



APIFARMA – ASSOCIAÇÃO PORTUGUESA DA INDÚSTRIA FARMACÊUTICA

**COMMENTS ON THE PRELIMINARY REPORT IN THE
PHARMACEUTICAL SECTOR INQUIRY**

1. INTRODUCTION

1. APIFARMA – Associação Portuguesa da Indústria Farmacêutica ("APIFARMA") is the national pharmaceutical industry association in Portugal. Its membership comprises more than 130 companies active in the manufacture, importation and marketing of medicinal products for human use. APIFARMA's members comprise both research-based and generic companies.
2. The purpose of this document is to present APIFARMA's comments on the Preliminary Report prepared by the European Commission in the context of the Pharmaceutical Sector Inquiry (the "Report"), particularly focusing on Portugal.

In general, and in the first place, APIFARMA regrets that many of the factual findings of the Report are based on submissions filed by other stakeholders, without any scrutiny. Such approach may have been the reason why the Report failed to accurately address essential factual and legal issues in a number of significant aspects, naturally calling into question the validity of the conclusions reached.

Secondly, the Report fails altogether to clarify – as it should – that patent law is not yet harmonised within the European Union and as such that it falls out of the scope of Community law.

The Report also reveals the European Commission's lack of information on the patent laws of Member States a fact which, at least in what concerns Portugal, leads to a misleading depiction of the situation insofar as it completely disregards the protection afforded by a patent right and the legal consequences of patent infringement in Portugal. Full knowledge of the legal regime in Portugal is required to correctly understand and put into context the litigation instances in this country.

All things considered, APIFARMA would like to express dismay for the method employed by the European Commission in the Report and the manner in which the facts were presented in the Report – often painting an incomplete picture of the reality of the market, in particular the Portuguese market – as well as the ambiguity and partialness in displaying those same facts. Such methodology inevitably compromises the European Commission's findings.

In this respect, APIFARMA subscribes to EFPIA's views presented to the European Commission and hopes that the approach of the Preliminary Report will not be reflected in a Final Report at the risk of causing considerable damage to the innovative sector.

APIFARMA therefore hopes that its constructive contributions may assist the European Commission in achieving a more balanced view of the challenges faced by the pharmaceutical sector, in particular, in Portugal.

3. As stated previously, in this document APIFARMA will focus mainly on the Portuguese situation, in particular, litigation issues.

Despite not seeking *"(...) to identify wrongdoings by individual companies or to reach any conclusion as to whether certain practices described in the report infringe EC Competition Law"* merely aiming to *"provide the Commission with a*

factual basis for deciding when further action is needed", when addressing the so-called Portuguese Case Study, the Report suggests that originator companies have effectively put in practice, in Portugal, an illegal strategy of delaying the entry of generics.

It is unfortunate that the Report is so largely influenced by some public positions, notably by the report of EGA on "Patent-related Barriers to Market Entry for Generic Medicines in the European Union", dated May 2008. Such approach may have been the reason why the Report failed to accurately address essential factual and legal issues in a number of significant aspects, naturally calling into question the validity of the conclusions reached.

Based on publicly available figures as well as on data provided by APIFARMA's members and by regulators, APIFARMA shall provide additional information and facts which clearly compromise these findings. APIFARMA will further demonstrate that the description made of the ongoing litigation as implicitly restrictive and unlawful is imprecise and does not reflect reality.

It should be pointed out that APIFARMA is not a party to any judicial proceeding taking place in Portugal concerning the cancellation/suspension of marketing authorisations and price approvals of products on grounds related to what the European Commission defines in the Report as being "patent linkage". Any comments concerning the claims made by the parties involved or the decisions taken in the context of such cases are based on information provided to APIFARMA by the abovementioned sources.

4. To fully understand the Portuguese situation a thorough analysis of the specific legal, judicial and economic context in Portugal is required.

Many of the factual premises on which the Report is based, when put into context with the Portuguese legal environment and the facts surrounding the court actions encompassed by the so-called "Portuguese Case Study" are, to a great extent, inaccurate and thus misleading.

In this submission, APIFARMA shall address said inaccuracies, beginning by outlining a number of general ambiguities and erroneous assumptions which can be found in the Report, before turning to the "Portuguese Case Study" and to the shortcomings of the Report in portraying the legal framework of the litigation at issue. A separate subsection is devoted to statistics on litigation outcomes in Portugal. The final section of this document provides data on the generic market in Portugal.

This information contradicts any finding of originator companies launching a litigation strategy to block generic market entry. Litigation actions undertaken by certain originator companies before the courts had no significant impact on generic entry. The numbers presented clearly demonstrate that the generic market in Portugal has experienced steady and significant growth.

