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PORTUGAL

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18 July 2012

Dear Mrs de Castro

Enforcement of IP rights – Portuguese Law 62/2011: Patent infringement and dispute resolution on medicines

The IP Federation represents the views of UK industry in both intellectual property policy and practice matters within the EU, the UK and internationally. Its membership comprises the innovative and influential companies listed at the end of this letter. It has wide experience of how intellectual property law, including patent litigation, works in practice in the UK, Europe and internationally.

Creating an environment conducive to innovation and investment is a key consideration for achieving the Internal Market. Innovation is also one of the pillars for development of the pharmaceutical industry and for helping Europe regain its leading position in pharmaceutical investigation, as acknowledged by the European Agenda. The significant investment required for innovation relies on a rapid and effective intellectual property ("IP") enforcement system that enables inventors to achieve a legitimate profit for their invention during a reasonable period of exclusivity. This is also essential to secure a revenue stream for investment in future medicines. Denying innovators the benefit of the full period of patent exclusivity discourages innovation and diminishes potential investment. Not only is this bad news for the pharmaceutical industry; it is also bad news for the patients who rely on new innovative medicines for the cures of tomorrow.

Portuguese Law No. 62/2011 published 12 December 2011

With this in mind, I would like to comment on the new law which the Portuguese Government has introduced. The aim of this new law is to:

i) require that any disputes concerning IP rights relating to medicines, including injunctive procedures, are to be settled by mandatory arbitration;

ii) prevent the authorization, price and reimbursement of medicines from being altered, suspended or revoked, due to IP rights; and

iii) place boundaries on what can be disclosed under freedom of information rules in relation to product authorization applications for medicines.

A copy of the Portuguese law (in English translation) is attached as **Appendix 1**.

Summary of IP Federation concerns

We are concerned that by requiring intellectual property disputes relating to generic medicines to be resolved using arbitration (Article 2) it denies access to the courts for such disputes.

Further, we are concerned that because of the short period of time (30 days) for a party to present its case (with no possibility to extend and with the loss of rights to conduct the case should the deadline not be met), combined with the lack of means for gathering of evidence, Law 62/2011 is far from allowing patent infringement cases be fully elucidated and heard – even in the non judicial forum. Thus, a party's right to be heard is not met.

We are concerned that it is unclear whether the new law provides for preliminary injunctive relief at all. If it does, and the arbitration panel is charged with such responsibility, immediate and timely relief will not be available since it takes months (as experience has already shown) for an arbitration panel to form. Thus, there is no means for stopping infringing generic activities on short notice if and when needed.

We are concerned that this law is in clear violation of European law specifically EC Directive 2004/48/EC.

We are concerned that this law is in clear violation of International law specifically GATT TRIPs.

We are concerned that a specialised IP court (required by the "*Memorandum of Understanding on Specific Economic Policy Conditionality"* of 3 May 2011 between the Portuguese government and the Troika) has reportedly come into operation in Portugal on 30 March 2012 but there is no visible movement to have this new specialist court handle pharmaceutical patent cases.

We are 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 contravenes the EU law and international law and is discriminatory to particular industries.

The IP Federation also understands that Law 62/2011 is in violation of Portuguese constitutional law and can be challenged on that basis.

Appendix 2 to this letter sets out in more detail the practical problems with law 62/2011 and clear reasons why it is in violation of EC Directive 2004/48/EC and GATT TRIPs.

IP Federation requests

With the above in mind, we request that every effort is made to influence with 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 in this regard the specialised IP court has been communicated to be operational in Portugal. It is imperative that the new Law/legal system for enforcement of IP rights is compliant with National, Union and International Legislation and agreements.

In more detail we respectfully make the following specific requests:

- That Portugal act to ensure that the specialized IP Court will be able to hear all patent 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 patent 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 decision 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 cases 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

Concerns about Portuguese law 62/2011 have been raised by the IP Federation to the European Commission and this detailed position has been presented to the Commission by EFPIA. A number of Embassies in Lisbon including the German and Danish Embassies have been advised of this position and IP Federation understands that some out-reach between European member states' Embassies in Lisbon is in progress. The IP Federation encourages the British Embassy to become part of that.

Should you require more information, IP experts from within the IP Federation would be happy to meet with you and discuss the content of this letter and the legal views expressed therein.

Yours faithfully

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c.c.

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IP Federation members 2012

The IP Federation represents the views of UK industry in both IPR policy and practice matters within the EU, the UK and internationally. Its membership comprises the innovative and influential companies listed below. Its Council also includes representatives of the CBI, and its meetings are attended by IP specialists from three leading law firms. It is listed on the joint Transparency Register of the European Parliament and the Commission with identity No. 83549331760-12.

AGCO Ltd
ARM Ltd
AstraZeneca plc
Babcock International Ltd
BAE Systems plc
BP p.l.c.
British Telecommunications plc
British-American Tobacco Co Ltd
BTG plc
Caterpillar U.K. Ltd
Delphi Corp.
Dyson Technology Ltd
Eli Lilly & Co Ltd
ExxonMobil Chemical Europe Inc
Ford of Europe
Fujitsu Services Ltd
GE Healthcare
GKN plc
GlaxoSmithKline plc
Hewlett-Packard Ltd
IBM UK Ltd
Infineum UK Ltd
Merck Sharp & Dohme Ltd
Microsoft Limited
Nokia UK Ltd
Nucletron Ltd
Pfizer Ltd
Philips Electronics UK Ltd
Pilkington Group Ltd
Procter & Gamble Ltd
Rolls-Royce plc
Shell International Ltd
Smith & Nephew
Syngenta Ltd
The Linde Group
UCB Pharma plc
Unilever plc
Vectura Limited

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Appendix 1: Portuguese law (in English translation)

