Patent Enforcement – Portugal enacts law mandating arbitration for pharmaceutical patent disputes between innovators and generics

In December 2011 the Portuguese government enacted Decree Law 62/2011 which for the first time moved certain IP disputes, in particular patent disputes, in the pharmaceutical sector away from the Jurisdiction of the court and mandated that they are handled exclusively through arbitration. The reasoning underlying this controversial and unprecedented change is clearly political but has not been unambiguously expressed. It has been implied that it is linked to austerity measures in Portugal and indeed a Memorandum of Understanding on Specific Economic Policy Conditionality was concluded between Portugal and the Troika (European Commission, IMF and ECB) in May 2011. However, whilst the Memorandum of Understanding contained a section on the Portuguese Judicial system and mentioned arbitration within the context of alternative dispute resolution as a way to facilitate resolution of backlog cases and out of court settlement, there was no mention of its mandatory use, or any contemplation of its use in IP law, and certainly not in a specific sector. The only reference to IP in the Memorandum of Understanding was to make a speciality court on IP fully operational by Q1 2012. What is plain, however, is that the specific IP disputes selected by the Law to be handled in arbitration are the critical innovator vs generics disputes that effectively govern when a generic copy-cat medicine can legally be commercialised in Portugal.

In essence, Law 62/2011 demands that the Portuguese medicines agency (Infarmed) publish a notification when they receive an application for regulatory approval of a generic copy of an innovator product (relying on the clinical research submitted by the innovator). Within 30 days from that publication by Infarmed the innovator, if it wishes to assert its IP rights to the pharmaceutical product, is obliged to file a request for arbitration invoking those rights including evidence substantiating the infringement. The arbitration can be through the Portuguese institutional arbitration system or can be a request for non-institutional arbitration. The applicant for generic marketing authorisation then has 30 days from the notification for that purpose by the arbitration panel to enter a pleading, otherwise it will be legally estopped from commencing commercialisation. It is important to note that this second deadline in respect of the brief from the applicant for generic marketing authorisation runs from the notification by the arbitration panel which means that the arbitration panel has to have formed in order to issue such notification. Experience shows this can take a considerable amount of time, sometimes many months, during which there is no certainty for the right holder. This uncertainty is compounded by the fact that there is no mention whatsoever of preliminary or precautionary relief in the new Law. Within 60 days of receipt of the defendant's pleading the arbitration panel need to conduct a hearing to establish the evidence. Aside from that there is no time limit on the rendering of a decision in the matter and no restriction on the further procedure including further hearings for evidence or legal argument. Furthermore, Law 62/2011 served to amend other Portuguese laws including Law 176/2006 (on the regulatory approval of medicinal products) and 48A/2010 (on state reimbursement of price of medicinal products) – which have the effect of excluding the use of the courts system to prevent the authorization, price and reimbursement of medicines from being altered, suspended or revoked, due to IP rights; and to place boundaries on what can be disclosed under freedom of information rules in relation to product authorization applications for medicines.

This gives rise to a number of high level immediate concerns, namely:

i. By requiring intellectual property disputes relating to generic medicines to be resolved using arbitration it denies access to the courts for such disputes.
ii. Because of the short initial deadline combined with the lack of means for gathering of evidence from Infarmed or the applicant for generic marketing authorization, Law 62/2011 cannot allow patent infringement cases to be fully elucidated and heard – even in the non-judicial forum. Thus, a party's right to be heard is not met.
iii. It is unclear whether the new law provides for preliminary injunctive relief at all. This is critical as there is potentially a tacit permission to proceed with commercialization if a pleading, regardless of merit, is filed by the defendant party, and the deadline for that pleading is, practically, only after the arbitration panel has formed which takes a considerable amount of time.
iv. If the new law intends for preliminary injunctive relief to be provided by the arbitration panel then, immediate and timely relief will not be available since, as mentioned above, it takes a considerable amount of time for an arbitration panel to form. Thus, there is no means for stopping infringing generic activities on short notice if and when needed to prevent irreparable harm.
v. This law is in clear violation of European law, specifically EC Directive 2004/48/EC.
vi. This law is in clear violation of International law, specifically GATT TRIPs.

On 30 March 2012 the specialised IP Court (required by the Memorandum of Understanding on Specific Economic Policy Conditionality of May 2011 between the Portuguese government and the Troika) came into operation in Portugal. However, this court was not and has not subsequently been given adequate resources (it consists of a single sitting Judge) and is reportedly overwhelmed. In any event there was and has been no visible movement to have this new specialist court handle pharmaceutical patent cases and so this was evidently not a 'temporary measure'.

The Federation is concerned that if the Law 62/2011 is allowed to continue unchallenged in Portugal it may inspire other countries both inside and outside of the EU to institute similar laws that clearly contravene the European and International Law and is discriminatory to particular industries. The Federation made a significant submission to the UK IPO and the UK embassy in Lisbon setting out in detail the Federation's concerns and substantiating its view that Law 62/2011 violates European and International law. The Federation encouraged the UK Government to make every effort to influence the Portuguese government to effect the removal of Law 62/2011 as soon as possible in favour of a Law / legal system for enforcement of IP rights that is applicable in all technical fields (including pharmaceuticals). The system should be operated by a state court and the new Law / legal system for enforcement of IP rights must be compliant with National, EU and International Legislation and agreements.

In more detail the Federation, in its official correspondence, sought the UK Government to support the following specific requests which have been formulated to avoid a legislative vacuum being caused by immediate abandonment of Law 62/2011:

- that Portugal act to ensure that the specialized IP Court will be able to hear all IP cases including patent and supplementary protection certificate (SPC) cases, within a reasonable time frame (1-3 years), and in this connection ensure the court be staffed with a sufficient number of IP competent judges;
- that Portugal act to repeal Law 62/2011 once the specialized IP Court is operational and able to hear pharmaceutical IP infringement cases;
- that responsibility for hearing requests for preliminary injunctive relief based on patent infringement is immediately transferred to the specialized IP Court (and ensure it is resourced to enable timely decisions of high quality);
- that Law 62/2011 is retained until the specialized IP Court is ready to take all patent infringement cases, but change the following:

    - Change the 30 days period for submitting the petition and defence, respectively. There should be a possibility to extend as needed for each party to present its case in sufficient detail for full elucidation of facts.

- Enable means for collecting of evidence, for instance by allowing access to documents at Infarmed that would be needed to verify patent infringement.
- Establish clear appeal procedures, including define which court will hear appeal cases from the arbitration panel.
- Clarify that responsibility for preliminary injunctive relief be with the specialized IP Court and ensure that such can be timely granted.

Moreover, the Federation informed the UK Government that European Federation of Pharmaceutical Industries and Associations (EFPIA) had made representations on the point to the European Commission and encouraged the UK Government through its Embassy presence, to become part of a growing wave of collaborative outreach activities between the Embassies of a number of member states in Lisbon.

The UK Embassy was grateful and offered the Federation to join the group of 'Strategic Partners'. However this has not, so far, been taken up (a significant fee is apparently required). The Federation stands ready to assist the UK Government through the IPO and the UK Embassy in Portugal in the pursuit of change to this Law in 2013.

Ivan Burnside, 13 January 2013