2. AMBIGUITIES AND ERRONEOUS ASSUMPTIONS IN THE REPORT

2.1. INCONSISTENT NOTION OF GENERICS

1. The Report emphasises on a number of occasions that the Sector Inquiry was launched "*because information relating to innovative and generic medicines suggested that competition may be restricted or distorted*". One of the reasons why the Commission so concluded was due to the occurrence of "*instances of delayed market entry of generic medicines, as compared to what might be expected*".

When addressing the "Portuguese Case Study", the Commission takes the view that actions performed by originators "*might result in delays in generic entry*".

2. One of the major ambiguities in the Report, which gives rise to serious misunderstandings such as the ones stated in the previous paragraph, is the concept of "generics" and, consequently, of "generics delayed market entry".

A "generic" is defined in the Report¹ as "a medicine containing the same active ingredient as a particular originator and is not (or no longer) patent-protected".

In line with this definition, the Report, in its initial statements², considers – correctly – that only "following the loss of (patent) exclusivity, generic can entry the market".

Two conclusions necessarily follow from the above definition and statement: (i) a generic can only enter the market when it is no longer patent protected, i.e. when it starts to be considered a real generic medicine under the Report's definition and, consequently, (ii) that there is no possible "delayed market entry" when the medicinal product at stake is still patent protected.

Notwithstanding, the Report consistently denies these conclusions and the assumption on which they are based when describing the so-called "strategies" of the originators to delay the generics' market entry.

3. In fact, although, under the Report's initial definition, a generic can not be qualified as such when a patent is still in force, in a later stage, the same Report states that this does not apply when the patent at issue has a secondary or divisional nature, i.e. from the European Commission's perspective the only patents that qualify for protection of exclusivity under the Report are the initial patents covering the active principle.

With this statement, the Report entirely disregards patent law, adopting a distinction between the scope of protection of initial and subsequent patents which such law absolutely does not consent.

If the marketing of a medicinal product infringes a patent of whichever nature (initial, secondary or divisional), its market entry must be deferred until the moment when such patent expires. Such a deferred launch should never be, for

¹ See page 18 of the Report.

² See page 7 of the Report.

contrary to patent law, considered as a "*delayed entry*" for the purposes defined in the Report.

4. APIFARMA believes that the above ambiguities and erroneous assumptions had an important role in distorting the analysis made in the Report in what concerns patent enforcement litigation conducted by originators in Portugal.

Contrary to what the European Commission conveys, the situations dealt with in the Portuguese Case Study do not refer to "*generics*" and could therefore never "*result in delays in generic entry*". In fact, to the best of APIFARMA's knowledge these situations relate to medicinal products the commercialisation of which could constitute a patent infringement.

2.2. DISREGARD TO THE PORTUGUESE LEGAL REGIME ON PATENT RIGHTS

1. The Report fails to acknowledge the different scope of protection of patent rights afforded under the different constitutional laws of the Member States.

At the outset, the Report does not clarify - as it should - that patent law is not yet harmonised within the European Union and that, as the European Court of Justice has recently stated³, it falls out of the scope of Community law.

Furthermore, the Report does not reveal that the scope of protection of any patent, even of a European Patent, is exclusively defined by each national law. It is also for national law to define the legal consequences of patent infringement in the respective territory.

2. As a result, when the Report refers to "*the protection offered by a patent*"⁴, confining it to the attribution of mere civil relative rights, it completely ignores the

³ Cf. Case C-431/05, Merck Genéricos v Merck&Co.Inc. and Merck Sharp&Dohme, [2007] ECR 7001, paragraphs 39-46. "39. Having regard to the principles noted in paragraphs 34 and 35 above, it is now appropriate to examine whether, in the particular sphere into which Article 33 of the TRIPs Agreement falls, that is to say, that of patents, there is any Community legislation. 40. As Community law now stands, there is none. (...) 46. The fact is that the Community has not yet exercised its powers in the sphere of patents or that, at the very least, at internal level, that exercise has not to date been of sufficient importance to lead to the conclusion that, as matters now stand, that sphere falls within the scope of Community law."

diversity of legal regimes on patent rights existent throughout the European Union.

Such approach particularly disregards the fact that, in Portugal, patent rights are not mere private rights, enjoying, on the contrary, a clear public nature. Patent rights benefit, in Portugal, from all the guaranties awarded to property rights, being considered as fundamental constitutional rights, which, in accordance with a Constitutional command, all public authorities must respect and safeguard. The Report additionally conceals the fact that, under Portuguese law, the infringement of a patent is qualified as a criminal offence.

3. This shortcoming of the Report partially explains why it fails to recognize that in Portugal it is legally admissible to challenge market authorisations and price approvals in the context of the enforcement of patent rights.