PARLIAMENT

Law no. 62/2011
of 12th December 2011

Creates a system for settlement of litigations derived from industrial property rights where reference medicines and generic medicines are in question, making the fifth amendment to Decree-Law no. 176/2006, of 30th August, and the second amendment to the general system of Government contributions to the price of medicines, approved as an annex to Decree-Law no. 48-A/2010, of 13th May

The Parliament decrees, pursuant to article 161st, paragraph a) of the Constitution, the following:

Article 1
Subject-matter

The present law creates a system for settlement of litigations derived from industrial property rights where reference medicines and generic medicines are in question, making the fifth amendment to Decree-Law no. 176/2006, of 30th August, amended by Decree-Laws nos. 182/2009, of 7th August, 64/2010, of 9th June and 106-A/2010, of 1st October, and by Law no. 25/2001, of 16th June, and the second amendment to the general system of Government contributions to the price of medicines, approved as an annex to Decree-Law no. 48-A/2010, of 13th May, altered by Decree-Law no. 106-A/2010, of 1st October.

Article 2
Mandatory arbitration

Litigations derived from the claim of industrial property rights, including preliminary injunction proceedings, regarding reference medicines, in the sense used in article 3rd no. 1, paragraph ii) of Decree-Law no. 176/2006, of 30th August, and generic medicines, irrespective of whether process patents, product patents or patents of use are at issue, as well as Supplementary Protection Certificates, shall be subject to mandatory arbitration, whether or not institutionalised.

Article 3
Inception of proceedings

1 – Within a 30-day term counted from the publication mentioned in article 15th-A of Decree-Law no. 176/2006, of 30th August, in the wording conferred thereon by the present law, any interested party who wishes to invoke its industrial property right in the terms of the preceding article should do so before the institutionalised Arbitration Court or request that the litigation be solved through non-institutionalised arbitration.

2 - Failure to file a reply within a 30-day term counted from the notification to do so by the Arbitration Court shall bar the applicant for the marketing authorisation or registration of the generic medicine from initiating the industrial or commercial exploitation thereof while the industrial property rights invoked in the terms of no. 1 remain in force.

3 – Evidence should be submitted by the parties together with the respective briefs.

4 – Once the reply has been filed, a date and time shall be set for the hearing of taking of evidence which has to be provided orally.

5 – The hearing mentioned in the preceding number shall take place within a maximum 60-day term after the opposition has been filed.

6 – Without prejudice to the ruling of the general system of voluntary arbitration in which refers to the deposit of the arbitration award, the absence of a reply or the arbitration award, as the case may be, shall be notified, by

electronic means, to the parties, the INFARMED, P.I and the Portuguese Industrial Portuguese Office, P.I., which shall publish it in the Industrial Property Bulletin.
7 – It is possible to lodge an appeal against the arbitration award before the High Court with jurisdiction to judge it, with mere devolutive effect.
8 – Wherever the preceding numbers do not expressly rule against it, the regulation of the arbitration centre, whether or not institutionalised, chosen by the parties, and, subsidiarily, the general system of voluntary arbitration, shall apply.

Article 4
Amendment to Decree-Law no. 176/2006, of 30th August

Articles 19th, 25th, 179th and 188th and annex I, part II, no 6 of Decree-Law no. 176/2006, of 30th August, amended by Decree-Laws nos. 182/2009, of 7th August, 64/2010, of 9th June and 106-A/2010, of 1st October, and by Law no. 25/2011, of 16th June, shall henceforth have the following wording:

"Article 19
[...]
1 - .....
2 - .....
3 - .....
4 - .....
5 - .....
6 - .....
7 - .....
8 – The realisation of the studies and tests necessary for the application of nos. 1 to 6, and the practical demands deriving therein, including the corresponding grant of authorisation mentioned in article 14th, do not collide with the rights concerning patents or supplementary protection certificates of medicines.

Article 25
[...]
1 - .....
2 – The application for marketing authorisation cannot be refused on the grounds of the possible existence of industrial property rights, without prejudice to the ruling of article 18th no. 4.
3 – In order to assess whether a medicine meets the conditions laid down in no. 1, paragraphs a) to f), the INFARMED shall take into account the relevant data, even if protected.
4 – *(Former no. 3).*

Article 179
[...]
1 - .....
2 – The marketing authorisation or registration of a medicine cannot be altered, suspended or revoked on the grounds of the possible existence of industrial property rights.
3 – *(Former no. 2).*
4 – *(Former no. 3).*
5 – *(Former no. 4).*
6 – *(Former no. 5).*
7 – *(Former no. 6).*

Article 188
[...]
1 – The civil servants and other co-workers of INFARMED, as well as any other person who, in the exercise of their duties, becomes aware of elements or documents submitted to the INFARMED, the European Commission or the Agency or competent authority of another member state, shall be bound by the obligation of confidentiality.
2 – Without prejudice to the ruling of the present Decree-Law, any elements or documents submitted to the INFARMED or conveyed thereto by the European Commission, the Agency or competent authority of another member state are confidential.
3 – It shall be assumed that each and every element or document provided for in the preceding numbers is classified or liable to reveal a commercial,

industrial or professional secret concerning a literary, artistic or scientific property right, except if the managing body of the INFARMED decides otherwise.

4 – Without prejudice to the ruling of the final part of the preceding number, the provision of information to third parties about an application for marketing authorisation or registration of a medicine for human use shall be postponed until the final decision is given.

5 – Whenever the petitioner for information on an application for marketing authorisation or registration of a medicine for human use is a third party who, as laid down in article 64th of the Code of Administrative Procedure, demonstrates to have a lawful interest in knowing such elements, and provided that a final decision has not yet been given on that application, only the following information shall be provided:

a) Name of the applicant for the marketing authorisation;
b) Date of the application;
c) Substance, dosage and pharmaceutical form of the medicine;
d) Reference medicine.

