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Pharma Patent Litigation in Portugal: A skewed perspective

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When it comes to the judicial enforcement of pharmaceutical patents in Portugal, over the past few decades the general public has been driven to the misconception that the system protects pharmaceutical industry originators' tactics to delay the market entry of generics.

The European Generic Medicines Association (EGA)'s "Patent-related Barriers to Market Entry for Generic Medicines in the European Union" report, published in May 2008, denounced allegedly originators abusive tactics, including that originators, in Portugal, tried "to force patent linkage upon regulatory authorities", i.e. promoted a system where the approval of market authorizations (MAs) for generics depended on the status of patents protecting the originators' medicines. The European Commission's DG Comp was quick to fall in step behind EGA, peddling a similar narrative in the famous Preliminary Report of the Pharmaceutical Sector Inquiry published a few months later, in November 2008.

Although the Preliminary Report acknowledged (page 7) Portugal as a Member State with one of the highest generic market shares (second only to Poland) and that the Portuguese courts had not granted a single interim injunction requested by originators between 2000-2007 (page 194, Figure 77 and paragraph 522), it still depicted Portugal as a case study of originators' tactics directed at delaying generics market entry.

The Preliminary Report was completely wide of the mark when it claimed (page 276) that in Portugal originator companies challenged MAs granted for generics, on the grounds that the reference products were still protected by a patent and that the ensuing result was a substantial delay in the release of the impacted generics. However, what actually happened was that, as the situation described in the report itself, the originators were left defenseless by the Court of Commerce against a landslide of generic entrants they deemed to infringe their patents, what forced them to seek for alternative relief with the administrative courts, claiming the invalidity of the MAs granted to infringing generics.

And contrary to what the EGA's report (page 104) and the DG Comp's Preliminary Report (page 261) implied, patent owners did not accuse the health authorities of patent infringement for granting MAs to generic medicines in the preliminary injunction proceedings successfully brought before the administrative courts. The patent owners complained about the breach, by those authorities, of constitutional and administrative laws protecting fundamental rights, as patent rights are.

Originators continued to file administrative actions until the end of 2011, when a new law (Law

62/2011, of 12 December 2011) made these actions impracticable by establishing that the grant of an MA or its effectiveness could not be challenged or stayed, respectively, based on patents

Law 62/2011 also created a special procedure applicable to patent litigation involving generic drugs, whereby patent holders wishing to enforce their rights against generics were all but forced to refer the matter exclusively to arbitration, which should be initiated within thirty days from the publication of the generic's MA application by the Portuguese medicines agency.

The rationale behind the litigation system enshrined by Law 62/2011 was the aim of an early assessment of prospective patent infringement, to take place tentatively before the grant of the respective MAs. But the arbitration proceedings did not stay the grant of the MAs or the effect of the MAs once granted, which meant that the system did not have any patent linkage effect.

The 2018 amendment to Law 62/2011 removed the mandatory arbitration requirement for disputes in connection with pharmaceutical patent infringements, subjecting them to the jurisdiction of the Intellectual Property Court.

The litigation system in place in Portugal has prompted a large number of agreements between patentees and generics companies that could hardly have been reached otherwise. The Reports on the Monitoring of Patent Settlements, published online by DG Comp, show that Portugal boasts the largest number of settlement agreements in the Union by far (over three hundred between 2009 and 2016).

And no originator was found guilty or even prosecuted with anti-competitive conduct for having brought legal proceedings against the Portuguese health agency or against any generic company, and no agreements between originators and generics concerning the Portuguese market were found to infringe competition law, as it is portrayed in the Commission's Report on Competition Enforcement in the Pharmaceutical Sector (2009-2017) published in January 2019.

However, EU authorities and generic companies continue to publicly criticize originators for exercising their patent rights against generics attempting to enter the market, which should however be regarded as only natural given the monopolistic nature of the patent rights and the interests at stake.

The European Parliament stated in its Resolution of 2 March 2017 on EU options for improving access to medicines that it "deplores the litigation cases aiming to delay generic entry" and in November 2020, another European generics organization, Medicines for Europe, further lambasted patent litigation in Portugal in its "White Paper: Anatomy of a failure to launch" report, which insinuates that originators are guilty of a kind of patent linkage practice in Portugal without offering any factual support or a single shred of evidence (pages 19 and 20).

The current system in Portugal could never be qualified as patent linkage, because the Portuguese law expressly prevents the patent status from interfering with the MA granting procedure.

The concerns raised by the White Paper in relation to "*an originator's right to bring an infringement action before the Portuguese Intellectual Property Court*" are completely baseless.

It has been a long-standing principle of general Portuguese procedural law that the holder of any kind of right can apply for an (either preliminary or permanent) injunction to prevent the infringement of their right. This principle does not require an actual infringement to occur for the

injunction to be granted, depending only on a threat thereof.

Law 62/2011 therefore does not vest originators with a special procedural right to preventive court actions to the detriment of any other rightsholders, but actually limits their right of action by establishing an extremely short statute of limitations, for both preliminary and permanent injunctions, namely thirty days from the publication of the generic MA application.

Contrary to what the “White Paper” states, an application for a generic MA is not a patent infringement under Portuguese law, and the action allowed by law following a generic MA application publication has no bearing on the progress of the MA administrative procedure.

One thing the Portuguese law cannot be accused of is setting forth any kind of patent linkage. The law simply seeks to encourage stakeholders to ascertain whether the generic medicines may infringe any patents prior to their launch and spare greater costs and losses to the stakeholders, which can only work to their benefit.

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