2.3. PATENT LINKAGE

2.3.1. PATENTS AND MARKETING AUTHORISATIONS

1. The "Portuguese Case Study" is mentioned in a part of the Report⁵ regarding "*Other Practices Affecting Generic Entry*", which include the intervention of originators before marketing authorisation bodies and pricing and reimbursement bodies, aiming to obtain there from what is qualified in the Report as "*patent linkage*".

Despite the expression "patent linkage" not being defined either in the Community Law or in the case law of the European Court of Justice, in several parts of the Report "patent linkage" is considered as "*the practice of linking the granting of MA, the pricing and reimbursement status or any regulatory approval*".

⁴ See page 97, paragraph (238), point 2.1.5. Opposition and Appeal at the EPO - National Validation and Patent Protection of the Report.

⁵ Chapter C, Section 2.5 of the Report.

*for a generic medicinal product to the status of a patent (application) for the original reference product"*⁶.

The Report unequivocally states that patent linkage is unlawful under EU Law⁷, due to the fact that the main function of market authorisation bodies "*is to ensure that the pharmaceutical products reaching the market are not harmful to public health*"⁸.

Additionally, the Report refers that neither Regulation (EC) 726/2004 nor Directive 2001/83/EC consider patent status as a ground to refuse, suspend or revoke a marketing authorisation.

2. The "Patent linkage" issue should have been addressed more carefully by the Report and put into context with the case-law of the European Court of Justice which states that "*the Directive seeks to approximate provisions laid down by law, regulation or administrative action in Member States relating to proprietary medicinal products **only in so far as such provisions are connected with public health***"⁹ (our highlight).

Both the aforementioned statutes provide clear indication that the Report's assumption may not encompass all the possible legal solutions regarding the interface between patent rights and market authorisations.

While Directive 2001/83/EC reminds in its article 10 (specifically directed to the marketing authorisation procedure referring to generic medicines) the need to respect the "*law relating to the protection of industrial and commercial property*", Regulation (EC) 726/2004, in Recital 13, states that although "*in the interest of public health, authorisation decisions under the centralised procedure should be taken on the basis of the objective scientific criteria of quality, safety and efficacy*"

⁶ See pages 15 and 261, paragraph (715), point 2.5.1.1. Pre-Litigation Contacts Related to Marketing Authorisation, of the Report.

⁷ See page 261, paragraph (715), point 2.5.1.1. Pre-Litigation Contacts Related to Marketing Authorisation, of the Report

⁸ See page 261, paragraph (715), point 2.5.1.1. Pre-Litigation Contacts Related to Marketing Authorisation, of the Report

⁹ Judgment of the Court of 26 January 1984, SA *Clin-Midy v Belgian State*, Case 301/82, ECR [1984] P. 251, paragraphs 5-10.

of the medicinal product concerned, to the exclusion of economic and other considerations", the "Member States should be able exceptionally to prohibit the use in their territory of medicinal products for human use which infringe objectively defined concepts of public policy and public morality".

This means that, although the patent status of the reference product may be, in fact, irrelevant to the decision on whether or not to grant a marketing authorisation, the fact that such an authorisation constitutes an administrative clearance for a third party's patent infringement can be important in the context of a given national patent rights regime.

3. This is particularly significant to correctly understand the situation in Portugal.

In effect, under the Portuguese legal system, the individual rights contained in a patent are *constitutional fundamental rights* and the infringement thereof is a *criminal offence*. This special status entails that both courts and administrative bodies must adopt all necessary measures to protect such rights and are prohibited from adopting any acts that facilitate the infringement thereof by third parties.

The relevant administrative bodies for the granting of marketing authorisations or price-approvals – INFARMED – *Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.* ("INFARMED") and DGAE – *Direcção Geral das Actividades Económicas* ("DGAE"), respectively – are therefore bound to obey to these constitutional and administrative principles and are thus prevented from executing administrative acts which have as their object the infringement of a patent and thus the commitment of a criminal offence.

The granting of a marketing authorisation (or the approval of the price) to a product the marketing of which will necessarily infringe a patent is an unlawful act under constitutional and administrative Portuguese law, insofar as its ultimate purpose and its sole useful effect is to allow marketing – thus to allow the infringement.

In fact, the primary function of a marketing authorisation – as the name itself clearly indicates – and of the subsequent administrative clearances (such as price approval, in the case of products subject to medical prescription) is to enable the medicine to enter the market. Any application made to obtain clearance to the existent administrative obstacles to market necessarily implies an actual intention of the applicant to market the medicine.

The above understanding has been upheld by the Portuguese administrative courts and has constituted the basis for suspension of the marketing authorisations of products the marketing of which will infringe valid patents.

4. In conclusion, the issue under discussion in the Portuguese administrative courts is not about linking the decision on whether or not to grant a marketing authorisation for a product to the status of a patent, but rather the fact that under Portuguese Law, such an authorisation is perceived as an administrative act which clears the path for the infringement, by a third party, of a valid patent.