6 – *(Former no. 5).*

Annex I
Part II
[...]

.....

1 - .....
2 - .....
3 - .....
4 - .....
5 - .....

6 – Documents for applications in exceptional circumstances.

When, in accordance with the ruling of article 25th no. 3, the applicant can demonstrate to be unable to provide complete data on the effectiveness and safety, under normal conditions of use, by virtue of:

- The medicine in question being applied in circumstances so rare that the applicant cannot be expected to provide complete data, or
- It being not possible to provide complete information at the current stage of scientific knowledge, or
- The gathering of such information being not in conformity with the generally accepted principles of medical deontology, then a marketing authorisation may be granted provided that some specific conditions are fulfilled.

Such conditions may include the following:

- Within the term established by the competent authorities, the applicant should conduct a specific study programme, the results of which shall base a reassessment of the benefit-risk ratio;
- The medicine in question should be a prescription-only product and may only be administered in certain cases under a strict medical control, possibly in a hospital or, in which refers to a radiopharmaceutical medicine, by an authorised person;
- The informative leaflet and any other information existing on the medicine in question being still inadequate in some specific aspects.

7 - ....."

Article 5
Addendum to Decree-Law no. 176/2006, of 30th August

Articles 15th-A and 23rd-A are added to Decree-Law no. 176/2006, of 30th August, amended by Decree-Laws nos. 182/2009, of 7th August, 64/2010, of 9th June and 106-A/2010, of 1st October, and by Law no. 25/2001, of 16th June, with the following wording:

"Article 15-A
Publication of the application

1 – The INFARMED, P.I. shall publish on its website all applications for marketing authorisation or registration of generic medicines, irrespective of the procedure applicable to such medicines.
2 – The publication provided for in the preceding number should take place within a five-day term after expiry of the term established in article 16th no. 1 and contain the following elements:
a) Name of the applicant and marketing authorisation;
b) Date of the application;
c) Substance, dosage and pharmaceutical form of the medicine;
d) Reference medicine.

Article 23-A
Subject-matter of the proceeding

1 – The grant by the INFARMED, P.I. of a marketing authorisation or registration to a medicine for human use, as well as the administrative proceeding conducting thereto, concern exclusively the assessment of the quality, safety and effectiveness of the medicine.
2 – The administrative proceeding mentioned in the preceding number does not concern the assessment of the existence of any possible industrial property rights."

Article 6
Addendum to the general system of Government contributions to the price of medicines, approved as an annex to Decree-Law no. 48-A/2010, of 13th May

Article 2-A is added to the general system of Government contributions to the price of medicines, contained in annex I to Decree-Law no. 48-A/2010, of 13th May and amended by Decree-Law no. 106-A/2010, of 1st October, with the following wording:

"Article 2-A

Scope of assessment and decision

1 – The decision on whether or not have a medicine covered by the contribution, as well as the proceeding conducting thereto, do not concern the assessment of the existence of any possible industrial property rights.
2 – The decision mentioned in the preceding number does not collide with the rights concerning patents or supplementary protection certificates of medicines.
3 – The application for obtainment of the decision mentioned in the preceding numbers cannot be refused on the grounds of the possible existence of industrial property rights.
4 – The decision on whether or not to have a medicine covered by the contribution may only be altered, suspended or revoked on the grounds laid down in article 4th nos. 1 and 2 of the present statute.
5 – The decision on whether or not to have a medicine covered by the contribution cannot be altered, suspended or revoked on the grounds of the possible existence of industrial property rights."

Article 7
Pricing of generic medicines

The consumer sales price (CSP) of the generic medicines to be launched on the national market, as well as that of those subject to the proceeding set out in article 31st no. 3 of Decree-Law no. 176/2006, of 30th August, shall be lower by, at least, 50% than the CSP of the reference medicine, for an equal dosage and the same pharmaceutical form, without prejudice to the specific rules established in law applying to the pricing of medicines.

Article 8
Authorisation to the pricing of medicines

1 – The decision to authorise the CSP of a medicine, as well as the

proceeding conducting thereto, do not concern the assessment of the existence of any possible industrial property rights.
2 – The authorisation for the CSP of a medicine does not collide with the rights concerning patents or supplementary protection certificates of medicines.
3 – The application for obtainment of the authorisation mentioned in the preceding numbers cannot be refused on the grounds of the possible existence of industrial property rights.
4 – The authorisation for the CSP of a medicine cannot be altered, suspended or revoked on the grounds of the possible existence of industrial property rights.

Article 9
Transitional provisions

1 – The wording conferred by the present law on articles 19th, 25th and 179th of Decree-law no. 176/2006, of 30th August, as well as the addendum made to the general system of Government contributions to the price of medicines and the ruling of the preceding article have interpretative nature.
2 – Within a 30-day term counted from the entry into force of the present law, the INFARMED, P.I. shall publish the elements set forth in article 15th-A of Decree-Law no. 176/2006, of 30th August, in the wording conferred thereon by the present law, concerning the medicines for which at least one of the decisions of marketing authorisation, of setting the consumer sales price or of having it covered by the Government contribution to the price of medicines has not yet been given.
3 – A 30-day term, counted from the publication mentioned in the preceding number, shall be available for interested third parties to invoke their industrial property right, pursuant to articles 2nd and 3rd of the present law.

Approved on 28th October 2011.
The President of the Parliament, *Maria da Assunção A. Esteves.*
Enacted on 28th November 2011.
To be published.
The President of Portugal, ANÍBAL CAVACO SILVA.
Countersigned on 29th November 2011.
The Prime Minister, *Pedro Passos Coelho*.

