity or annulment of patents and SPCs²; and
- (iii) the attribution of competence to arbitral courts is able to cause distortions at a competition level and contradictory awards.

In favor of the competence of an arbitral court to declare *inter partes* the nullity of a Patent or the invalidity of a SPC is invoked that:

- (i) Article 35.º of the Industrial Property Code does not exclude the right to invoke *inter partes* the nullity of a patent as *incidenter tantum*;
- (ii) the right to appeal to state courts from an arbitral award, could allow the *erga omnes* effect;
- (iii) the law that submitted the disputes to mandatory arbitration does not exclude any means of defense admissible under civil procedure law or in the law of arbitration³; and
- (iv) denying such right of defense is an infringement of due process, fair trial and effective legal protection constitutional rights⁴.

Majority of arbitration jurisprudence tend to consider that the arbitral courts do not have competence to declare the nullity of a patent or a SPC, while jurisprudence of the **Courts of Appeal was divided**, with several contradictory decisions⁵.

The **Supreme Court balanced the arguments pro and against and decided that arbitral courts are incompetent to appreciate the nullity or invalidity of patents and SPCs**, even as *incidenter tantum*. However, the **Supreme Court opened the door to eventual suspension of arbitral procedures while suits for declaration of nullity of a patent or a SPC are pending at state courts**. According to the Supreme Court, such suspension – to be decided in a case by case basis – could be granted when infringement of due process, fair trial and effective legal protection constitutional rights are effectively at stake.

² Article 35.º of the Portuguese Industrial Property Code: “DECLARATION OF NULLITY AND ANNULMENT

1 – A declaration of nullity or annulment may only result from a judicial decision.

2 – The Public Prosecutor’s Office or any interested party is entitled to bring the suit referred to in the previous paragraph and, in addition to the holder of the right registered against whom the suit is brought, all those who on date of publication of the annotation set forth in Article 30(1)(d) have requested annotation of derivative rights at the National Industrial Property Institute must also be cited.

3 – After the judicial verdict has become final, the court secretariat shall send to the National Industrial Property Institute, whenever possible by electronic data transmission, a typed copy or another acceptable form for publication of the document and notice in the Industrial Property Bulletin and for annotation.

4 – Whenever the suits referred to in this article are brought, the court shall inform the National Industrial Property Institute of the fact, if possible by electronic data transmission, for the purpose of annotation.”

³ Law n.º 62/2011, of 12 December.

⁴ Article 20.º of the Portuguese Constitution.

⁵ Appeals dated of 03/12/2015 and 13/1/15, Process nº 1356/13 were in favour and Appeals dated of 13/2/14, Process. 1053/13 and dated of 4/2/16, Process. 138/15 were against.