The findings of the Report in this respect have been flawed by the Commission's difficulty to understand that under the different constitutional laws of the various Member States, the scope of protection of patent rights may extend further than what the Commission has suggested in its Report.

2.3.2. PATENTS AND PRICE APPROVALS

1. The Report extends its reflections regarding patent linkage and the supposed unlawfulness thereof to the pricing and reimbursement regime, by saying that "*under EU law, patent protection is not a criterion to be considered by the authorities when approving prices or granting reimbursement*"¹⁰.
2. This statement is particularly misleading.

¹⁰ See page 275, paragraph (758), point 2.5.2.2. Litigation against Pricing and Reimbursement Bodies, of the Report

In fact, the reason why EU law does not consider patent protection in the context of those acts is not because it condemns such link but, and as is expressly foreseen in article 4.3 of the Directive 2001/83/EC, because EU law is alien to the criteria by which pricing and reimbursement are conceded by the Member State's authorities. Under EU law pricing and reimbursement rules are only harmonised in what concerns certain procedural aspects.¹¹

APIFARMA further refers to the considerations made in Section 2.3.1 above.

3. THE "PORTUGUESE CASE STUDY"

3.1. INTRODUCTION

Prior to addressing the aspects related with the so-called "Portuguese Case Study", APIFARMA would like to reiterate that it is not a party to any judicial proceeding taking place in Portugal before administrative courts concerning the cancellation/suspension of marketing authorisations and price approvals of products on grounds related to the so-called "patent linkage".

Nonetheless APIFARMA is aware that judicial proceedings aimed at fostering the protection of industrial property rights have been and are still being submitted by originators to Portuguese judicial instances. APIFARMA believes that said behaviour is compliant with national and Community legal orders, and that companies are acting within the limits of the law, which includes, according to the Portuguese judicial system, the appeal to different instances, comprising both administrative and civil courts.

3.2. ACCESS TO JUSTICE IS A FUNDAMENTAL RIGHT

1. As stated previously, the description of the situation in Portugal made by the Report fails to accurately portray the legal framework of the litigation at issue.

¹¹ See Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems.

In effect, and although allegedly the Report does not seek to “(...) *identify wrongdoings by individual companies (...)*”, when describing the Portuguese case, the European Commission seems to have forgotten the underlying purpose of the Pharmaceutical Sector Inquiry, suggesting that originators are following an illegal dilatory strategy by pursuing “*deliberate actions, including litigation, creating administrative difficulties for generic companies which might result in delays in generic entry.*”¹².

With the above statement, the Report conveys the idea that the sole objective that the “*companies deliberately pursue*” is to create “*delays in generic entry*” for no serious and/or valid reasons. This is simply not true.

2. It should be underlined that this so-called “fact-finding” statement forgets what patent litigation by definition is all about: the patent holder has an exclusive right and is therefore entitled to use all the legally possible means to force the patent infringer to stay out, or to step out, of the market. Resorting to courts for that purpose is a fundamental right deeply enshrined in the constitutional system and no person or entity should be censured for doing so, except in those cases where the court is presented with misleading facts or frivolous reasons are pursued with the aim of harassing the other party.
3. Companies – whether originators or generics - must be permitted to take their legitimate concerns to the regulators and/or to courts and to resort to the existent legal mechanisms to protect and enforce their rights and should not be discouraged from expressing their *bona fide* concerns for fear of antitrust scrutiny.

To understand otherwise would be a serious threat to access to justice, a fundamental right that can only be restricted in “*wholly exceptional circumstances.*”¹³

¹² See page 276, paragraph (759) point 2.5.2.2. Litigation against Pricing and Reimbursement Bodies, of the Report

¹³ Case T-111/96 *ITT Promedia NV v Commission* [1998] ECR II-2937, paragraph 60 (“As access to the Court is a fundamental right and a general principle ensuring the rule of law, it is only in wholly

3.3. THE CHOICE OF THE ADMINISTRATIVE COURTS

1. The organisation of the judiciary system and thus the definition of the competences of each court is, as the European Commission is certainly aware, a matter of exclusive competence of the Member States.

Notwithstanding the above, APIFARMA considers it paramount to comment on the allegations made in the Report in what regards the choice, by originator companies, of the administrative courts for the enforcement of their patent rights.

2. Said choice, contrary to what the European Commission suggests in the Report, should not be viewed as obeying to any devious strategy of delaying generic market entry, but rather to the originators' imperative need to react to the lack of efficient protection of industrial property rights by the Portuguese civil courts, i.e. the courts of commerce.

In effect, as the Report clearly portrays¹⁴, Portuguese civil courts are very much dilatory in deciding patent enforcement cases, including interim injunctions requests, and extremely reluctant in conceding pre-emptive relief to patent owners.