Appendix 2: Practical problems with Portuguese Law 62/2011

The purpose of Appendix 2 is to:

A. Set out members' more specific concerns on Law 62/2011 and its function in practice.
B. Set out clear reasons why Law 62/2011 is in violation of EC Directive 2004/48/EC (EU Enforcement Directive)
C. Set out clear reasons why Law 62/2011 is in violation of GATT TRIPs

A. Specific concerns on Law 62/2011 and its function in practice

Law 62/2011 has a substantial impact on the ability of an "originator" to obtain effective relief in case of (assumed) infringement or the imminent launch of an infringing generic medicament in Portugal. This is analysed in greater detail below:

(i) *Mandatory arbitration:* Article 2 of Law 62/2011 requests that intellectual property disputes between "originators" and manufacturers of generic medicaments shall now be subject of arbitration proceedings and this arbitration is without any alternative. An arbitration tribunal does, in our view, not constitute a state court and differs from the latter by its nature. Law 62/2011 renders it impossible for an "originator" to obtain "regular" relief in case of patent infringement, i.e. to initiate a "normal" infringement case, be it on a preliminary basis or as merits proceeding prior or parallel to or after arbitration proceeding. Law 62/2011 does not refer to the revocation of a patent in related revocation proceedings. One can therefore assume that this option shall not be afforded.

(ii) *Law 62/2011 is apparently not 'a temporary measure'.* The shortcomings and deficiencies of the Portuguese legal system are well-known and, for instance, mentioned and acknowledged in the "*Memorandum of Understanding on Specific Economic Policy Conditionality"* of 3 May 2011 between the Portuguese government and the Troika (consisting of the European Commission, the European Central Bank and the International Monetary Fund) which, amongst other things, obligated the Portuguese government to render specialised courts on competition and on intellectual property rights fully operational by Q1 2012.[1] It is noteworthy that the same Agreement does not obligate Portugal to bring in an mandatory arbitration scheme – the closest it comes is to introduce a law on arbitration (by September 2011) and to make arbitration accessible in debt collection cases by (February 2012) and to give priority to alternative dispute resolution in the courts (see Art 7.6 and 7.8). In no part of the Troika agreement is Arbitration required to be mandated. Against that background, one might reasonably expected that the mandatory arbitration system would at most be short-term measure intended to alleviate pressure in the Portuguese judicial system until the new specialised IP courts had been made operational. However that is apparently not the case. The Specialised IP courts were made operational on 30 March 2012 and there has been no indication whatsoever that Law 62/2011 no longer applies or is in-line to be repealed.

[1] See Memorandum of Understanding on Specific Economic Policy Conditionality of 3 March 2011, section 7.11: "Make specialized courts on competition and on intellectual property rights fully operational".

(iii) *Gathering of evidence not considered:* Law 62/2011 does not provide any means for gathering of evidence. Such evidence may, however, be needed by a patent owner in order to verify whether there is at all an infringement of its patent rights. Article 3 (8) of Law 62/2011 refers to the regulation of the institutionalized arbitration centre or, secondly, the general voluntary arbitration regime. Law 63/2011[2], which addresses the latter and provides new rules, awards the arbitration tribunal the right to grant preliminary orders[3], even ex parte. Yet it appears highly questionable whether those regulations provide effective measures in order to gather evidence for verifying patent infringing activities, in particular quick enough so that the evidence needed cannot be modified or destroyed. This appears even more questionable as a preliminary order "shall be binding on the parties but shall not be subject to enforcement by a State Court".[4]

(iv) *Gathering of evidence from INFARMED:* Law 62/2011 also changes the scope of secrecy obligations of INFARMED and other authorities in relation to the documents obtained regardless of whether those documents might be helpful or required for the "originator" for substantiating and verifying patent infringement. Article 4 of Law 62/2011 that amends Article 188 of Law 176/2006, provides the assumption that all elements or documents supplied to INFARMED in relation to a marketing authorization request shall be considered confidential[5] unless INFARMED management takes a different view. In any case, prior to making "a final decision", only rudimentary information shall be passed on to a third person – such as the "originator" seeking verification of patent infringement. Information from INFARMED will quite likely be available only after market launch. In view of the 30 days opposition period (see below) this must substantially impact the "originator's" ability to obtain fair and appropriate relief simply as a consequence of the fact that the evidence needed to demonstrate infringement within that period cannot be obtained.

(v) *Limited time to prove infringement:* The "originator" has 30 days to oppose the marketing authorization request of a generic company under Article 3 (1). That section does not provide the opportunity to seek or obtain an extension[6]. It must be assumed that non-compliance with that deadline will result in a loss of rights, in particular the "originator's" ability to obtain relief against the assumed infringing generic medicament. In our view, it is therefore crucial that one enables the "originator" to obtain all evidence needed in order to avoid that oppositions are filed without any merits simply because evidence from INFARMED is not obtainable. Currently, the "originator" can either oppose the request for marketing approval - and run the risk of being dismissed in view of not being able to evidence infringement as information - or let the 30 days deadline expire - and accept that the claims against the presumed infringer then become time-barred even if the facts needed to prove infringement become available only

[2] The comments are based on the English version of the law: http://arbitragem.pt/legislacao/lav-english--27-12-2012.pdf. The Portuguese version can be found at: http://arbitragem.pt/noticias/2011-12-14--lav--dr.pdf

[3] See Article 22 of Law 63/2011.

[4] See Article 23 (5) of Law 63/2011.

[5] See Article (2) Law 62/2011.

[6] Article 3 (1) of Law 62/2011 does not mention or refer to any option to extend that period.

later. To summarise: In view of that 30 days period, granting access to the INFARMED file is an indispensable prerequisite for ensuring fair proceeding and effective remedy.

(vi) *Preliminary injunctive relief not available:* Strictly speaking, the new law does not deny the availability of preliminary injunctive relief. Article 3 (8) refers to the regulations of the "institutionalized arbitration centre" chosen by the parties. Therefore, it may well be the case that the rules then applicable do not provide options for the petitioner to obtain injunctive relief. "The voluntary arbitration regime" which is the default option mentioned in Article 3 (8) of Law 62/2011, is subject to the already mentioned Law 63/2011 of 14 December 2011. Law 63/2011 does, as outlined before, provide for preliminary orders and interim measures. While a preliminary order (Article 22, Law 63/2011) can be granted on an ex parte basis[7], an "interim measure" (Article 20) cannot; in the latter case, the other party needs to be given the opportunity to present its arguments in a hearing.

(vii) *Preliminary injunctive relief available prior to the constitution of arbitration tribunal:* As far as imminent market launch of a potentially (infringing) product is concerned, Article 20 of said Law 63/2011 might provide a basis for granting of an injunction.[8] But this would require that the arbitration tribunal has already been constituted; the question arises how quickly relief can actually be available if the parties, first of all, will have to reach an agreement about the constitution of the tribunal.

(viii) *Mandatory arbitration at all appropriate to handle patent issues in preliminary proceedings:* Another aspect that should be considered is that patent matters are, by their nature, complex and complicated. Should an arbitration tribunal consist of arbitrators without sufficient experience or knowledge in this area, the question whether such tribunal will be prepared to grant preliminary injunctive relief becomes even more complex if one further takes into consideration that the defendant may, and likely will, argue that the patent-in-dispute is invalid; a related revocation action is not mentioned in either law and it is therefore unclear how it might impact the respective proceeding. To sum up: It is unclear whether, under the new law, preliminary injunctive relief will at all (if institutionalized arbitration centres are concerned) be available or at least to a

[7] However, Article 22 (1) of Law 63/2011 states:" *Unless otherwise agreed by the parties, a party may, without notice to any other party, make a request for an interim measure together with an application for a preliminary order directing a party not to frustrate the purpose of the interim measure requested*." Therefore, the question arises whether a request for ex parte preliminary relief needs to be filed together with a request for an interim measure.

[8] Article 20 (2) has the following wording: "*For the purpose of this law an interim measure is a temporary measure, whether in the form of an award or in another form, by which, at any time prior to the issuance of the award by which the dispute is finally decided, the arbitral tribunal orders a party to:*

a. *Maintain or restore the status quo pending determination of the dispute;*

b. *Take action that would prevent, or refrain from taking action that is likely to cause, harm or prejudice to the arbitral process etc.;*

c. *Provide a means of preserving assets out of which a subsequent award may be satisfied;*

d. *Preserve evidence that may be relevant in material to the resolution of the dispute*."

sufficient extent (based on the voluntary arbitration regime according to Law 63/2011).

(ix) "*Right to be heard*"*:* The new Law 62/2011 stipulates for either party - the patent owner as well as the (assumed) infringer – to have a 30 days period for submitting the petition and the defence, respectively, including related evidence. If one assumes that the parties shall not be allowed to submit further evidence[9], neither party will be able to prepare its position sufficiently. Besides, Law 62/2011 denies in our understanding the patent owner the right to pursue its rights in front of a state court and compels it to use an arbitration tribunal instead, which is usually characterized by its private, i.e. non-governmental character. This is not in line with commonly accepted principles according to which arbitration proceedings cannot be imposed upon the parties against their will. Further, a Member State cannot escape its obligation to provide justice in ordinary courts if international agreements impose an obligation on the Member State to ensure judicial remedies.

B. Law 62/2011 is in violation of EC Directive 2004/48/EC

In our view, Law 62/2011 disregards the aims and some of the key requirements of the Directive. Hereinafter, we will briefly summarize the background and the ratio of the Directive and then discuss how and to which extent we deem Law 62/2011 in breach of it.

1. Overview of the Directive

The Directive is intended to harmonize the enforcement of intellectual property rights in the Community. Intellectual property rights are viewed as crucial for creating a market in which innovation and investments meet favourable conditions (see recitals 1 and 8 of the Directive), and such innovations and investments require the safeguarding of the underlying intellectual property.[10]

Historically, Member States had provided for different measures to ensure that rights holders could enforce their intellectual property rights such as trademark rights, patent rights, copyrights and others. The protection afforded each of these rights was not the same in the Member States which led to disturbances of the internal market when rights holders wished to pursue their rights on an EU-wide basis. In order to achieve a truly harmonized approach towards the enforcement of intellectual property rights across the Community, in particular in these areas of concern, the Directive was passed in 2004. Most of the Member States have by now implemented the Directive into national law, some with considerable delay but nevertheless the national laws now reflect, to a large extent and with exceptions, the requirements of the Directive.

One of the exceptions is the implementation in Portugal. While dissatisfactory for a long while, in particular for manufacturers of generic medicaments, the implementation of Law 62/2011 that was intended to lessen the burden on generics manufacturers, severely contravenes the requirements of the Directive, as will be shown below. The key aspects of the Directive that the Law 62/2011 does not comply with

[9] See Article 3 (3): "*Evidence must be submitted by the parties with the respective pleadings*".
[10] See also the Report from the Commission to the European Parliament on the Application of Directive 2004/48/EC on the enforcement of intellectual property COM(2010) 779.

are, in particular, the general principles that the Directive requires (measures must be fair, equitable, not unnecessarily complicated or too costly, and without unreasonable time-limits or delays), the requirements to provide for securing of evidence, for a right to information, for provisional and precautionary measures, for corrective measures, and for damage claims.

2. Breach of the Key Aspects

The Directive allows in particular for the following measures that Law 62/2011 violates:

(i) *General Measures:* In its Article 3, the Directive imposes the implementation of certain general measures on the Member States[11]. The aim is to obligate the Member States to introduce measures, proceedings and remedies that strike a fair balance between the potential infringer and the rights holder. These general requirements for any measures to be implemented by the Member States shall also ensure the efficiency of these measures so as to not leave the rights holders with a blunt instrument. The Portuguese Government has failed in complying with these general principles on numerous occasions throughout Law 62/2011:

- One may already doubt whether the decision of the Portuguese government to deny a patent owner the opportunity to seek relief against infringement of its patent rights through a state court and to compel it to rely on an arbitration tribunal instead, i.e. a non-state body of law, complies with the requirements of Article 3 of the Directive. [12] One may well assume that Article 3 of the Directive requires each Member State of the EU to provide the respective means and measures through state courts.