3. Since the coming into force of the law transposing Directive 2004/27/EC, amending Directive 2001/83/EC – i.e. since 31 August 2006, generic versions of medicines containing approximately 58 active substances were granted marketing authorisations. For at least 11 of these substances, patent rights were still in force.

As in other European jurisdictions, the preferred course of action of originators in Portugal with a view to enforce their patent rights would have been to resort *solely* to the civil courts, notably the courts of commerce.

exceptional circumstances that the fact that legal proceedings are brought is capable of constituting an abuse of a dominant position within the meaning of Article [82] of the Treaty.”)

¹⁴ See pages 192 and 194 of the Report.

However, the systematic delays in even hearing the case for precautionary or interim measures before such courts that place Portugal far from the European average¹⁵, proved this course of action to be ineffective, irreparably hindering the rights emerging from the patents at stake and causing irrecoverable damage.¹⁶

The honourable president-judge with the Lisbon Court of Commerce has publicly exposed this fact in an interview given to a large circulation daily Portuguese newspaper (*Jornal de Negócios*, April 9, 2008 quoting Maria José Costeira) describing the situation before the Courts of Commerce in Portugal as being in "*complete rupture*" and expressly acknowledged the delays in deciding interim requests and the implications of such delays on the protection of industrial property rights.

This state of affairs, favoured the illegal conduct of companies that intended to launch products on the market prior to patent expiry, for they felt they could launch patent infringing medicines at no risk, since no effective and timely court system would bar their way. Furthermore, an inexistent experience of deterrent damages condemnations led generic companies to feel immune to any negative consequences of patent infringement.

Originators were therefore totally exposed to the offence of their exclusive rights by patent infringing products the marketing of which they were unable to prevent.

¹⁵ The available judicial reaction mechanisms to guarantee effective protection of intellectual property rights consist on the possibility of the intellectual property right holder obtaining, within a reasonable timeframe, a precautionary measure based on the presumption of validity of the patent. The experience of research-based companies shows that the average period to obtain a precautionary measure is between four to ten weeks in most of the Member States. According to information provided by company members of APIFARMA, in the Lisbon Court of Commerce, which has jurisdiction to decide the large majority of the cases, a preliminary injunction request is only heard between 1 and 2 years after being filed.

¹⁶ Another reason which makes the situation in Portugal rather worse for the defence of intellectual property rights when compared with other Member States is the complexity of the requirements for an injunction to be ruled favourably, which, in practice, render access to precautionary justice extremely difficult.

4. Faced with the absence of effective judicial protection of the Courts of Commerce, some research-based companies, in strict compliance with Portuguese procedural laws, resorted to the administrative courts with a view to defending their patent rights.

The choice of administrative courts was not the outcome of any deliberate strategy of originators to hinder the generics market, but a feasible and legitimate way of effectively enforcing patent rights against prospective infringers¹⁷. This is an admissible legal avenue for originator companies wishing to protect valid patents as acknowledged by the administrative courts that have unanimously considered themselves as having jurisdiction on this matter.

3.4. THE LEGAL GROUNDS FOR ACTION BEFORE THE ADMINISTRATIVE COURTS

1. Contrarily to what is reported by the European Commission¹⁸, in the judicial procedures brought before the administrative courts, the "*patent linkage*" issue, as defined in the Report, was not raised in the majority of the cases where originators challenged the marketing authorisations or the price approvals of infringing products not yet launched onto the market.

In effect, to the best of APIFARMA's knowledge, originators are not claiming that a market authorisation should not be granted or the price should not be approved when the reference product is patent protected.

2. The marketing authorisations and the price approvals have been questioned by certain originator companies before the administrative courts on the grounds that said acts violate Portuguese constitutional and administrative principles and statutory stipulations aiming to defend fundamental constitutional rights – as are the industrial property rights - and to prevent public administration bodies from

¹⁷ As the Report finds, patent litigation in Portugal is amongst the lengthiest in Europe, yet preliminary injunctions are almost never granted (see Figures 75 and 77 – Litigation in Portugal takes 6.5 years and the courts have never granted an injunction over the period investigated).

¹⁸ See page 275, paragraph (758) point 2.5.2.2. Litigation against Pricing and Reimbursement Bodies, of the Report.

performing administrative acts having as their object the performance of a criminal offence – the infringement of a patent.

In effect, what is being sustained is that if a marketing authorisation is granted or a price is approved thereby clearing the path to patent-infringement, then such administrative requirements which enable the marketing of the infringing product should be invalidated on the basis of Portuguese constitutional and administrative law and principles.

The legal basis on which originators have grounded their claims against the marketing authorisation and price approvals does not lie in any pharmaceutical regulatory matter but ultimately in the infringement of clear principles of Portuguese public policy directly derived from the Constitution.