- The new dispute resolution mechanism does not provide for an effective mechanism for the avoidance of patent infringements. It is not unlikely that the arbitration procedure that has to be initiated ends after the beginning of the commercialization of the relevant generics (see above II.2.(v))[13]. Thus even if the arbitration board decides positively on the infringement side, the arbitration action does still not constitute a timely and effective remedy against the infringement of the patent right.

- The Law 62/2011 stipulates that any rights holder needs to initiate arbitration proceedings within 30 days of publication of the grant of marketing authorization. This timeline will only give the rights holders sufficient time to evaluate the situation, ascertain risks and costs involved in the arbitration proceedings, if the evidence needed to prove infringement is easily available. This is, however, not

[11] *"Member States shall provide for the measures, procedures and remedies necessary to ensure the enforcement of the intellectual property rights covered by this Directive. Those measures, procedures and remedies shall be fair and equitable and shall not be unnecessarily complicated or costly, or entail unreasonable time-limits or unwarranted delays."*

[12] Geimer/Schütze, Internationales Zivilprozessrecht, 5th ed., at no. 3766: „Niemand darf an den Spruch eines Schiedsgerichts gebunden werden, dem er sich nicht freiwillig unterworfen hat" ("nobody must be bound to the verdict of an arbitration tribunal unless he became subject to that tribunal on a voluntary basis").

[13] The process for marketing authorization usually lasts approx. 6 months and nothing in the law requires the arbitration proceedings to be finalized in that time frame.

the case: no access will be granted to the INFARMED dossier of the alleged infringer.

- If no arbitration proceedings are initiated within the 30-day-period stipulated in the Law 62/2011, any enforcement rights regarding intellectual property seem to be lost (see above II.2.(ii)).

(ii) *Securing of Evidence:* Sufficient information in the form of evidence is decisive for determining whether intellectual property rights are infringed. Thus rights holders require effective means to ensure that they can present, obtain and preserve the relevant information and evidence to pursue their case. Article 6 of the Directive[14] prescribes that Member States shall ensure the necessary means to achieve this aim. This provision effectively gives the rights holders the possibility to require potential infringers to produce documentation and information that the rights holder needs in order to investigate and potentially prove infringement, but that is not available to it.

Even prior to the commencement of proceedings on the merits of the case, the courts may order prompt and effective judicial measures to preserve relevant evidence in respect of an alleged infringement (subject to the protection of potential confidential information, Article 7 of the Directive).[15] Most importantly, the Directive requires the Member States to ensure that these measures prior to commencement of a proceeding can also be taken without the other party being heard if this is necessary where any delay could cause irreparable harm or where there is a demonstrable risk that evidence may be destroyed. Thus the Member States need to provide for preliminary measures to be available on an ex parte basis if this is necessary. Therefore the securing of evidence shall not only be ensured during a proceeding on the merits but also in advance of any proceeding to make up for the lack of insight that the rights holder usually has. This aims, in particular, at owners of method patents who traditionally cannot determine infringement of their patent unless they gain sufficient insight in the manufacturing process of the potential infringer. In both cases (securing of evidence prior to proceedings and during proceedings) it is up to the courts to determine the

[14] *"Member States shall ensure that, on application by a party which has presented reasonably available evidence sufficient to support its claims, and has, in substantiating those claims, specified evidence which lies in the control of the opposing party, the competent judicial authorities may order that such evidence be presented by the opposing party, subject to the protection of confidential information. For the purposes of this paragraph, Member States may provide that a reasonable sample of a substantial number of copies of a work or any other protected object be considered by the competent judicial authorities to constitute reasonable evidence."*

[15] *"Member States shall ensure that, even before the commencement of proceedings on the merits of the case, the competent judicial authorities may, on application by a party who has presented reasonably available evidence to support his claim that his intellectual property right has been infringed or is about to be infringed, order prompt and effective provisional measures to preserve relevant evidence in respect of the alleged infringement, subject to the protection of confidential information. Such measures may include the detailed description, with or without the taking of samples, or the physical seizure of the infringing goods, and, in appropriate cases, the materials and implements used in the production and/or distribution of these goods and the documents relating thereto. Those measures shall be taken, if necessary without the other party having been heard, in particular where any delay is likely to cause irreparable harm to the rightholder or where there is a demonstrable risk of evidence being destroyed."*

necessary measures to safeguard potential confidential information of the other party, the potential infringer.

This has not been properly implemented in Portugal. Law 62/2011 does not comply with Articles 6 and 7 by providing an express rule that grants the rights holders any right to apply for taking of evidence. To the contrary: Law 62/2011 states in its Article 3 (3) that evidence must be submitted by the party with the respective pleading. Thus the rights holder must submit all the evidence necessary in support of its claim at the time of pleading. Any matter that is not expressly regulated is subject to the regulations of the institutionalized arbitration centre or the general voluntary arbitration regime, Art. 3 (8) of Law 62/2011. Without thorough review of the arbitration rules applicable to these situations, a determination of whether these rules contain a proper implementation of Articles 6 and 7 of the Directive is not feasible, but it is fair to assume that the general arbitration rules do not contain such specific IP-related provisions regarding the production and securing of evidence.

The non-implementation of this requirement renders Portugal non-compliant with the Directive as it leaves rights holders without any option to obtain evidence on the infringement from the potential infringer, also due to the very limited information disclosure requirements imposed on INFARMED (see above II.2.(iii)). This problem becomes particularly difficult in relation to method patents where the rights holders will naturally not know the method of manufacturing of the generic in detail.