3. It should be stressed that the case law of the administrative courts has upheld the above understanding.

As from February 2008, the Central Administrative Court of the South (administrative court of appeal) has decided by large majority (to the best of APIFARMA's knowledge and based on the information provided by its members, at least 13 cases in favour and only 1 against) to grant preliminary injunctions suspending generic's market authorisations, on the grounds of an imminent threat of patent infringement cleared by such administrative acts.

This undoubtedly confirms that originators were right in lodging their claims before the administrative courts and that their cases were based on reasonable and well founded factual and legal arguments.

Note that besides being upheld by the courts, the originators' claims were never called into question on the basis of a finding of *vexatious* litigation – a legal mechanism autonomously provided for under Portuguese law.

4. It is unfortunate that the European Commission does not report this result – despite in various instances making reference to facts occurred after the term of

the period covered by the Sector Inquiry – as a clear indicator that patent holders were legally entitled to apply for the suspension of marketing authorisations before the administrative courts, on the grounds they did.

3.5. THE CORRECT DATA CONCERNING THE PORTUGUESE REALITY

1. In general, the main idea put across by the Report is that originator companies lose the majority of the cases they bring before the courts. This would suggest that the concerns raised by such companies are generally unsubstantiated and thus part of a dubious generic entry-blocking strategy.
2. The Report highlights various situations in which originator companies are purported to have initiated litigation and to have lost the majority of the cases.

Portugal is mentioned as a special case in what concerns litigation related to marketing authorisations and pricing and reimbursement decisions insofar as most of the claims are based on patent linkage alone¹⁹.

3. In what concerns *litigation related to Marketing Authorisations*, out of a total of 137 cases – based on data from mid-2008 – the Report mentions that more than 50 occurred in Portugal.²⁰

The Report conveys the idea that although the majority of the cases are still pending - 58 cases were identified in Portugal²¹ -, in most of these the claims of originator companies were eventually not upheld by the courts.

Specifically, the Report states that "*the courts rejected the claims of the originator companies in 24 final judgments and 37 legal actions were withdrawn by the*

¹⁹ For the grounds of action substantiating the originators claims see paragraph 2, Section 3.4. above.

²⁰ See pages 264-5, paragraphs (724) to (727), point 2.5.1.2 Litigation Related to Marketing Authorisation, of the Report.

²¹ See pages 264-5, paragraphs (724) to (727), point 2.5.1.2 Litigation Related to Marketing Authorisation, of the Report.

*originator company before a final judgment was made. Only one final court judgement confirmed the claims of the originator company."*²²

4. Without prejudice to the belief that litigation statistics are no basis for asserting that concerns raised are generally unsubstantiated, the data received from APIFARMA's Associates refutes these findings - at least, for Portugal.
5. In effect, to the best of APIFARMA's knowledge, in Portugal, only three main actions regarding the validity or invalidity of a marketing authorisation have been decided by the administrative courts – although appeals are still pending – and were decided in favour of the originator.

The Report is therefore misleading when it presents the figures of the success of the cases. These are conveyed in such a way that the reader is compelled to understand that the courts have rejected the claims in the "*large majority of the cases*". This is untrue, at least in what refers to the Portuguese litigation of which APIFARMA is aware of.

6. The Report is also misleading in what regards interim injunctions *related to Marketing Authorisations*. It does not report that a great number of court decisions have been issued and were favourable to the originators.

As noted previously, as from February 2008, the Central Administrative Court of the South (administrative court of appeal) has decided by large majority to grant preliminary injunctions suspending generic's market authorisations, on the grounds of an imminent threat of patent infringement.

7. The Report also fails to inform that in all cases – at least in the cases brought to APIFARMA's knowledge – the originators are enforcing product patents or process patents regarding which the infringement is presumed by the Portuguese law. This means that, in all the cases at issue, there is a strong

²² See page 265, paragraph (727), point 2.5.1.2 Litigation Related to Marketing Authorisation, of the Report.

likelihood, as the courts have stated, of a patent infringement being about to be committed.

8. Finally, the Report is silent about the fact that the market authorisations challenged by the originators in Portugal refer to products the commercialisation of which would infringe patents still valid for a large number of years (some of which will expire on or after 2015).

This reveals that in applying for a marketing authorisation for a patent-protected product when the patent at stake is still valid for a large number of years, the generic producers could have no other intent than to market the product during the period of validity of the patent.

9. In what concerns *litigation related to pricing and reimbursement*, Portugal is mentioned as a special case insofar as "*most claims are said to be based on patent infringement only*". The Report blatantly mentions that "*under EU law, patent protection is not a criterion to be considered by the authorities when approving prices or granting reimbursement status.*"²³

The Portuguese situation is given as an isolated case study, where it is stated that originator companies pursue "*deliberate actions, including litigation, creating administrative difficulties for generic companies which might result in delays in generic entry*", usually coinciding with the price application by a generic company to the responsible authorities for marketing authorisations and pricing and reimbursement²⁴.

The Report further notes that legal action brought by originators before administrative courts challenging marketing authorisations have affected the pricing process for the products concerned, it being reported that DGAE

²³ See page 274, paragraph (754), point 2.5.2 Interventions before Pricing and Reimbursement Bodies, of the Report.

²⁴ See page 274, paragraph (759), point 2.5.2.2. Litigation against Pricing and Reimbursement Bodies, of the Report.

*"suspends the price approval process for generic medicines when originator companies launch legal proceedings based on an alleged patent violation."*²⁵.

Finally, the Report states that *"several requests for approval of prices for generic medicines were suspended in 2007 and 2008, pending the judgments of the administrative courts to which the cases had been referred"*²⁶, the price approval process for more than 120 generic products being suspended, in mid-2008²⁷. Altogether, according to the Report, more than 70 court cases are pending in Portugal²⁸.

10. A number of facts provided to APIFARMA, both by its members and DGAE, contradict the Report's findings.
11. In what concerns the grounds for legal action, their compatibility with EU law and the aims pursued by originator companies when resorting to administrative courts, APIFARMA refers to Section 3.4. Paragraph 2 above.

Secondly, it is not true that DGAE is suspending the price approval procedure whenever there is a patent litigation. Price approval procedures have only been suspended under the terms of Portuguese administrative procedural rules.

Lastly, the reference made in the Report to 70 court cases pending in Portugal which have affected the price approval process of more than 120 products is highly misleading. Not only does it create the impression that a strategy of obstructing generic market entry has been put into place, but also it suggests that such a strategy had a great effect on generic entry.

²⁵ See page 274, paragraph (759), point 2.5.2.2. Litigation against Pricing and Reimbursement Bodies, of the Report.

²⁶ See page 274, paragraph (759), point 2.5.2.2. Litigation against Pricing and Reimbursement Bodies, of the Report.

²⁷ See page 274, paragraph (759), point 2.5.2.2. Litigation against Pricing and Reimbursement Bodies, of the Report.

²⁸ See page 274, paragraph (759), point 2.5.2.2. Litigation against Pricing and Reimbursement Bodies, of the Report.

12. According to data received from APIFARMA's Associates, the reality is that those cases refer to approximately 11 molecules only, regarding which there are several marketing authorisations granted and price applications filed²⁹.

Data provided by DGAE in turn shows that in 2007 and until October 2008, the prices of products corresponding to at least 58 active substances were approved. In the year 2007, 1784 price requests for generics were approved, whereas until October 2008, approximately 1475 price requests for generics were approved.

In addition, until October 2008, DGAE only suspended approximately 117 price requests connected to pending legal action before the administrative courts. These cases relate to 11 active substances for which patents were in force. Of these 11, only 8 active substances had no price approved in October last. This entails that only in relation to 8 active substances can it be sustained that there is no generic competition with the originator product.

13. Having regard for the aforementioned data and clarifications, it is not plausible to sustain that originator companies have put into effect a litigation strategy in order to delay generic market entry or, for that matter, that such a so-called strategy compromised entry.

On the contrary, the generic market in Portugal has experienced an increasing and steady growth since 2003, as explained in the following section.

4. PERMANENT GROWTH OF THE GENERIC MARKET

1. The Report begins to point out that the level of generic penetration is relatively high in Portugal, when compared to other European countries. Whereas some countries are depicted as having low generic penetration rates, Portugal is explicitly mentioned as evidencing a relatively high penetration rate ranging

²⁹ Under Portuguese law, for each dosage, and under each dosage, for each presentation, a separate price application request must be filed.

between 30 and 40%.³⁰ In value terms, the generic market share in Portugal is the second EU15 highest, at 32%.³¹

The data collected in the context of the Sector Inquiry also shows that the number of applications for marketing authorisations increased over the period 2000-2007 for a large number of Member States, in particular, Portugal, where the number of applications for generics increased more significantly when compared to those for originators.³² More importantly, the Report points out that, in Portugal, the number of marketing authorisations granted actually increased over the considered period.

2. The abovementioned conclusions are confirmed by data published by INFARMED which clearly demonstrates that the market share of generics in the Portuguese market has experienced a steady and significant increase as from 2003.

Figure 1: Evolution of the Generic Market in Portugal (in value³³)

Year	Yearly growth rate of generic products	Market Share (in value)
2003	220,0 %	5,7 %
2004	52,3 %	7,9 %
2005	66,9 %	12,7 %
2006	22,0 %	15,2 %
2007	22,5 %	17,9 %
2008 (Jan. – Nov.)	6,5 %	18,8 %

Source: INFARMED

³⁰ See paragraph (147), page 59 and 60 and Figure 9: Generic market shares in Europe (value and volume), of the Report.