(iii) *Right of Information:* In addition to the securing of evidence, the Directive envisages further beneficial measures for the rights holders, in particular a right to information in the Directive's Article 8. In the context of infringement proceedings the rights holder may claim information on the origin and distribution networks of goods and/or services which infringe the rights holder's intellectual property right. This provision generally serves to safeguard a high level of protection that had been available in some Member States even prior to enactment of this Directive (see recital 21). There is no corresponding express implementation in Law 62/2011 that would grant the rights holders a right to this information. It is questionable whether the procedural arbitration rules provide for this possibility.

(iv) *Provisional and Precautionary Measures:* One of the crucial elements of the Directive is the requirement for Member States to ensure that the judicial authorities may issue preliminary measures against a potential infringer upon request by the rights holder to prevent or prohibit any (imminent) infringement of an intellectual property right (Article 9 of the Directive).[16] Alternatively, such

[16] "*1. Member States shall ensure that the judicial authorities may, at the request of the applicant:*
(b) issue against the alleged infringer an interlocutory injunction intended to prevent any imminent infringement of an intellectual property right, or to forbid, on a provisional basis and subject, where appropriate, to a recurring penalty payment where provided for by national law, the continuation of the alleged infringement of that right, or to make such continuation subject to the lodging of guarantees intended to ensure the compensation of the rightholder; an interlocutory injunction may also be issued, under the same conditions, against an intermediary whose services are being used by a third party to infringe an

continuation may be made subject to a lodging of guarantees to ensure compensation of the rights holder. The injunction can not only be issued against a potential infringer but also against an intermediary who is used by the potential infringer. Moreover, it can be issued on an ex parte basis, i.e. without hearing the other party. In considering the petition for a preliminary measure the courts shall take into account the specifics of the individual case and proportionality of the measures, and, if necessary, award a possibility for defence to the other party. Where appropriate, the provisional measures shall include corrective actions ordered against the infringer such as recall and removal from the distribution channels, or even destruction of the infringing goods and, if appropriate, of the materials and implements that are used to create or manufacture these goods (recital 24). Article 9 (2) of the Directive implements this intention by obliging the Member States to ensure that courts have the possibility to order such measures.

Law 62/2011 does not provide specifically for preliminary and precautionary measures. It only stipulates that any intellectual property right needs to be invoked within 30 days before an arbitration court. According to Art. 3 (8) of Law 62/2011 anything not expressly regulated in this law is subject to the regulations of the institutionalized arbitration court, and secondly the general voluntary arbitration regime. Lacking information on the regulations of any specific institutionalized arbitration court, the newly introduced regime on voluntary arbitration (Law 63/2011) shall be taken into consideration. To begin with, assigning preliminary measures to an arbitration court which, when called upon, is not even constituted but requires appointment in a formalized process, will result in significant delays in achieving a preliminary order and Law 63/2011 hardly provides means to ensure efficient preliminary relief, in particular relief that is available within a few days if necessary: there is not arbitration tribunal in existence yet and it is impossible to constitute the tribunal within a few days which may sometimes be crucial for the efficiency of urgent requests. It is also unclear how the arbitration tribunal would constitute itself in cases where a preliminary order is desired on an ex parte basis because the new arbitration law contains, as a rule, the requirement that both parties each appoint an arbitrator who in turn appoints the third arbitrator. There is no specific rule how to proceed if one party is not involved in the process of constituting the board. According to Chapter IV of the new legislation, interim measures are permissible. However, they cannot provide for efficient preliminary injunctive relief: according to Article 23 of the new Law 63/2011, any preliminary order will be valid for 20 days only.

(v) *Corrective Measures:* The Member States shall ensure that upon application by the applicant the competent courts can, without prejudice to any damage claims of the rights holder, issue an order on corrective measures regarding goods that are found to be infringing, Article 10 of the Directive.[17] Such measures are recall

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intellectual property right; injunctions against intermediaries whose services are used by a third party to infringe a copyright or a related right are covered by Directive 2001/29/EC;

(c) *order the seizure or delivery up of the goods suspected of infringing an intellectual property right so as to prevent their entry into or movement within the channels of commerce."*

[17] *"Without prejudice to any damages due to right holders by reason of the infringement, and without compensation of any sort, Member States shall ensure that the competent judicial authorities may order, at the request of the applicant, that appropriate measures be taken with regard to goods that they have found to be infringing an intellectual property right and, in appropriate cases, with regard to*

from the channels of commerce, definitive removal from the channels of commerce, and destruction.

The Law 62/2011 does not foresee such measures.

(vi) *Damage Claims:* According to Article 13 of the Directive, Member States shall ensure that the competent judicial authorities order the infringer to pay appropriate damages suffered as a result of the infringement.[18] While the Law 62/2011 does not prohibit the granting of damages by the arbitration court, there are certain scenarios in which claims for damages cannot be realized. Lacking evidence of the infringement, a party may decide to not initiate proceedings within the 30-days exclusion period. If it then learns new information that proves infringement, and results in damages in the future, any reversion to the arbitration board or any other court is precluded because of the time-limit. While this is substantially an issue revolving around the right to due process of law which is denied by the new Law 62/2011 in imposing this time-limit, the result is that damages can no longer be claimed.