³¹ See page 7, point 1.2. Product Life Cycle, of the Report.

³² See page 104, paragraph (252), point 2.2. Marketing Authorisations, of the Report.

³³ Determined on the basis of the value of sales at the final retail sales price.

3. Subject to information made available by INFARMED³⁴, referent to November 2008, the market share of generics in terms of value amounted to 18,8 % and covered a large variety of active substances in different therapeutic domains, such as anti-ulcerants (3,9%), anti-dyslipidemics (3,7%), anti-hypertensives (2,0%), anxiolitics, sedatives and hypnotics (1,9%), systemic antibacterians (1,3%) and anti-depressives (0,9%).

In terms of volume, during the first 11 months of 2008, 31.23 million packages of generics were sold, whereas in 2007 that number only went up to 27.2 million. The market share of generics has therefore increased from 11,69% to 13,62%, an increase which corresponds to a growth rate of 14,7%.³⁵

Data regarding December last, confirms that this tendency continues to the present.

4. Another important element is the penetration rate of generic products per active substance.

In fact, in November 2008, generic products represented more than 80% of the market in six out of ten of the active substances mostly prescribed by physicians, in terms of number of packages sold. These six active substances are: Citalopram (anti-depressive), Glimepiride (diabetes), Omeprazole (digestive problems), Simvastatin (cholesterol), Isotretinoin (acne) and Ciprofloxacin (antibiotic). In the remaining four active substances - Alendronic Acid (Osteoporosis), Flutamide (prostate cancer), Fluoxetine (anti-depressive) and Meloxicam (anti-inflammatory) -, generics now represent more than 70% of the market³⁶.

Finally, of the 30 active substances which achieved the highest sales levels in 2007 - representing 26% of the total retail pharmacy -, and in relation to which

³⁴ INFARMED's Report, November 2008 (Relatório do Observatório do Medicamento e Produtos de Saúde do Infarmed, Novembro 2008), available at www.infarmed.pt

³⁵ Press Release, Press Cabinet INFARMED, 19 December 2008
<http://www.infarmed.pt/portal/pls/portal/docs/1/1868241.PDF>

³⁶ INFARMED's Report, November 2008 (Relatório do Observatório do Medicamento e Produtos de Saúde do Infarmed, Novembro 2008), available at www.infarmed.pt.

generic products existed, generics represented approximately 51% of the total sales of these top-selling substances³⁷.

5. In conclusion, it seems that despite the strategy of "*delaying the entry of generics*" allegedly put into practice by originator companies, the Portuguese generic medicines market has nevertheless experienced a constant and significant growth in the past years. No such strategy can be observed from the pattern of generic entry and no quantifiable harm can be established to have resulted from this alleged strategy.

In reality, the above facts clearly demonstrate that litigation before the administrative courts undertaken by the originator companies has not compromised the growth of generics in the Portuguese market in recent years.

6. In light of the above, APIFARMA believes that in Portugal generics can and do enter the market and they do so with increasing speed.

5. CONCLUSION

APIFARMA believes that the above comments make clear the need to review the findings of the European Commission, as expressed in the Report.

In Portugal the industrial property rights are *constitutional fundamental rights* and the infringement thereof constitutes a *criminal offence*. Given their nature, in accordance with a Constitutional command, all public authorities – both courts and administrative bodies – must adopt all the necessary measures to protect such rights and are prohibited from adopting any acts that facilitate the infringement thereof by third parties.

Due to the absence of effective judicial protection in the civil courts, notably the courts of commerce, originator companies holders of valid patent rights resorted to the administrative courts – a legitimate course of action - challenging marketing authorisations and price approvals whenever the marketing of the

³⁷ Based on IMS Health data for 2007.

products at stake could infringe those patents and therefore the granting of these acts would violate clear principles of Portuguese public policy directly derived from the Constitution.

In the large majority of cases, the administrative courts have upheld the originators' claims, confirming that their cases were based on reasonable and well founded factual and legal arguments and thus suspended the challenged acts. No claim for vexatious litigation was ever held.

Lastly, it should be noted that litigation before the courts undertaken by certain originator companies has had no significant impact on generic entry. On the contrary, the generic market in Portugal has experienced a significant and constant growth in the past years.

In more general terms, APIFARMA supports the policy recommendations proposed by EFPIA that should be included in the Final Report to ensure the benefits of low cost generic products and to guarantee that innovative medicines are available more rapidly in the interest of public health.

Specifically, APIFARMA considers that the Final Report should contain policy recommendations concerning the improvements needed in the current patent system in order to reduce costs and increase legal and commercial certainty for all parties.

30 January 2009