C. Law 62/2011 is in violation of GATT TRIPs

The TRIPs Agreement lays down minimum standards and rights in intellectual property law.[19] It ensures the availability of a minimum level of protection of intellectual property rights and does not constitute a harmonized system but obliges all member states to apply the same standards.[20]

While it is unclear whether and to which extent the TRIPs Agreement shall be directly applicable in the jurisdictions of the Members, the Portuguese Supreme Court confirmed such applicability in relation to Article 33 TRIPs Agreement in a 2007 ruling.[21]

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materials and implements principally used in the creation or manufacture of those goods. Such measures shall include:

(a) recall from the channels of commerce,

(b) definitive removal from the channels of commerce, or

(c) *destruction."*

[18] *"Member States shall ensure that the competent judicial authorities, on application of the injured party, order the infringer who knowingly, or with reasonable grounds to know, engaged in an infringing activity, to pay the rightholder damages appropriate to the actual prejudice suffered by him as a result of the infringement."*

[19] The TRIPS Agreement is an international agreement by the World Trade Organisation (WTO) and is therefore mandatory for all WTO members. As a member of the European Union, Portugal is a member of the WTO since 1 January 1995 (http:www.wto.org/English/thewto_e/countries_e/Portugal_e.htm.

[20] Robert Howse, "Trade Related Aspects of Intellectual Property Rights. A commentary on the TRIPS Agreement", New York 2007, page 8.

[21] Decision of the Supremo Tribunal de Justiçia (Portugal) of 15 November 2007: "This court thus can and must exercise its jurisdiction in order to rule on its understanding that Art. 33 TRIPS is directly applicable within the framework of national law". According to the ECJ, decision of 11 September 2007, C-431/05, ECR I-07001, Merck Genéricos-Produtos Farmacêuticos L^{da} v. Merck & Co. Inc., Merck Sharp &Dohme L^{da}, Reference for a preliminary ruling under Article 234 EC from the Supremo Tribunal de Justiçia (Portugal), made by decision of 3 November 2005: "If it would be found that there are Community rules in the sphere in question, Community law will apply, which will mean that it is necessary, as far as may be possible, to supply an interpretation in keeping with the TRIPS Agreement, although no direct effect may be given to the provision of that agreement at issue".

1. The "general obligations" of a Member State under the TRIPs Agreement

According to Article 41 the Member States shall ensure that "enforcement procedures as specified in this part are available under their law so as to permit effective action against any act of infringement of intellectual property rights covered by this agreement." Amongst the obligations specified in Articles 42 through 49 of the TRIPs Agreement are, for instance the principle of fair and equitable procedures, specific principles concerning evidence, injunctions, damages and other remedies as well as the right of information which are imposed upon the "judicial authorities" of the members.

It is questionable whether the arbitration tribunals referred to in Law 62/2011 are such "judicial authorities". This cannot be clarified by looking into the details of the TRIPs Agreement alone. However, an excursion into the Brussels regulation[22] demonstrates clearly that this is not the case. Inter alia, the Brussels regulation provides a mandatory regime for the national courts in relation to pan-European matters which they cannot escape. In respect of the international jurisdiction dealt with in Article 2 of the Brussels regulation, Geimer/Schütze, one of the leading commentaries of the Brussels regulation[23] states: "If the international jurisdiction of a member state arises in accordance with Article 2 et seqq. then it has no discretion whether or not it wishes to grant legal protection. It is rather obligated to provide justice. This obligation may, however, not apply if the parties consented on settling the dispute by means of an arbitration tribunal."[24]

The same applies in relation to the obligations of a Member State to provide adequate remedies in case of infringement of an intellectual property right, e.g. arising from the positions of the TRIPs Agreement: In that case as well the obligations of a Member State will only be satisfied if the remedies determined in the TRIPs Agreement are available through a state court. An arbitration tribunal is not equivalent. Therefore, the mandatory arbitration introduced into the Portuguese law is not compliant with Portugal's obligations under the TRIPs Agreement and under the Brussels regulation.

2. Provisional Measures

The TRIPs Agreement obligates the members to provide provisional measures in conjunction with the infringement of intellectual property rights. In particular, Article 50 requires that the "judicial authorities" have the authority to order prompt and effective provisional measures to prevent imminent infringement and to "preserve relevant evidence in regard to the alleged infringement".[25] Article 50 (2) of the TRIPs

[22] EC No. 44/2001 of 22 December 2001 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters.

[23] Geimer/Schütze, Europäisches Zivilverfahrenrecht,

[24] Geimer/Schütze, loc. cit., Article. 1 no. 146: „*Ist ein Mitgliedstaat nach den Regeln der Artikel 2 ff. international zuständig, dann steht es nicht in seinem Belieben, ob er Rechtschutz gewähren will oder nicht. Er ist vielmehr zur Justizgewährung verpflichtet. Diese Pflicht entfällt jedoch, wenn die Parteien die schiedsgerichtliche Erledigung des Rechtsstreits vereinbart haben*".

[25] See Article 50 (1) of the TRIPS Agreement:

"1. The judicial authorities shall have the authority to order prompt and effective provisional measures:

> *(a) to prevent an infringement of any intellectual property right from occurring, and in particular to prevent the entry into the channels of commerce in their jurisdiction of goods, including imported goods immediately after customs clearance;*

Agreement explicitly requests that *ex parte* preliminary injunctive relief is available "where any delay is likely to cost irreparable harm to the right holder, also where there is a demonstrable risk of evidence being destroyed". As already mentioned above, Law 62/2011 does not provide any preliminary measures in case of patent infringement, neither injunctive relief nor any option to get access to documents or products in order to verify infringement. Whether such options may result or are provided in the rules of "institutionalized arbitration centres" referred to in Article 3 (8) is unclear. The rules of the voluntary arbitration regime, which apply as a default rule, see Article 3 (8) of Law 62/2011, determine that the arbitration tribunal can grant preliminary orders and interim measures. Their exact scope is, however, unspecific. It is, in particular, absolutely unclear whether such tribunal might be inclined to comply with Portugal's obligation under the TRIPs Agreement. This indicates that Portugal has failed to ensure compliance in particular with Article 50 of the TRIPs Agreement.

(b) to preserve relevant evidence in regard to the alleged infringement."